Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

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Frederick Memorial Hospital	USA	O'Connor, Brian Marcial
Eastern Maine Medical Center	USA	Openshaw, Thomas H.
Penobscot Bay Medical Center	USA	Openshaw, Thomas H.
Harold Alfond Center for Cancer Care	USA	Openshaw, Thomas H.
William Beaumont Hospital-Royal Oak	USA	Zakalik, Dana
Ascension Providence Hospitals - Southfield	USA	Vakhariya, Cynthia Mahesh
Saint Joseph Mercy Hospital	USA	Stella, Philip J.
University of Michigan Comprehensive Cancer Center	USA	Schott, Anne F.
Wayne State University/Karmanos Cancer Institute	USA	Simon, Michael Steven
Henry Ford Hospital	USA	Doyle, Thomas J.
Ascension Saint John Hospital	USA	Stella, Philip J.
Allegiance Health	USA	Stella, Philip J.
Spectrum Health at Butterworth Campus	USA	Yost, Kathleen J.
Genesys Hurley Cancer Institute	USA	Stella, Philip J.
Regions Hospital	USA	Flynn, Patrick James
Mercy Hospital	USA	Zera, Richard T.
Essentia Health Cancer Center	USA	Friday, Bret E.B.
Mayo Clinic	USA	Ruddy, Kathryn J.
Saint Francis Regional Medical Center	USA	Zera, Richard T.
Mayo Clinic Health Systems-Mankato	USA	Ruddy, Kathryn J.
Sanford Joe Lueken Cancer Center	USA	Steen, Preston D.
Fairview Clinics and Surgery Center Maple Grove	USA	Flynn, Patrick James
Washington University School of Medicine	USA	Ademuyiwa, Foluso Olabisi
Mercy Hospital Saint Louis	USA	Carlson, Jay W.
CoxHealth South Hospital	USA	Carlson, Jay W.
Mercy Hospital Springfield	USA	Carlson, Jay W.
Saint Louis Cancer and Breast Institute-South City	USA	Carlson, Jay W.
University of Kansas Cancer Center - Lee's Summit	USA	Sharma, Priyanka
Kalispell Regional Medical Center	USA	Marchello, Benjamin T.
Wake Forest University Health Sciences	USA	Levine, Edward A.
Duke University Medical Center	USA	Marcom, Paul Kelly
Mission Hospital	USA	Harkness, Cameron Blair
Carolinas Medical Center/Levine Cancer Institute	USA	Tan, Antoinette R.
CaroMont Regional Medical Center	USA	Charles, William J.
FirstHealth of the Carolinas-Moore Regional Hospital	USA	Kuzma, Charles S.
Margaret R Pardee Memorial Hospital	USA	Radford, James Earl
Southeastern Medical Oncology Center-Jacksonville	USA	Atkins, James N.
Sanford Roger Maris Cancer Center	USA	Steen, Preston D.
Trinity Cancer Care Center	USA	Unnikrishnan, Madhu
Altru Cancer Center	USA	Seeger, Grant Richard
Nebraska Methodist Hospital	USA	Leu, Kirsten M. Hotton

CHI Health Saint Francis	USA	Copur, Mehmet Sitki
Southeast Nebraska Cancer Center - 68th Street Place	USA	Hauke, Ralph J.
Nebraska Hematology and Oncology	USA	Soori, Gamini S.
Faith Regional Health Services Carson Cancer Center	USA	Hauke, Ralph J.
Dartmouth-Hitchcock Medical Center/Norris Cotton Cancer Center	USA	Arrick, Bradley A.
Morristown Medical Center	USA	Reeder, Jennifer G.
Rutgers Cancer Institute of New Jersey	USA	Toppmeyer, Deborah Lynn
Lovelace Medical Center-Downtown	USA	Dayao, Zoneddy Ruiz
University of New Mexico Cancer Center	USA	Dayao, Zoneddy Ruiz
Laura and Isaac Perlmutter Cancer Center at NYU Langone	USA	Adams, Sylvia
NYP/Weill Cornell Medical Center	USA	Cigler, Tessa
University of Rochester	USA	Barr, Paul Michael
Montefiore Medical Center-Einstein Campus	USA	Anampa Mesias, Jesus Del Santo
Northwell Health/Center for Advanced Medicine	USA	Weiselberg, Lora R.
Ohio State University Comprehensive Cancer Center	USA	Ramaswamy, Bhuvaneswari
Cleveland Clinic Foundation	USA	Gerds, Aaron Thomas
UH Seidman Cancer Center at Southwest General Hospital	USA	Shenk, Robert R.
Kettering Medical Center	USA	Gross, Howard M.
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Allegheny General Hospital	USA	Julian, Thomas Benjamin
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Delaware County Memorial Hospital	USA	Chowdhury, Nabila
Riddle Memorial Hospital	USA	DeNittis, Albert S.
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Fox Chase Cancer Center	USA	Obeid, Elias
Reading Hospital	USA	Cescon, Terrence Paul
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3. SUPPLEMENTARY METHODS

3.1 DUAL PLATFORM MODEL USED TO CONDUCT THE OLYMPIA TRIAL

This trial was conducted as a partnership between academia, non-profit organisations, government agencies, participating hospitals and industry. The Breast International Group (BIG), Frontier Science and Technology Research Foundation (and its Affiliate, Frontier Science (Scotland) Ltd), the National Cancer Institute, NRG Oncology and AstraZeneca have all played key roles. The guiding principles for the conduct of the study are those of BIG and NRG/ NCI. Data is collected, reviewed and analysed following the Standard Operating Procedures of Frontier Science (non-profit organisation) and NRG/ NCI. All of these organisations have representation on the trial Steering Committee along with representatives of the geographic areas involved in the trial and consumer representatives. A detailed Publication Policy governs all publications using trial data and decisions to publish come from the Steering Committee, not from any individual or individual organization.

Two protocols, identical in terms of study objectives and scientific content differing only in logistical and regulatory content appropriate for the country(ies) they covered (eg. drug distribution, mechanisms for SAE reporting during the study, etc), are employed in the study. The protocol under AZ sponsorship covers all patients recruited from non-US sites and the protocol under NRG sponsorship covers patients within the US. The protocols were developed as a collaboration between the partners described above.

The trial used a single randomization system hosted by Frontier Science (FS) and is reported as one study. Randomization was done using a permuted block algorithm with block-size 4. The randomization system has a built-in random number generator to start the allocations, and blocks are generated randomly as they are required, so there are no random lists generated ahead of time. Non-US sites used the FS front end to get into the randomization system. US sites used the NCI OPEN system which collected pre-randomization information and then connected to the FS system to complete randomization. All patients, treating physicians, and study personnel were blinded to treatment allocation with exception of the Independent Statistical Center, which was provided with treatment codes by the randomization system administrator in order to prepare reports for the Independent Data Monitoring Committee (IDMC).

The collection of the patient data is done using two instances of Rave EDC system (one for the US patients, maintained by NRG, and one for all other patients outside of the US, maintained by FS)). FS and NRG collaborated on the design of the two databases and the respective eCRFs to ensure as much consistency as possible in the data collection. Some differences have been necessary due to differences in company and/or regional data collection standards and these differences are all documented in consistency documentation maintained by AZ. Quality control of the data is done by Frontier Science and NRG for the respective Rave instances. The data from both databases are routinely combined into a single consolidated database at regular intervals. All statistical analyses as well as reports for periodic review by the IDMC have been conducted and reported from the single consolidated database, built, maintained and held by Frontier Science. The Sponsors (NRG/ NCI and AstraZeneca) had no access to this database during the conduct of the trial. Subsets of blinded data were provided for specific purposes as required, e.g. DSUR reporting data to AZ and a subset of PRO data to NRG to allow them to test analysis programs.

3.2 ELIGIBILITY CRITERIA

Inclusion criteria

1. Provision of informed consent prior to any study specific procedures

2. Female or male patients must be ≥18 years of age

3A. For patients who underwent initial surgery and received adjuvant chemotherapy

- TNBC patients must have been axillary node-positive (≥pN1, any tumour size) or axillary node-negative (pN0) with invasive primary tumour pathological size > 2 cm (≥pT2)
- ER and/or PgR positive/HER 2 negative patients must have had ≥4 pathologically confirmed positive lymph nodes

3B. For patients who underwent neoadjuvant chemotherapy followed by surgery

- TNBC patients must have residual invasive breast cancer in the breast and/or resected lymph nodes (non pCR)
- ER and/or PgR positive/HER 2 negative patients must have residual invasive cancer in the breast and/or the resected lymph nodes (non pCR) AND a CPS&EG score ≥3. Instructions how to calculate CPS&EG score (Mittendorf et al 2011; Jeruss et al 2008) are provided in Appendix 4 in the protocol.

4. Histologically confirmed non-metastatic primary invasive adenocarcinoma of the breast that is one of the two following phenotypes:

a) TNBC defined as:

- ER and PgR negative defined as IHC nuclear staining <1%.

AND

- HER2 negative (not eligible for anti-HER2 therapy) defined as:
  - o IHC 0, 1+ without ISH **OR**
  - o IHC 2+ and ISH non-amplified with ratio less than 2.0 and if reported, average HER2 copy number < 4 signals/cells **OR**
  - o ISH non-amplified with ratio less than 2.0 and if reported, average HER2 copy number < 4 signals/cells (without IHC)

b) ER and/or PgR positive, HER2 negative breast cancer defined as:

- ER and/or PgR positive defined as IHC nuclear staining ≥1%.

AND

- HER2 negative (not eligible for anti-HER2 therapy) defined as:
  - o IHC 0, 1+ without ISH **OR**
  - o IHC 2+ and ISH non-amplified with ratio less than 2.0 and if reported, average HER2 copy number < 4 signals/cells **OR**
  - o ISH non-amplified with ratio less than 2.0 and if reported, average HER2 copy number < 4 signals/cells (without IHC)

Patients with multifocal or multicentric invasive disease are eligible as long as all the lesions for which HER2 characterization is available are HER2 negative.

Patients with synchronous bilateral invasive disease are eligible as long as all the lesions assessed for HER2 on both sides are negative.

In both the above cases the lesion considered at highest risk for recurrence based on the investigator's discretion will be used for eligibility determination.

5. Documented germline mutation in *BRCA1* or *BRCA2* that is predicted to be deleterious or suspected deleterious (known or predicted to be detrimental/lead to loss of function).

Local *gBRCA* testing results, if available, will be used for establishing eligibility. If local *gBRCA* testing results are not available, central testing will be provided for those patients who otherwise appear to be eligible (see Section 6.2.1 in the protocol).

6A. Completed adequate breast surgery defined as:

- The inked margins of breast conservation surgery or mastectomy must be histologically free of invasive breast cancer and ductal carcinoma in situ with the exception of the posterior margin if this margin is the pectoralis major fascia or the anterior margin if this is the dermis. Patients with resection margins positive for lobular carcinoma *in situ* are eligible.
- Patients with breast conservation must have adjuvant radiotherapy. Patients having mastectomy may have adjuvant radiotherapy according to local policy and/or international guidelines.

6B. Completed adequate axilla surgery defined as:

Adjuvant Chemotherapy Patients:

- Sentinel lymph node biopsy alone if negative or if lymph node(s) only contain micrometastases (≤2.0 mm) **OR**
- Positive sentinel lymph node biopsy followed by axillary nodal dissection or radiotherapy as per local guidelines **OR**
- Axillary dissection

Neoadjuvant Chemotherapy Patients:

- Sentinel lymph node biopsy performed *before* neoadjuvant chemotherapy:
    - If negative or if lymph node(s) only contain micrometastases (≤2.0 mm) additional axillary surgery is not required
    - If positive, axillary node dissection or axillary nodal radiotherapy should follow completion of neoadjuvant chemotherapy
- Sentinel lymph node biopsy performed *after* neoadjuvant chemotherapy:
    - If negative, additional axillary surgery not mandated
    - If positive (micrometastases are regarded as positive), additional axillary surgery is required unless the patient is enrolled in a Phase III multicenter clinical trial proposing radiotherapy as alternative treatment of the axilla. The trial must be pre-approved by the OlympiA Executive Committee
- Axillary dissection

7. Completed at least 6 cycles of neoadjuvant or adjuvant chemotherapy containing anthracyclines, taxanes or the combination of both. Prior platinum as potentially curative treatment for prior cancer (e.g. ovarian)

or as adjuvant or neoadjuvant treatment for breast cancer is allowed. (For neoadjuvant patients all chemotherapy should be delivered prior to surgery. No further cycles of chemotherapy post surgery are allowed.)

8. Patients must have adequate organ and bone marrow function measured within 28 days prior to randomisation with no blood transfusions (packed red blood cells and/or platelet transfusions) in the past 28 days prior to testing for organ and bone marrow function as defined below:

- Haemoglobin ≥10.0 g/dL
- Absolute neutrophil count (ANC) ≥1.5 x 109/L
- Platelet count ≥100 x 109/L
- Total Bilirubin ≤ ULN (institutional upper limit of normal) except elevated total bilirubin <1.5 x ULN due to Gilbert's disease or similar syndrome involving slow conjugation of bilirubin
- AST (SGOT)/ALT (SGPT) ≤2.5 x ULN
- ALP ≤2.5 x ULN

To rule out metastatic breast cancer, patients with screening ALT/AST or ALP above institutional upper limit of normal should have liver ultrasound, CT or MRI at any time point between diagnosis of current breast cancer and randomisation.

Screening bone scan is required if ALP and/or corrected calcium level are above the institutional upper limit. (Note: PET CT scan may be used as an alternative imaging technique).

9. Serum or plasma creatinine ≤1.5 x ULN

10. ECOG performance status 0-1

11A. Women who are not postmenopausal or have not undergone hysterectomy must have documented negative pregnancy test within 28 days prior to randomisation:

Postmenopausal is defined as:

- Age ≥60 years
- Age <60 years and amenorrheic for 1 year or more in the absence of chemotherapy and/or hormonal treatment
- Follicle stimulating hormone (FSH) and plasma estradiol levels in the postmenopausal range for women under 60 years
- Radiation-induced oophorectomy with last menses >1 year ago
- Bilateral oophorectomy

11B. Women of child bearing potential and their partners, who are sexually active, must agree to the use of two highly effective forms of contraception in combination. This should be started from the signing of the informed consent and continue, throughout the period of taking study treatment and for at least 1 month after last dose of study drug, or they must totally/truly abstain from any form of sexual intercourse. Male patients must use a condom during treatment and for 3 months after last dose of study drug when having sexual intercourse with a pregnant woman or with a woman of childbearing potential. Female partners of male patients should also use a highly effective form of contraception (see Appendix E in the protocol for acceptable methods) if they are of childbearing potential.

12. Patient is willing and able to comply with the protocol for the duration of the study including undergoing treatment and scheduled visits and examinations

13. Formalin fixed, paraffin embedded (FFPE) tumour sample from the primary tumour, mandatory*.
*NOTE: For adjuvant patients, this refers to the surgical specimen; for neoadjuvant patients, both the pre-treatment core biopsy and the surgical specimen with residual disease are requested but only one is mandatory. If the surgery tumour blocks are available, but cannot be submitted, sites may submit a portion of invasive tumour from the original block, either by taking at least one core of at least 3 mm in diameter, or by splitting the original block in two parts, and re-embedding one in a new block for central submission. If blocks containing pre-neoadjuvant treatment core biopsies are available but cannot be submitted, sections mounted on glass slides prepared from the block can be provided. If tumour sample can't be provided as requested above or if it's not available, approval by Study Team for patient's entry into the trial is required.
14. Patient should be randomised in the trial ideally within a maximum of 8 weeks of completion of their last treatment (surgery, chemotherapy or radiotherapy), but in no case longer than 12 weeks.

Exclusion criteria (protocol text abbreviated)

1. Involvement in the planning and/or conduct of the study
2. BRCA1 and/or BRCA2 mutations that are considered non detrimental
3. Previous randomisation in the present study
4. Evidence of metastatic breast cancer
5. Exposure to an investigational product within 30 days or 5 half-lives (whichever is longer) prior to randomisation
6. Previous treatment with a PARP inhibitor and/or known hypersensitivity to any of the excipients of study treatment
7. Patients with second primary cancer, unless they meet protocol-specified exceptions
8. Resting ECG with QTc > 470 msec detected on 2 or more time points within a 24-hour period or family history of long QT syndrome
9. Patients receiving systemic chemotherapy within 3 weeks prior to randomisation
10. Patients receiving adjuvant radiotherapy within 2 weeks prior to randomisation
11. Concomitant use of known strong or moderate CYP3A inhibitors or Concomitant use of known strong or moderate CYP3A inducers.
12. Persistent toxicities (>=CTCAE grade 2) caused by previous cancer therapy
13. Patients with current or past history of hematologic malignancies and any clonal non-malignant haematological disorder which predisposes the patient to develop a haematological malignancy. Exception: lymphoma (refer to Exclusion Criterion 7).
14. Major surgery within 2 weeks of starting study treatment
15. Patients considered a poor medical risk due to a serious, uncontrolled medical disorder, non-malignant systemic disease or active, uncontrolled infection
16. Patients unable to swallow orally administered medication and patients with gastrointestinal disorders likely to interfere with absorption of the study medication
17. Pregnant or breastfeeding women
18. Patients with known active Hepatitis B or C or HIV
19. Previous allogeneic bone marrow transplant
20. Whole blood transfusions in the last 120 days prior to entry to the study which may interfere with gBRCA testing

3.3 CALCULATION FOR THE CPS&EG STAGING SYSTEM

The CPS&EG score is a staging system for disease specific survival in patients with breast cancer treated with neoadjuvant chemotherapy.[1] This incorporates pretreatment clinical stage, estrogen receptor status, nuclear grade and post-neoadjuvant chemotherapy pathological stage.

Calculation instructions: Add the points for Clinical Stage + Pathologic Stage + ER status + Nuclear grade to derive a sum (CPS&EG score) between 0 and 6.

Stage/feature		Points
Clinical Stage (AJCC staging [1])	0	0
	IIA	0
	IIB	1
	IIIA	1
	IIIB	2
	IIIC	2
Pathologic Stage (AJCC staging [1])	0	0
	I	0
	IIA	1
	IIB	1
	IIIA	1
	IIIB	1
	IIIC	2
Receptor status	ER negative [2]	1
Nuclear grade [3]	Nuclear grade 3	1

[1] AJCC: American Joint Committee on Cancer (https://cancerstaging.org/Pages/default.aspx).

[2] ER: Estrogen receptor; definitions for ER negativity see eligibility criteria in the protocol Section 4.1.4.a.

[3] In the unlikely situation nuclear grade cannot be determined, regular histologic grade should be used; if
only Nottingham overall grade is reported, the Nottingham overall grade must be 9 to be scored as 1 point in the CPS&EG score (http://pathology.jhu.edu/breast/grade.php).

3.4 POOLING STRATEGY FOR STRATIFICATION FACTORS

The primary stratified log-rank test of IDFS will be based on the stratification factors determined from the following pooling strategy.

In the event that there are fewer than 5 IDFS events per treatment arm within any individual stratum (initially starting with 16 strata; 16=2x2x2x2 including treatment group), one stratification factor will be removed at a time until there are at least 5 IDFS events within each individual stratum in the following order:

1. Prior platinum use for breast cancer (yes/no)

2. Prior chemotherapy (neo-adjuvant vs. adjuvant)

3. Hormone receptor status (ER and/or PgR positive/HER2 negative vs. TNBC)

Result: When all three factors were included, there were strata with fewer than 5 IDFS events per treatment arm. Hence, prior platinum was removed as a stratification factor. When the remaining two factors were included, there were strata with fewer than 5 IDFS events per treatment arm. Hence, prior chemotherapy was removed as a stratification factor. Therefore, the primary stratified Cox proportional hazards model and the stratified log-rank test of IDFS were based on the stratification factor of hormone receptor status only.

3.5 SENSITIVITY ANALYSES

The protocol specified that seven (7) sensitivity analyses were to be performed if specific criteria were met. In this section we describe the sensitivity analyses, and, for those that met the criteria for conducting the sensitivity analysis, results are presented in tables within this Supplementary Appendix.

1: Confirmed (central Myriad test) germline *BRCA1* and *BRCA2* deleterious/suspected deleterious variant

The protocol specified that, If applicable, an analysis would be performed for IDFS based on all randomised patients confirmed to have *BRCA1* or *BRCA2* germline deleterious/suspected deleterious variant (gBRCA-D/SD-variant) by the central Myriad test. This analysis is only required if the analysis population differs from the primary ITT population (i.e. only required if any of the randomised patients are not confirmed to have gBRCA-D/SD-variant by the central Myriad test).

1539 patients had a Myriad confirmed gBRCA D/SD variant (see Table S2A in this Supplementary Appendix).

Results: The results of this analysis are presented within Table S9 in this Supplementary Appendix.

2: Mis-stratification in the randomisation system

Any patients mis-stratified in the randomisation system (i.e. incorrect details are entered at the time of randomisation) were included in the primary stratified analysis based on the information from the randomisation system. Cross-tabulations of stratification factors from the randomisation system and the correct baseline data from the eCRF were performed. If >5% of randomised patients are incorrectly stratified (i.e. randomisation system data does not match baseline data confirmed in the eCRF) then a sensitivity analysis would be performed for IDFS using the same model as described above but using the eCRF information instead of the randomisation system information. [Note: For all patients, the characteristics reported in the eCRF were used to determine subgroups for the subgroup analyses, while the randomisation system information was used to stratify the logrank and Cox model analyses.]

In accordance with the pooling strategy only hormone receptor status was fitted as a stratification factor. Of the 1836 in the ITT population, 32 (1.7%) had discordant hormone receptor status between what was reported in the randomisation system and what was reported on the eCRF.

Results: Because the 5% threshold was not met, this sensitivity analysis was not performed.

3: Central pathology review

The protocol specified that if the results of ER and PgR status from the local and central labs differ in >5% of randomised patients, then a sensitivity analysis would be performed for IDFS using the same model as described above, but using the central lab result to determine the HR status stratification factor and compared with the primary analysis result.

Of the 1452 patients that have both a central and a local hormone receptor status, 147 (10%) have discordant results (Table S5 in this Supplementary Appendix). 247 patients did not have material available for central pathology review because of regulatory requirements by authorities in China. Central receptor status review results excluding patients from China are shown in Table S4 in this Supplementary Appendix.

Results: Because the 5% threshold for discordance between local and central hormone receptor status was met, this sensitivity analysis was performed. The results of this analysis are presented in Table S9 in this Supplementary Appendix.

4: Important protocol deviations (IPDS)

Important protocol deviations (IPD)s are a concise list of pre-defined protocol deviations which have a very high likelihood of influencing the primary efficacy and/or the secondary safety results. The protocol stated that a 'deviation bias' sensitivity analysis may be performed excluding patients with IPD's that may affect the efficacy of the trial therapy. This sensitivity analysis would be performed excluding patients with IPD's that may affect the efficacy of the trial therapy if > 10% of patients in either treatment group did not have the intended disease or indication or did not receive any randomised therapy.

Of the 1836 patients in the ITT population, 30 (1.6%) did not have intended disease or indication, or did not receive any randomised treatment (see Table S18 in this Supplementary Appendix).

Results: Because the 10% threshold for IPDs was not met, this sensitivity analysis was not performed.

5. Unadjusted analysis

The protocol stated that an unadjusted (unstratified Cox model) analysis would be performed as a sensitivity analysis and compared with the primary results.

Results: This unstratified Cox model analysis was performed. The results of this analysis are presented in Table S9 in this Supplementary Appendix.

6. Assumption of proportional hazards

The protocol stated that the assumption of proportional hazards underlying the log-rank test and the Cox model used for the primary analysis would be assessed. Proportionality will be assessed using two approaches, firstly by inspecting plots of complementary log-log (time) versus log (time) and secondly by formally testing using the Grambsch–Therneau test (G-T) based on scaled Schoenfeld residuals from a Cox model including treatment group as a factor. If the G-T test is significant ($p<0.05$), and proportionality is rejected, Restricted Mean Survival Time (RMST) methods would be used to estimate and test the treatment difference while allowing for non-proportional hazards.

Results: The G-T tests reached the $p<0.05$ threshold. This indicates that proportional hazards cannot be assumed. a rejection of the null hypothesis of proportional hazards. The p-value for the G-T test with identity transformation of time was $p=0.02$, and the p-value for the G-T test with rank transformation of time was $p=0.02$ (see Table S9 in this Supplementary Appendix).

Because the null hypothesis of proportionality was rejected, as specified in the Statistical Analysis Plan, a sensitivity analysis was performed based on the restricted mean survival time (RMST) method, restricting the calculation of RMST to within the first 4.1 years (49 months) of follow-up. The restriction time was defined as the minimum of the maximum of the longest IDFS event time between the two treatment groups. Under non-proportional hazards, the estimated hazard ratio can be interpreted as an average hazard ratio over the observed follow-up period. This hazard ratio may under and overestimate the hazard during different periods of the follow-up. The results of the RMST analysis reach the same conclusion as the main analysis of IDFS, that there is a treatment benefit for the olaparib group. The results of the RMST analysis is presented in Table S9 in this Supplementary Appendix.

7. Interval censored cox regression

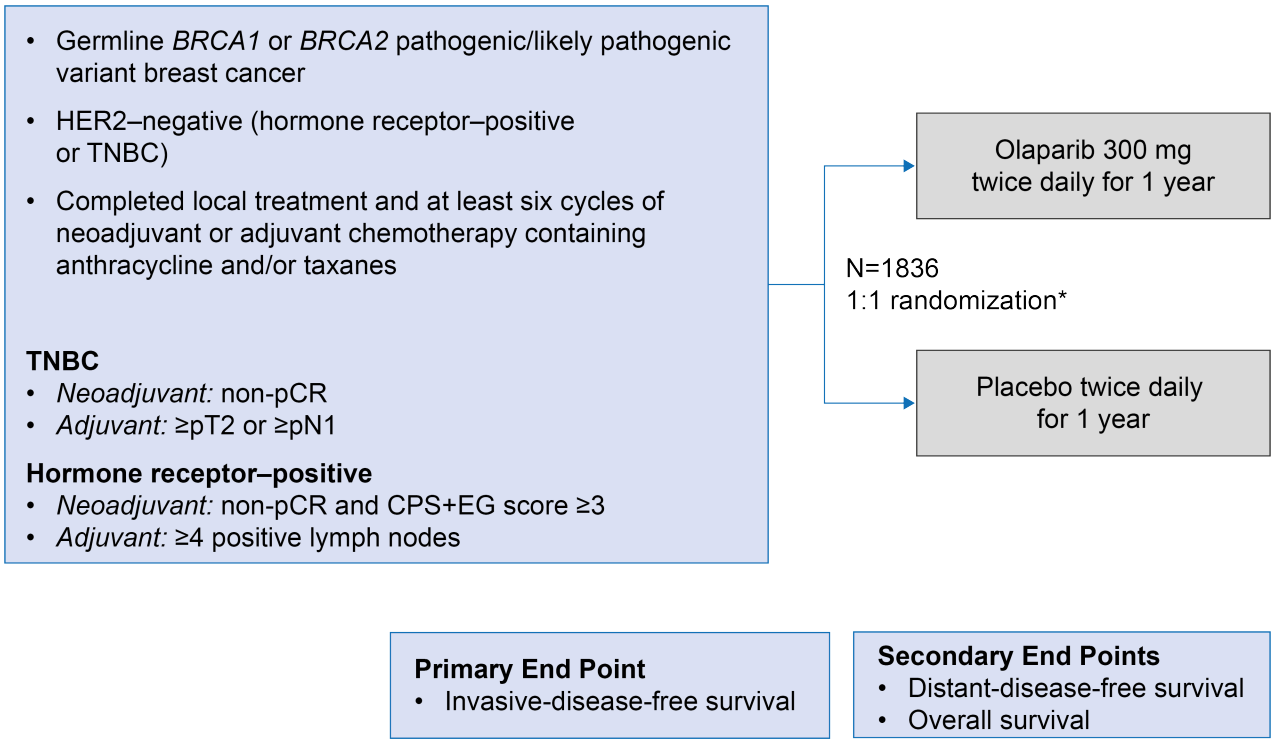
The protocol stated that an interval censored analysis would be performed as a sensitivity analysis and compared with the primary results. Patients whose visit schedule has not been according to the protocol are fitted in the Cox model using interval censoring,

- For patients experiencing an event, and without follow-up according to the protocol (defined as over 18 months between the event and the last visit), the interval from the last date at which the subject was known to be IDFS free to the date of recurrence or death, will be used.
- For patients that were previously censored, or had an event and were seen according to the protocol defined visit schedule, the lower limit of the interval will be set to the censoring/event date, while the upper limit will be set to missing.

Results: No patients met the criteria to initiate this sensitivity analysis.

4. SUPPLEMENTARY FIGURES

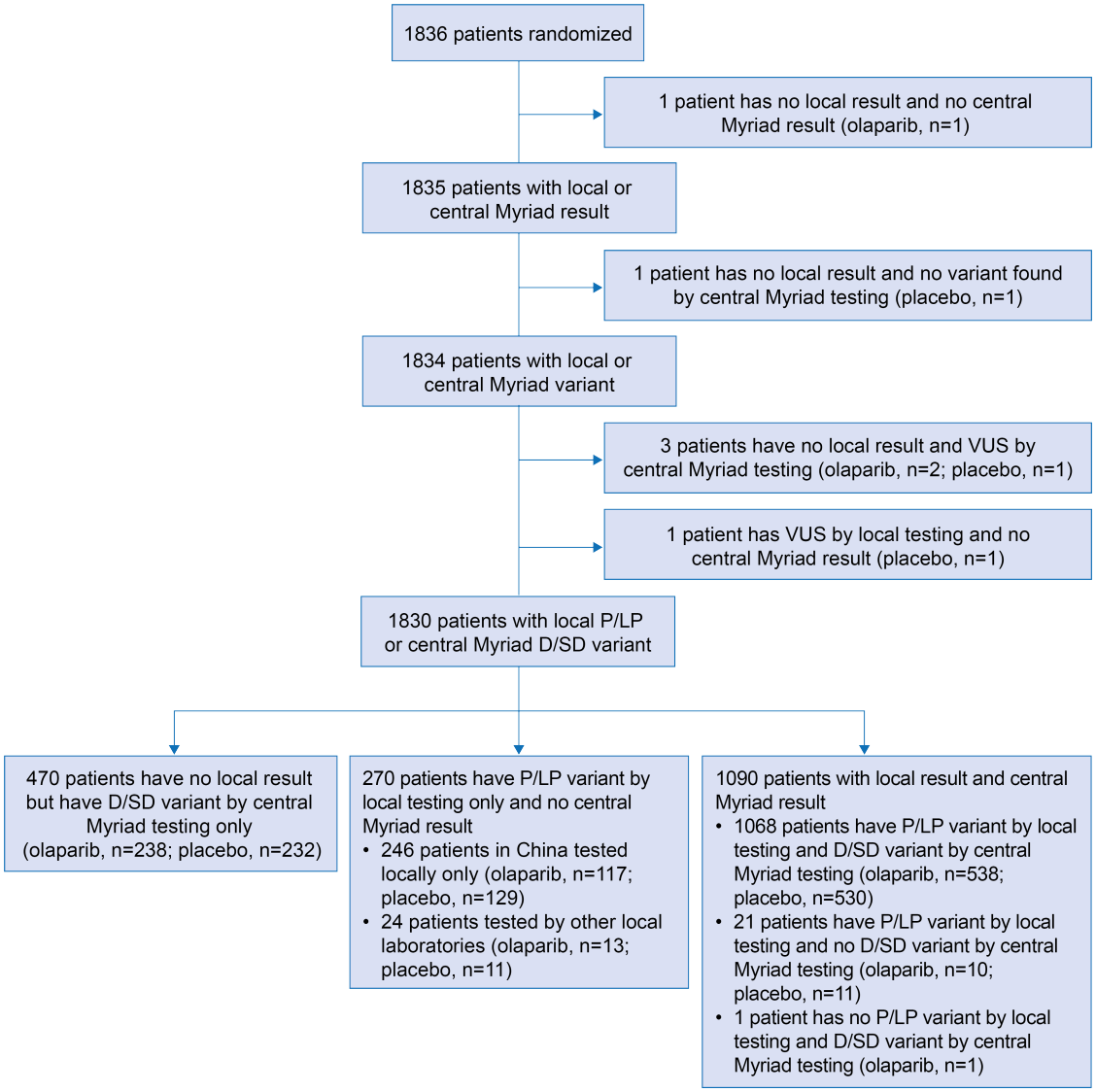
FIGURE S1: OLYMPIA TRIAL SCHEMA



CPS+EG score (see Section 3.3) incorporates pretreatment clinical stage, estrogen receptor status, nuclear grade and pathological stage after neoadjuvant chemotherapy[1]; HER2 denotes human epidermal growth factor receptor 2; pCR denotes pathologic complete response; TNBC denotes triple negative breast cancer.

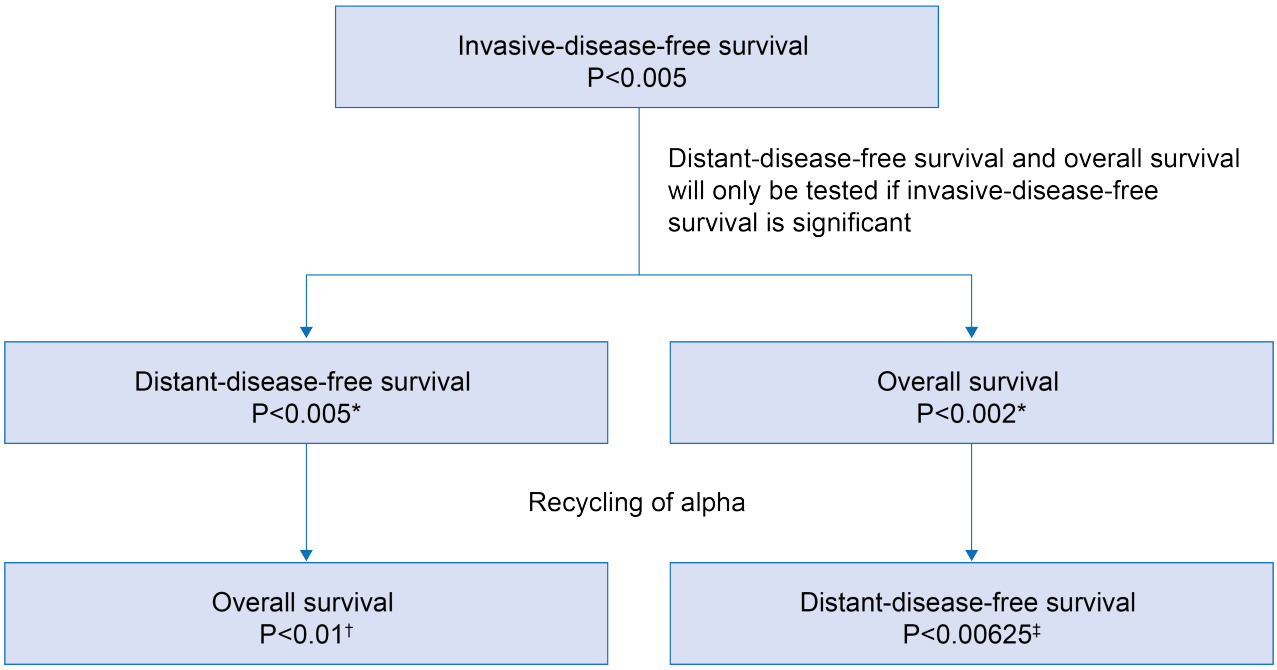
* Stratification factors: (i) hormone receptor–positive vs. TNBC; (ii) neoadjuvant vs. adjuvant; (iii) prior platinum-based chemotherapy (yes vs. no).

FIGURE S2: AVAILABILITY OF BRCA TESTING RESULTS: LOCALLY (INCLUDING BGI GENOMICS FOR ALL PATIENTS IN CHINA) AND CENTRALLY BY MYRIAD GENETICS [1]



[1] This schema illustrates the availability of *BRCA1* and *BRCA2* testing in OlympiA. If testing results were not available for patients who otherwise appeared to be eligible, screening was conducted using BGI Genomics in China and Myriad elsewhere. 6 patients who enrolled in the study without confirmed evidence of a gBRCA-P/LP (D/SD)-variant are described in the top 4 boxes on the right side of the figure (the 1 patient with VUS was screened in China at BGI Genomics). The bottom 3 boxes describe 470 patients with gBRCA-D/SD-variant by central Myriad test but no local result available, 270 patients with gBRCA-P/LP-variant by local test but no central Myriad test result available (246 of whom were screened in China at a single laboratory - BGI Genomics), and 1090 patients with both local and central Myriad results available, showing that 22 of these 1090 patients (2.0%) had discordant local versus central results. Please see Table S2B for the P/LP (D/SD) BRCA 1/2 variants occurring in more than 1 patient. These have been reviewed by a Genetic Advisory Committee made up of academic cancer geneticists and oncologists independent of the sponsors and Co-chaired by J Garber (Co-PI and author) and J Balmana (author) with membership listed on page 4).

FIGURE S3: MULTIPLE TESTING PROCEDURE AT THE INTERIM ANALYSIS

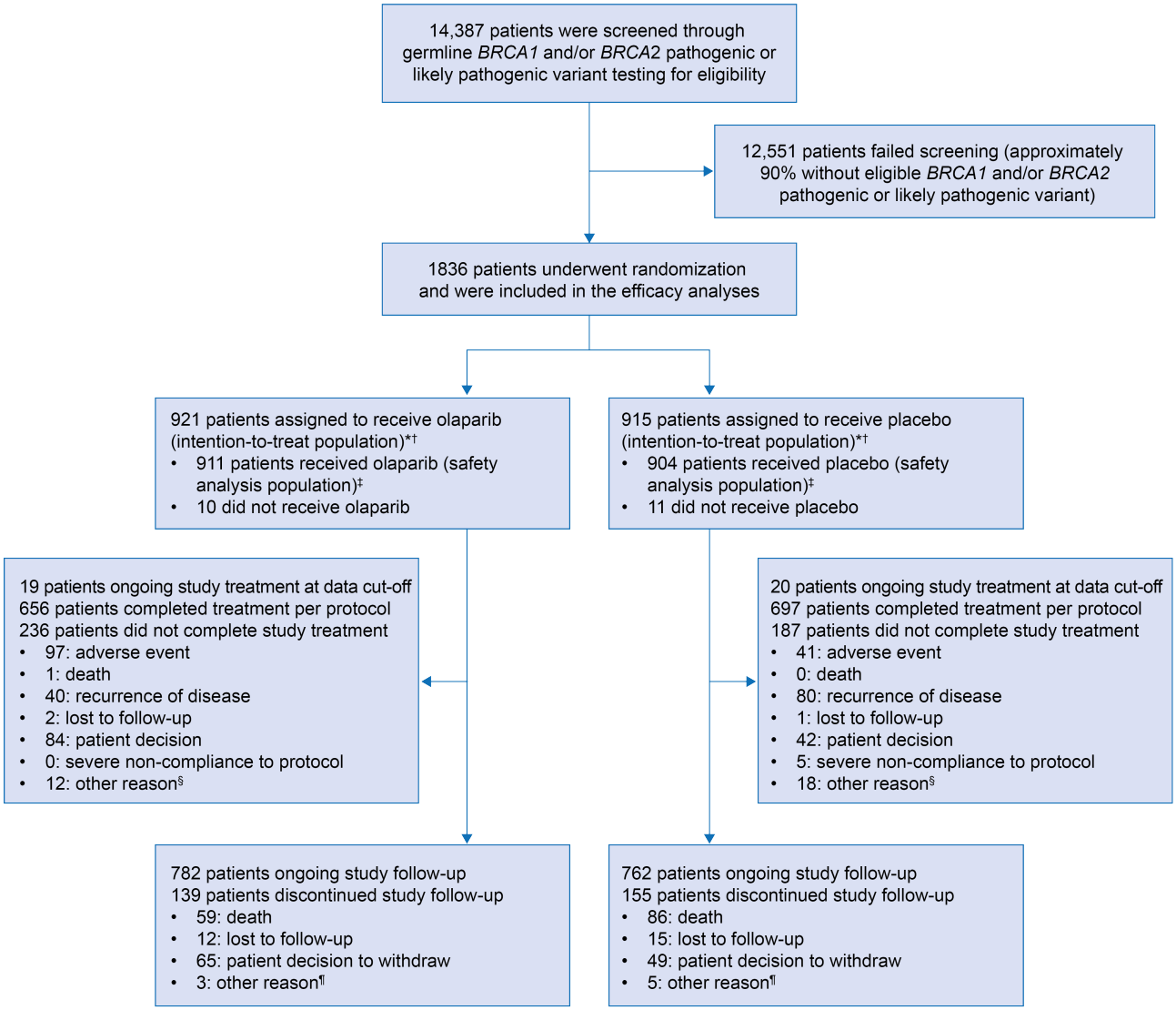


* Distant-disease-free survival and overall survival will be tested only if invasive-disease-free survival is significant.

† If distant-disease-free survival is significant, overall survival will be tested at P<0.01.

‡ If overall survival is significant, distant-disease-free survival will be tested at P<0.00625.

FIGURE S4: CONSORT DIAGRAM FOR THE OLYMPIA TRIAL - PATIENT POPULATION AND DISPOSITION



*All randomized patients were included in the intention-to-treat population. The invasive disease free survival time was censored at 0.5 days for 14 patients because: a) they had had an event prior to randomization (olaparib, n = 2; placebo, n = 3); b) were identified as inadvertent randomisations (i.e. patient was randomised and the site later realised that they should not have been randomised, they have had no follow-up nor did they receive treatment) (olaparib, n = 1; placebo, n = 2); or c) have withdrawn consent, received no treatment, and will not be providing any follow-up data (olaparib, n = 2; placebo, n = 4).

† The first 900 patients randomized were included in the mature cohort evaluated by the Independent Data Monitoring Committee at the time of the prospectively planned interim analysis (olaparib, n = 449; placebo, n = 451).

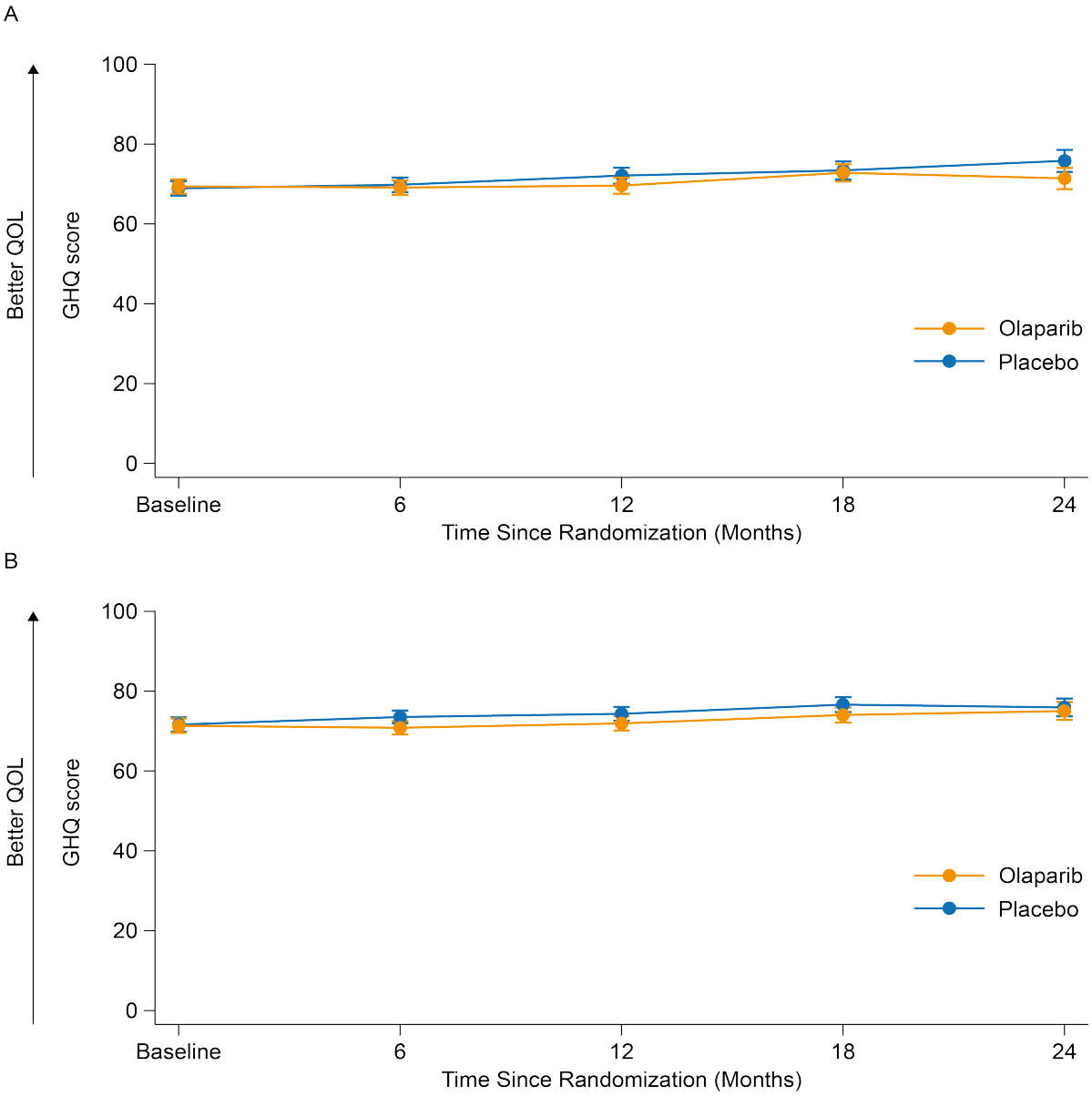
‡ 21 patients who did not receive any study treatment were not included in the safety populations (olaparib, n=10; placebo, n=11).

§ Other reasons for discontinuation of treatment include: For olaparib: site error (n=8); surgery (n=2); Investigator's decision (n=1); Patient has lost insurance and could no longer come in for the study treatment (n=1); Patient was waiting to initiate IP (never started) and then was diagnosed with second primary (n=1). For placebo: site error (n=14); surgery (n=2); Treating investigator's decision (n=1); Patient had a chronic infection that did not resolve for months following her registration to study (n=1).

¶ Other reasons for discontinuation of study follow-up include; For olaparib: Investigator and sponsor decision (n=1); Randomized by mistake while waiting for radiotherapy treatment (n=1); Recurrence prior to randomization (n=1). For placebo: Incorrect randomization (unmet inclusion criteria 3b) (n=1); MD and patient decision to come off study (n=1); Non-compliance to protocol, patient is RAD51C and BRCA negative (n=1); Patient was randomized by mistake, in study physician's opinion patient was not eligible as ER+ and node negative (n=1); physician decision to withdraw patient (n=1).

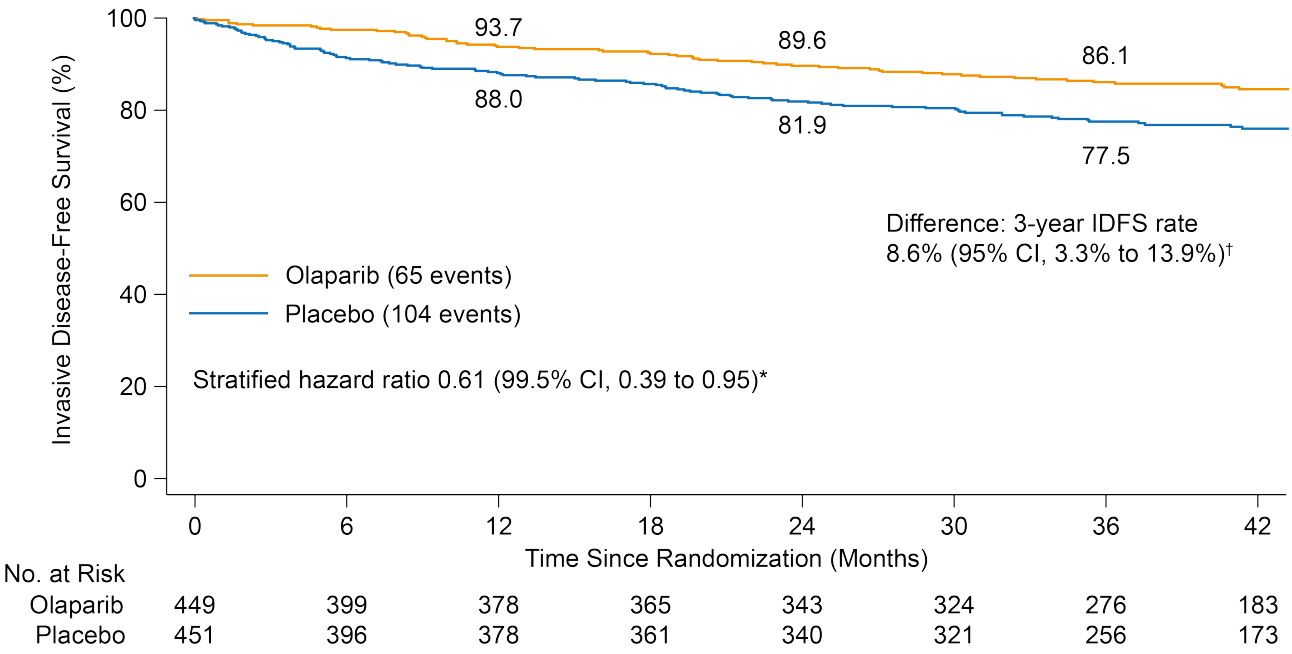
FIGURE S5: EORTC QLQ-C30 GHQ SCORE

The Patient Reported Outcomes (PRO) sub-study will be reported separately. In order to provide some quality of life data for this report of the primary outcome, we have analyzed the 2-item General Health Status/Quality of Life (GHQ) scale of the EORTC QLQ-C30 questionnaire. The PRO data analysis plan stratifies the study sample and considers separate analyses for those who received neoadjuvant or adjuvant chemotherapy prior to trial randomization. Here we show plots of mean EORTC QLQ-C-30 GHQ score by treatment assignment for patients who received neoadjuvant therapy and adjuvant chemotherapy. These indicate that GHQ did not decline during the 12 months of treatment with either olaparib or placebo and improved slightly in both groups between 12 and 24 months. A clinically meaningful difference in GHQ would be greater than 10 points, and the difference between the treatment arms is clinically insignificant.



Legend: Mean response of EORTC QLQ-C30 GHQ score over time by treatment group. Panel A: patients who have completed neoadjuvant chemotherapy. Panel B: patients who have completed adjuvant chemotherapy. GHQ score ranges from 0 to 100, higher score indicates better QOL. Adjusted least-square mean responses and 95% CI for time points other than baseline are obtained from mixed model for repeated measures analysis of the GHQ score. The model includes treatment, time and treatment by time interaction, corresponding baseline score, and the baseline score by time interaction. Mean and 95% CI at baseline are based on the raw data.

FIGURE S6: KM PLOTS FOR IDFS IN THE MATURE COHORT



No. at Risk								
Olaparib	449	399	378	365	343	324	276	183
Placebo	451	396	378	361	340	321	256	173

CI denotes confidence interval.

* Stratified Cox proportional hazards model.

† Kaplan–Meier estimates.

5. SUPPLEMENTARY TABLES

TABLE S1: PATIENTS RANDOMIZED IN OLYMPIA, BY COUNTRY

	Olaparib (N = 921)		**Placebo (N = 915)**		**Total (N = 1836)**	
Country	*no. of patients (%)*					
Argentina	16	(1.7)	12	(1.3)	28	(1.5)
Australia	30	(3.3)	30	(3.3)	60	(3.3)
Austria	28	(3.0)	25	(2.7)	53	(2.9)
Belgium	12	(1.3)	26	(2.8)	38	(2.1)
Canada	11	(1.2)	23	(2.5)	34	(1.9)
China	117	(12.7)	130	(14.2)	247	(13.5)
France	77	(8.4)	65	(7.1)	142	(7.7)
Germany	106	(11.5)	92	(10.1)	198	(10.8)
Hungary	8	(0.9)	9	(1.0)	17	(0.9)
Iceland	5	(0.5)	1	(0.1)	6	(0.3)
Israel	30	(3.3)	35	(3.8)	65	(3.5)
Italy	30	(3.3)	27	(3.0)	57	(3.1)
Japan	64	(6.9)	76	(8.3)	140	(7.6)
Korea (Republic of)	53	(5.8)	44	(4.8)	97	(5.3)
Netherlands	11	(1.2)	18	(2.0)	29	(1.6)
Poland	50	(5.4)	59	(6.4)	109	(5.9)
Portugal	7	(0.8)	6	(0.7)	13	(0.7)
Spain	63	(6.8)	46	(5.0)	109	(5.9)
Sweden	20	(2.2)	15	(1.6)	35	(1.9)
Switzerland	4	(0.4)	17	(1.9)	21	(1.1)
Taiwan	8	(0.9)	4	(0.4)	12	(0.7)
United Kingdom of Great Britain and Northern Ireland	60	(6.5)	46	(5.0)	106	(5.8)
United States of America	111	(12.1)	109	(11.9)	220	(12.0)

TABLE S2A: *BRCA1/2* VARIANT STATUS ANALYSED LOCALLY AND/OR CENTRALLY AT MYRIAD GENETICS [1]

	Olaparib 300 mg bd (N=921)	Placebo (N=915)	Overall (N=1836)
		no. of patients (%)	
Local germline *BRCA1* or *BRCA2* status [2]			
gBRCA-P/LP variant	679 (73.7)	680 (74.3)	1359 (74.0)
Variant of Uncertain Significance (VUS)	1 (0.1)	1 (0.1)	2 (0.1)
No variant	0 (0.0)	0 (0.0)	0 (0.0)
No local result available	241 (26.2)	234 (25.6)	475 (25.9)
BRCA1			
gBRCA-P/LP variant	490 (53.2)	508 (55.5)	998 (54.4)
Variant of Uncertain Significance (VUS)	0 (0.0)	1 (0.1)	1 (0.1)
BRCA2			
gBRCA-P/LP variant	188 (20.4)	168 (18.4)	356 (19.4)
Variant of Uncertain Significance (VUS)	1 (0.1)	0 (0.0)	1 (0.1)
BRCA*1 & *BRCA2			
gBRCA1-P/LP variant + g*BRCA2*-P/LP variant	1 (0.1)	4 (0.4)	5 (0.3)
Central Myriad germline *BRCA1* or *BRCA2* status [3]			
gBRCA-D/SD-variant	777 (84.4)	762 (83.3)	1539 (83.8)
Variant of Uncertain Significance (VUS)	12 (1.3)	8 (0.9)	20 (1.1)
No variant	1 (0.1)	4 (0.4)	5 (0.3)
No central Myriad result available [4]	131 (14.2)	141 (15.4)	272 (14.8)
BRCA1			
gBRCA1-D/SD-variant	552 (59.9)	553 (60.4)	1105 (60.2)
Variant of Uncertain Significance (VUS)	6 (0.7)	5 (0.5)	11 (0.6)
BRCA2			
gBRCA2-D/SD-variant	224 (24.3)	206 (22.5)	430 (23.4)
Variant of Uncertain Significance (VUS)	6 (0.7)	3 (0.3)	9 (0.5)
BRCA1 & BRCA2			
gBRCA1-D/SD-variant + g*BRCA2*-D/SD-variant	1 (0.1)	3 (0.3)	4 (0.2)

[1] Local results include BGI Genomics results for China. Central testing was done by Myriad. OlympiA eligibility required either local results considered Pathogenic (P)/ Likely Pathogenic (LP) variants, as now reported by convention in cancer genetics, or Myriad central laboratory results reported as Deleterious (D)/ Suspected Deleterious (SD) for the same variant status.

[2] Local BRCA results are available only for patients for whose germline *BRCA1* or *BRCA2* variant status was known prior to study entry. Central Myriad results are not available for 247 patients enrolled from China. For countries other than China, central Myriad results are available for 1564 of the 1589 patients (98.4%) (see Supplementary Appendix Figure S2).

[3] Result of confirmatory test carried out centrally by Myriad.

[4] Includes 246 patients randomized in China (olaparib, n=117, placebo, n=129) whose local result from BGI Genomics in China confirmed gBRCA-P/LP-variant that meets study eligibility criteria and 1 patient screened in China with a variant of uncertain significance in the placebo arm. Also includes 25 patients from other countries (olaparib, n=14, placebo, n=11) tested locally with eligible gBRCA1- or gBRCA2-P/LP-variants for whom central Myriad results are not available, 2 of whom (olaparib, n=1; placebo, n=1) have neither local nor central Myriad P/LP variant.

TABLE S2B: P/LP *BRCA1/2* VARIANTS FOR >1 PATIENT [1]

Gene Name	Variant listing	No. patients with variant
BRCA1	c.5266dupC (p.Gln1756Profs*74)	N = 134
BRCA1	c.68_69del (p.Glu23Valfs*17)	N = 72
BRCA1	c.181T>G (p.Cys61Gly)	N = 44
BRCA1	c.188T>A (p.Leu63*)	N = 29
BRCA1	c.5470_5477DEL	N = 24
BRCA1	c.1687C>T (p.Gln563*); c.3700_3704del (p.Val1234Glnfs*8); c.4065_4068del (p.Asn1355Lysfs*10); c.2800C>T (p.Gln934*); c.4327C>T (p.Arg1443*); c.211A>G (p.Arg71Gly); c.5333-36_5406+400del; c.5251C>T (p.Arg1751*); c.3756_3759del (p.Ser1253Argfs*10); c.3607C>T (p.Arg1203*)	N = 10 - 19 (total = 121)
BRCA2	c.5946del (p.Ser1982Argfs*22); c.2808_2811del (p.Ala938Profs*21); c.6275_6276del (p.Leu2092Profs*7); c.7480C>T (p.Arg2494*)	N = 10 - 19 (total = 56)
BRCA1	c.3481_3491del (p.Glu1161Phefs*3); c.4186-1787_4358-1668dup; c.2722G>T (p.Glu908*); c.5095C>T (p.Arg1699Trp); c.3485del (p.Asp1162Valfs*48); c.5123C>A (p.Ala1708Glu); c.2338C>T (p.Gln780*); c.66dupA (p.Glu23Argfs*18); c.1961del (p.Lys654Serfs*47); c.2685_2686del (p.Pro897Lysfs*5); c.3048_3052dup (p.Asn1018Metfs*8); c.4035del (p.Glu1346Lysfs*20); c.5030_5033del (p.Thr1677Ilefs*2); c.798_799del (p.Ser267Lysfs*19); c.815_824dup (p.Thr276Alafs*14); C.5521DEL; C.981_982DEL; c.5503C>T (p.Arg1835*); c.5445G>A (p.Trp1815*); c.390C>A (p.Tyr130*); c.4689C>G (p.Tyr1563*); c.3018_3021del (p.His1006Glnfs*17); c.5496_5506delinsA (p.Val1833Serfs*7); c.470_471del (p.Ser157*); c.843_846del (p.Ser282Tyrfs*15); c.(134+1_135-1)_(441+1_442-1)del; c.427G>T (p.Glu143*); c.5080G>T (p.Glu1694*); c.212+3A>G; c.5324T>G (p.Met1775Arg); c.4065_4068DEL; c.5444G>A (p.Trp1815*); c.1016dupA (p.Val340Glyfs*6); c.1504_1508del (p.Leu502Alafs*2); c.2269del (p.Val757Phefs*8); c.2681_2682del (p.Lys894Thrfs*8); c.3331_3334del (p.Gln1111Asnfs*5); c.3442del (p.Glu1148Argfs*7); c.3627dupA (p.Glu1210Argfs*9); c.5137del (p.Val1713*); c.191G>A (p.Cys64Tyr); c.(5193+1_5194-1)_(5277+1_5278-1)del; c.4675+1G>A; c.213-11T>G; c.213-12A>G; c.1A>G (p.Met1?); c.2572C>T; C.3770_3771DEL; c.4183C>T (p.Gln1395*); c.962G>A (p.Trp321*); c.4287C>A (p.Tyr1429*); c.930del (p.Gln310Hisfs*4); c.981_982del (p.Cys328*); c.19_47del (p.Arg7Cysfs*24); c.1510del (p.Arg504Valfs*28); c.1831del (p.Leu611*); c.1874_1877dupTAGT (p.Val627Serfs*4); c.2125_2126insA (p.Phe709Tyrfs*3); c.2433del (p.Lys812Argfs*3); c.2475del (p.Asp825Glufs*21); c.3228_3229del (p.Gly1077Alafs*8); c.3770_3771del (p.Glu1257Glyfs*9); c.4335_4338dupAGAA (p.Gln1447Argfs*16); c.4936del (p.Val1646Serfs*12); c.4964_4982del (p.Ser1655Tyrfs*16); c.5035_5039del (p.Leu1679Tyrfs*2); c.676del (p.Cys226Valfs*8); c.190T>C (p.Cys64Arg); c.(134+1_135-1)_(212+1_213-1)del;	N = 2 - 9 (total = 509)

	c.(441+1_442-1)_(547+1_548-1)del; c.(80+1_81-1)_(4986+1_4987-1)del; c.4986+3G>C; c.4986+6T>C; c.5278-1G>C; c.5467+1G>A; c.2035A>T (p.Lys679*); c.3442DEL; c.3607C>T; c.4801A>T; c.5074G>A; c.5332+1G>A; c.5333-2A>G; c.3841C>T (p.Gln1281*); c.928C>T (p.Gln310*); c.1082_1092del (p.Ser361*); c.1121_1123delinsT (p.Thr374Ilefs*3); c.1175_1214del (p.Leu392Glnfs*5); c.1380dupA (p.Phe461Ilefs*19); c.1508del (p.Lys503Serfs*29); c.70_80del (p.Cys24Serfs*13); c.1823_1826del (p.Lys608Ilefs*3); c.1892dupT (p.Ser632Lysfs*4); c.2019del (p.Glu673Aspfs*28); c.2110_2111del (p.Asn704Cysfs*7); c.2197_2201del (p.Glu733Thrfs*5); c.2214dupT (p.Lys739*); c.117_118del (p.Cys39*); c.124del (p.Ile42Tyrfs*8); c.2359dupG (p.Glu787Glyfs*3); c.131_132del (p.Cys44*); c.2679_2682del (p.Lys893Asnfs*106); c.2940del (p.Pro981Hisfs*19); c.3013del (p.Glu1005Asnfs*19); c.3108dupT (p.Lys1037*); c.3296del (p.Pro1099Leufs*10); c.3549_3550delinsT (p.Lys1183Asnfs*27); c.3820dupG (p.Val1274Glyfs*13); c.3839_3843delinsAGGC (p.Ser1280*); c.3901_3902del (p.Ser1301*); c.4041_4042del (p.Gly1348Asnfs*7); c.4165_4166del (p.Ser1389*); c.4243del (p.Glu1415Lysfs*4); c.116G>A (p.Cys39Tyr); c.131G>T (p.Cys44Phe); c.5074G>A (p.Asp1692Asn); c.(80+1_81-1)_(134+1_135-1)del; c.(4357+1_4358-1)_(4986+1_4987-1)del; c.(441+1_442-1)_(4357+1_4358-1)del; c.(547+1_548-1)_(4185+1_4186-1)del; c.(5074+1_5075-1)_(5193+1_5194-1)dup; c.3661G>T (p.Glu1221*); c.3748G>T (p.Glu1250*); c.5092G>T (p.Glu1698*); c.4357+1G>C; c.4986+4A>T; c.5193+1G>A; c.213-2A>C; c.5339T>C (p.Leu1780Pro); c.1916T>A (p.Leu639*); c.1608DEL; c.1660G>T; c.2012_2013DUP; c.2110_2111DEL; c.212G>A; c.2960DEL; c.3359_3363DEL; c.3472G>T; c.4185+1G>A; c.4755DEL; c.5030_5033DEL; c.5074+1G>A; c.5153-1G>T; c.5511G>C; c.66DUP; EXON13DELETION; EXON18-19DELETION; EXON18-20DELETION; EXON2-22DELETION; c.4186C>T (p.Gln1396*); c.2309C>A (p.Ser770*); c.5072C>A (p.Thr1691Lys); c.5154G>A (p.Trp1718*); c.1266T>G (p.Tyr422*); c.1965C>A (p.Tyr655*)	
BRCA2	c.5576_5579del (p.Ile1859Lysfs*3); c.6952C>T (p.Arg2318*); c.9371A>T (p.Asn3124Ile); c.3264dupT (p.Gln1089Serfs*10); c.6405_6409del (p.Asn2135Lysfs*3); c.9117G>A (p.Pro3039Pro); c.1813dupA (p.Ile605Asnfs*11); c.3847_3848del (p.Val1283Lysfs*2); c.5722_5723del (p.Leu1908Argfs*2); c.9097dupA (p.Thr3033Asnfs*11); c.9076C>T (p.Gln3026*); c.5682C>G (p.Tyr1894*); c.1310_1313del (p.Lys437Ilefs*22); c.658_659del (p.Val220Ilefs*4); c.7007G>A (p.Arg2336His); c.9382C>T (p.Arg3128*); c.5645C>A (p.Ser1882*); c.2701del (p.Ala902Leufs*2); c.3545_3546del (p.Phe1182*); c.3975_3978dupTGCT (p.Ala1327Cysfs*4); c.5351dupA (p.Asn1784Lysfs*3); c.8904del (p.Val2969Cysfs*7); c.9403del (p.Leu3135Phefs*28); c.771_775del (p.Asn257Lysfs*17); c.8167G>C (p.Asp2723His); c.5857G>T (p.Glu1953*); c.9004G>A (p.Glu3002Lys); c.156_157insAlu; c.2312T>G (p.Leu771*); c.7558C>T (p.Arg2520*); c.1599_1600del (p.Glu534Serfs*3); c.3170_3174del (p.Lys1057Thrfs*8); c.3195_3198del (p.Asn1066Leufs*10); c.3680_3681del (p.Leu1227Glnfs*5); c.3744_3747del (p.Ser1248Argfs*10); c.3860del (p.Asn1287Ilefs*6); c.4449del (p.Asp1484Thrfs*2); c.4936_4939del (p.Glu1646Glnfs*23); c.5073dupA (p.Trp1692Metfs*3); c.5197_5198del (p.Ser1733Argfs*9); c.5213_5216del (p.Thr1738Ilefs*2); c.5217_5223del (p.Tyr1739*); c.5303_5304del (p.Leu1768Argfs*5); c.6024dupG (p.Gln2009Alafs*9); c.6468_6469del (p.Gln2157Ilefs*18); c.6486_6489del	N = 2 - 9 (total = 203)

	(p.Lys2162Asnfs*5); c.469_470del (p.Lys157Valfs*25); c.7913_7917del (p.Phe2638*); c.8575del (p.Gln2859Lysfs*4); c.662_663del (p.Phe221Serfs*3); c.9026_9030del (p.Tyr3009Serfs*7); c.156_157insAlu; c.(7007+1_7008-1)_(7805+1_7806-1)del; c.8629G>T (p.Glu2877*); c.7806-2A>G; c.8487+1G>A; NM_000059.3(BRCA2):C.3109C>T; c.3860DEL; c.5164_5165DEL; c.6591_6592DEL; c.7007G>T; c.9401DEL; c.3883C>T (p.Gln1295*); c.8002A>T (p.Arg2668*); c.9154C>T (p.Arg3052Trp); c.4965C>G (p.Tyr1655*)

[1] Variants are listed for patients with a P/LP variant, either by central Myriad result, BGI, or by other local test for those with no central Myriad P/LP variant. Variants are only presented if they were seen in more than one patient. There are 2 patients with P/LP variants in both *BRCA1* and *BRCA2* genes listed in Table S2B.

TABLE S3: DISCORDANT LOCAL *BRCA1/2* STATUS VS CENTRAL MYRIAD *BRCA1/2* STATUS FOR 22 (2.0%) PATIENTS AMONG THE 1090 PATIENTS WITH BOTH LOCAL AND CENTRAL MYRIAD RESULTS AVAILABLE [1]

		Central Myriad germline *BRCA1* or *BRCA2* status		
		no. of patients (%)		
Overall	**Local germline *BRCA1* or *BRCA2* status**	***gBRCA* D/SD variant**	**Variant of Uncertain Significance (VUS)**	**No variant**
Olaparib 300 mg bd (N=550)	gBRCA-P/LP variant	N/A	10 (1.8)	1 (0.2)
	Variant of Uncertain Significance (VUS)	1 (0.2)	N/A	0 (0.0)
	No variant	0 (0.0)	0 (0.0)	N/A
Placebo (N=540)	gBRCA-P/LP variant	N/A	7 (1.3)	3 (0.6)
	Variant of Uncertain Significance (VUS)	0 (0.0)	0 (0.0)	N/A
	No variant	0 (0.0)	N/A	0 (0.0)
Total (N=1090)	gBRCA-P/LP variant	N/A	17 (1.6)	4 (0.4)
	Variant of Uncertain Significance (VUS)	1 (0.1)	N/A	0 (0.0)
	No variant	0 (0.0)	0 (0.0)	N/A

[1] Local results include BGI Genomics results for China; central testing was done by Myriad. Percentages presented are based on those for whom both local results and central Myriad results are available. (See Figure S2 in this Supplementary Appendix)

TABLE S4: CENTRAL RECEPTOR STATUS EXCLUDING CHINESE PATIENTS

	Olaparib 300 mg bd (N=921)	Placebo (N=915)	Overall (N=1836)
		no. of patients (%)	
Patients with central pathology results	781	767	1548
HER2 IHC results			
0	661 (84.6)	652 (85.0)	1313 (84.8)
1+	64 (8.2)	57 (7.4)	121 (7.8)
2+	16 (2.0)	12 (1.6)	28 (1.8)
3+	0 (0.0)	2 (0.3)	2 (0.1)
Not interpretable	0 (0.0)	0 (0.0)	0 (0.0)
Missing	40 (5.1)	44 (5.7)	84 (5.4)
HER2 ISH results [1]			
Amplified	1 (0.1)	3 (0.4)	4 (0.3)
Equivocal	0 (0.0)	0 (0.0)	0 (0.0)
Not amplified	15 (1.9)	11 (1.4)	26 (1.7)
Not interpretable	0 (0.0)	0 (0.0)	0 (0.0)
Missing	40 (5.1)	44 (5.7)	84 (5.4)
Hormone Receptor status			
Positive	169 (21.6)	177 (23.1)	346 (22.4)
Negative	563 (72.1)	543 (70.8)	1106 (71.4)
Missing	49 (6.3)	47 (6.1)	96 (6.2)
ER status			
Positive	149 (19.1)	156 (20.3)	305 (19.7)
Negative	591 (75.7)	571 (74.4)	1162 (75.1)
Missing	41 (5.2)	40 (5.2)	81 (5.2)
PgR status			
Positive	118 (15.1)	115 (15.0)	233 (15.1)
Negative	616 (78.9)	604 (78.7)	1220 (78.8)
Missing	47 (6.0)	48 (6.3)	95 (6.1)

Percentages based on those with central pathology results. Central pathology review was performed at the European Institute of Oncology (IEO) in Milan, Italy.

HR+ is defined as ER positive and/or PgR positive, where positive is defined as ≥ 1% of cells stained positive.

Missing includes status 'not done', 'unknown' or 'missing'.

[1] Only reported for those that are not IHC 0 or 1+

TABLE S5: LOCAL VS CENTRAL LABORATORY RESULTS: HORMONE RECEPTOR STATUS

		Central status[1]		
		HR(+)	**HR(-)**	**Missing [2]**
	Local Status	*no. of patients (%)*		
Olaparib 300 mg bd (N=921)	HR(+)	121 (13.1)	**25 (2.7)**	22 (2.4)
	HR(-)	**48 (5.2)**	538 (58.4)	167 (18.1)
Placebo (N=915)	HR(+)	119 (13.0)	**16 (1.7)**	23 (2.5)
	HR(-)	**58 (6.3)**	527 (57.6)	172 (18.8)
Overall (N=1836)	HR(+)	240 (13.1)	**41 (2.2)**	45 (2.5)
	HR(-)	**106 (5.8)**	1065 (58.0)	339 (18.5)

HR+ is defined as ER positive (≥1%) and/or PgR positive (≥1%).

[1] Central laboratory review was not possible for patients recruited in China. Central pathology review was performed at the European Institute of Oncology (IEO) in Milan, Italy.

[2] Missing includes HR status 'unknown' or 'missing', as well as all patients from China.

Of the 1452 patients that have both a central and a local hormone receptor status, 147 (10%) have discordant results.

TABLE S6: DEMOGRAPHIC AND BASELINE DISEASE CHARACTERISTICS OF THE PATIENTS

Characteristic	Olaparib Group (N=921)		Placebo Group (N=915)		Overall (N = 1836)	
Age - median (IQR)	42	(36-49)	43	(36-50)	43	(36-50)
Female - no. of patients (%)	919	(99.8)	911	(99.6)	1830	(99.7)
Male - no. of patients (%)	2	(0.2)	4	(0.4)	6	(0.3)
BRCA gene - no. of patients (%)[1]						
BRCA1	657	(71.3)	670	(73.2)	1327	(72.3)
BRCA2	261	(28.3)	239	(26.1)	500	(27.2)
BRCA1 & BRCA2	2	(0.2)	5	(0.5)	7	(0.4)
Missing	1	(0.1)	1	(0.1)	2	(0.1)
Local or central Myriad *BRCA1* or *BRCA2* germline testing result available [1]	920	(99.9)	915	(100)	1835	(99.9)
Local or central Myriad *BRCA1* or *BRCA2* P/LP variant [2]	918	(99.7)	912	(99.7)	1830	(99.7)
Local testing only [3]	130	(14.1)	141	(15.4)	271	(14.8)
Central Myriad testing only	240	(26.0)	234	(25.6)	474	(25.8)
No local or central Myriad testing available	1	(0.1)	0	(0.0)	1	(0.1)
Local and central BRCA result [4]	550	(59.7)	540	(59.0)	1090	(59.4)
Local (+)/Central (+)	538/550	(97.8)	530/540	(98.1)	1068/1090	(98.0)
Local (-)/Central (+)	1/550	(0.2)	0/540	(0.0)	1/1090	(0.1)
Local (+)/central (-)	11/550	(2.0)	10/540	(1.9)	21/1090	(1.9)
Race - no. of patients (%)						
White	626	(68.0)	599	(65.5)	1225	(66.7)
Black/African-American	19	(2.1)	29	(3.2)	48	(2.6)
Asian	259	(28.1)	272	(29.7)	531	(28.9)
Other	17	(1.8)	15	(1.6)	32	(1.7)
Ethnicity - no. of patients (%)						
Hispanic or Latino	34	(3.7)	24	(2.6)	58	(3.2)
Not Hispanic or Latino	805	(87.4)	812	(88.7)	1617	(88.1)
Not known, not recorded or refused	82	(8.9)	79	(8.6)	161	(8.8)
Jewish descent - no. of patients (%) [5]						
Yes, of Ashkenazi descent	41	(4.5)	36	(3.9)	77	(4.2)
Not of Ashkenazi descent	880	(95.5)	876	(95.7)	1756	(95.6)
Geographic region - no. of patients (%)						
North America	122	(13.2)	132	(14.4)	254	(13.8)
South America	16	(1.7)	12	(1.3)	28	(1.5)
Europe	481	(52.2)	452	(49.4)	933	(50.8)
Asia Pacific and South Africa	302	(32.8)	319	(34.9)	621	(33.8)
Prior Neo/Adjuvant chemotherapy - no. of patients (%)						

Adjuvant	461	(50.1)	455	(49.7)	916	(49.9)
Neoadjuvant	460	(49.9)	460	(50.3)	920	(50.1)
Anthracycline and taxane regimen	871	(94.6)	849	(92.8)	1720	(93.7)
Anthracycline regimen (without taxane)	7	(0.8)	13	(1.4)	20	(1.1)
Taxane regimen (without anthracycline)	43	(4.7)	52	(5.7)	95	(5.2)
Regimen not reported	0	(0.0)	1	(0.1)	1	(0.1)
Less than 6 cycles (neo)adjuvant chemotherapy	7	(0.8)	15	(1.6)	22	(1.2)
Neo/ Adjuvant platinum therapy - no. of patients (%)						
No	674	(73.2)	676	(73.9)	1350	(73.5)
Yes	247	(26.8)	239	(26.1)	486	(26.5)
Concurrent hormone therapy (hormone receptor positive only) - no. of patients (%)	146/168	(86.9)	142/157	(90.4)	288/325	(88.6)
Grade - no. of patients (%) [6]						
Gx: Cannot be assessed	11/714	(1.5)	7/720	(1.0)	18/1434	(1.3)
G1: Well differentiated	2/714	(0.3)	3/720	(0.4)	5/1434	(0.3)
G2: Moderately differentiated	128/714	(17.9)	114/720	(15.8)	242/1434	(16.9)
G3: Poorly differentiated/ undifferentiated	562/714	(78.7)	582/720	(80.8)	1144/1434	(79.8)
Not done	11/714	(1.5)	14/720	(1.9)	25/1434	(1.7)
Pathological AJCC stage (adjuvant chemotherapy only) - no. of patients (%)						
0	0/461	(0.0)	0/455	(0.0)	0/916	(0.0)
IA [7]	5/461	(1.1)	2/455	(0.4)	7/916	(0.8)
IB	15/461	(3.3)	11/455	(2.4)	26/916	(2.8)
IIA	264/461	(57.3)	250/455	(54.9)	514/916	(56.1)
IIB	70/461	(15.2)	75/455	(16.5)	145/916	(15.8)
IIIA	73/461	(15.8)	70/455	(15.4)	143/916	(15.6)
IIIB	0/461	(0.0)	2/455	(0.4)	2/916	(0.2)
IIIC	28/461	(6.1)	41/455	(9.0)	69/916	(7.5)
NA [8]	6/461	(1.3)	4/455	(0.9)	10/916	(1.1)
CPS + EG score (neo adjuvant chemotherapy only)						
no. of patients (%)						
CPS+EG score of 2, 3 or 4	398/460	(86.5)	387/460	(84.1)	785/920	(85.3)
CPS+EG score of 5 or 6	22/460	(4.8)	15/460	(3.3)	37/920	(4.0)
HR+/HER2-						
CPS+EG score ≤2 [7]	13/460	(2.8)	6/460	(1.3)	19/920	(2.1)
CPS+EG score of 3 or 4	88/460	(19.1)	85/460	(18.5)	173/920	(18.8)
CPS+EG score of 5 or 6	3/460	(0.7)	1/460	(0.2)	4/920	(0.4)

Not recorded	0/460	(0.0)	0/460	(0.0)	0/920	(0.0)
Triple Negative Breast Cancer						
CPS+EG score ≤2	151/460	(32.8)	144/460	(31.3)	295/920	(32.1)
CPS+EG score of 3 or 4	179/460	(38.9)	197/460	(42.8)	376/920	(40.9)
CPS+EG score of 5 or 6	19/460	(4.1)	14/460	(3.0)	33/920	(3.6)
Not recorded	7/460	(1.5)	13/460	(2.8)	20/920	(2.2)
Hormone receptor status - no. of patients (%) [9]						
Hormone receptor + / HER2- [10]	168	(18.2)	157	(17.2)	325	(17.7)
Triple Negative Breast Cancer [11]	751	(81.5)	758	(82.8)	1509	(82.2)
Menopausal status (females only) - no. of patients (%)						
Premenopausal	572/919	(62.2)	553/911	(60.7)	1125/1830	(61.5)
Postmenopausal	347/919	(37.8)	358/911	(39.3)	705/1830	(38.5)
Bilateral invasive breast cancer - no. of patients (%)						
No	881	(95.7)	888	(97.0)	1769	(96.4)
Yes	40	(4.3)	27	(3.0)	67	(3.6)
Primary breast cancer surgery - no. of patients (%)						
Mastectomy	698	(75.8)	673	(73.6)	1371	(74.7)
Conservative surgery only	223	(24.2)	240	(26.2)	463	(25.2)
Missing	0	(0.0)	2	(0.2)	2	(0.1)
Local therapy for primary breast cancer - no. of patients (%)						
Mastectomy plus radiation therapy	426	(46.3)	410	(44.8)	836	(45.5)
Mastectomy without radiation therapy	272	(29.5)	263	(28.7)	535	(29.1)
Conservative surgery plus radiationtherapy	215	(23.3)	231	(25.2)	446	(24.3)
Conservative surgery without radiation therapy	8	(0.9)	9	(1.0)	17	(0.9)
Missing	0	(0.0)	2	(0.2)	2	(0.1)
Bilateral mastectomy prior to randomisation - no. of patients (%)	332	(36.0)	317	(34.6)	649	(35.3)
Bilateral mastectomy after randomisation - no. of patients (%)	98	(10.6)	108	(11.8)	206	(11.2)
Bilateral oophorectomy and/or salpingectomy prior to randomisation - no. of patients (%)	185	(20.1)	166	(18.1)	351	(19.1)
Bilateral oophorectomy and/or salpingectomy after randomisation - no. of patients (%)	375	(40.7)	386	(42.2)	761	(41.4)

[1] For a detailed description of local and central Myriad *BRCA1/2* testing in patients enrolled on OlympiA please see Figure S2 in this Supplementary Appendix.

Variant interpretation by Myriad Genetics (BRCAnalysis) (n=1564) and BGI Genomics (n=247) is performed using multiple established databases (e.g., ClinVar, ClinGen, ENIGMA) and published and internal functional and clinical data, compliant with ACMG published guidelines. The 24 P/LP variants from local labs without central Myriad confirmation were confirmed by the OlympiA Genetics Advisory Committee using published databases as above. Discordant data are enumerated.

[2] There are 6 patients with an important protocol deviation reported for no documented gBRCA-P/LP-variant in *BRCA1* or *BRCA2* (olaparib, n= 3; placebo n = 3) including 5 patients entered (olaparib, n= 2; placebo n = 3) where either the local or central Myriad testing was done, but with no evidence of a gBRCA-P/LP-variant, and 1 patient in the olaparib group where no local or central Myriad result is available. (See Supplementary Appendix Figure S2).

[3] Includes 246 patients randomized in China (olaparib, n=117, placebo, n=129) whose local result from BGI Genomics in China confirmed gBRCA-P/LP-variant that meets study eligibility criteria and 1 patient screened in China with a variant of uncertain significance in the placebo arm all of whom have no central Myriad result available. Also includes 24 patients from other countries (olaparib, n=13, placebo, n=11) for whom central Myriad results are not available. (See Supplementary Appendix Figure S2).

[4] Patients eligible for the trial are those with a gBRCA-P/LP (D/SD)-variant defined by local testing or central Myriad testing. Patients randomised based on a local test result should also have central Myriad testing done. *BRCA1* and *BRCA2* testing was done by BGI Genomics in China, there are no Myriad results available for these or 25 other patients tested locally only (See Supplementary Appendix Figure S2).

[5] Not Ashkenazi Jewish can mean that the patient is either Jewish but not Ashkenazi Jewish, not Jewish or descent recorded as unknown.

[6] Includes only those patients receiving neoadjuvant chemotherapy for whom eCRF indicates histological grade was assessed on treatment naïve core biopsy and on all patients receiving adjuvant chemotherapy

[7] Reported as protocol deviations.

[8] These include 2 occult BC (placebo, n = 2), 6 pTx (olaparib, n = 4; placebo, n = 2) and 2 pNx (olaparib, n = 2).

[9] Defined by local test results.

[10] The original protocol activated in 2014 was developed for patients with HER2-negative disease but included only patients with TNBC following regulatory review. When hormone-receptor-positive recurrence risk and combination olaparib and endocrine combination safety rationale was accepted by regulators the protocol was amended in 2015 to include patients with high-risk hormone-receptor positive disease and increase the sample size to the current 1800 level (see Protocol History on www.nejm.org). The first patient with hormone-receptor positive disease was enrolled in December 2015.

[11] Triple negative breast cancer was defined in eligibility criteria as: ER and PgR negative defined as IHC nuclear staining <1%. AND HER2 negative (not eligible for anti-HER2 therapy) defined as: IHC 0, 1+ without ISH OR IHC 2+ and ISH non-amplified with ratio less than 2.0 and if reported, average HER2 copy number < 4 signals/cells OR ISH non-amplified with ratio less than 2.0 and if reported, average HER2 copy number < 4 signals/cells (without IHC)

Two patients are excluded from the summary of the TNBC subset because they do not have confirmed negative HER2 status.

TABLE S7: TYPE OF FIRST IDFS EVENT [1]

	Olaparib 300 mg bd (N=921)	Placebo (N=915)
	no. of patients (%)	
IDFS events	**106 (11.5)**	**178 (19.5)**
Distant	**72 (7.8)**	**120 (13.1)**
Distant CNS recurrence	**22 (2.4)**	**36 (3.9)**
Brain metastasis	21 (2.3)	36 (3.9)
Meningitis carcinomatosa	1 (0.1)	0 (0.0)
Distant excl. CNS recurrence	**50 (5.4)**	**84 (9.2)**
Bone	5 (0.5)	14 (1.5)
Lymph nodes (other than local or regional)	5 (0.5)	9 (1.0)
Lung	16 (1.7)	34 (3.7)
Liver	20 (2.2)	23 (2.5)
Pleural effusion	3 (0.3)	4 (0.4)
Other	1 (0.1)	0 (0.0)
Regional (ipsilateral) recurrence	**6 (0.7)**	**14 (1.5)**
Axillary lymph nodes	6 (0.7)	9 (1.0)
Supraclavicular lymph nodes	0 (0.0)	3 (0.3)
Internal mammary lymph nodes	0 (0.0)	1 (0.1)
Skin or soft tissue within the regional area	0 (0.0)	1 (0.1)
Local (ipsilateral) recurrence	**7 (0.8)**	**11 (1.2)**
Breast surgical scar	1 (0.1)	3 (0.3)
Breast	3 (0.3)	4 (0.4)
Anterior chest wall	2 (0.2)	2 (0.2)
Skin or soft tissue within the local area	1 (0.1)	2 (0.2)
Contralateral invasive breast cancer	**8 (0.9)**	**12 (1.3)**
Second primary malignancies	**11 (1.2)**	**21 (2.3)**
Second primary invasive non-breast ovarian/fallopian tube malignancy	2 (0.2)	8 (0.9)
Second primary invasive non-breast non-ovarian malignancies	9 (1.0)	13 (1.4)
Deaths without a prior IDFS event [2]	**2 (0.2)**	**0 (0.0)**

[1] If two recurrence events are reported within 2 months of each other this is referred to as a simultaneous event and will be considered as a single event. In this situation the worst case will be taken as the event 'type' but the date of recurrence will be the earliest date of the two events. (reference Hudis et al, 2007)

[2] The 2 deaths without a prior IDFS event were a cardiac arrest and cause unknown.

TABLE S8: ALL DEATHS

	Olaparib 300 mg bd (N=921)	**Placebo (N=915)**
	no. of patients (%)	
Total number of deaths	59 (6.4)	86 (9.4)
Primary cause of death		
Breast cancer	55 (93.2)	82 (95.3)
Adverse event [1]	1 (1.7)	3 (3.5)
Other [2]	3 (5.1)	1 (1.2)
Missing	0 (0.0)	0 (0.0)

[1] Olaparib: Cardiac arrest (n = 1); Placebo: AML (n = 2), Ovarian cancer (n = 1)

[2] Olaparib: Pulmonary embolism (n = 1), Unknown (n= 1), Pneumonia (n = 1); Placebo: Unknown (n=1)

TABLE S9: RESULTS OF SENSITIVITY ANALYSES

	Olaparib	Placebo
Sensitivity analysis of IDFS in confirmed Myriad gBRCA D/SD patients (n= 1539) [1]		
Number of patients	**777**	**762**
Number of events (%)	89 (11.5)	163 (21.4)
Estimate of hazard ratio	0.51	
99.5% CI for hazard ratio	(0.35 , 0.73)	
Sensitivity analysis of DDFS in confirmed Myriad gBRCA D/SD patients (n= 1539) [1]		
Number of patients	**777**	**762**
Any distant recurrence of disease, second primary cancer, or death (%)	74 (9.5)	138 (18.1)
Estimate of hazard ratio	0.50	
99.5% CI for hazard ratio	(0.33 , 0.75)	
Sensitivity analysis of OS in confirmed Myriad gBRCA D/SD patients (n= 1539) [1]		
Number of patients	**777**	**762**
Number of deaths (%)	47 (6.0)	79 (10.4)
Estimate of hazard ratio	0.58	
99% CI for hazard ratio	(0.35 , 0.92)	
Number of deaths deemed attributable to breast cancer	44 (5.7)	75 (9.8)
Central pathology review IDFS analysis (n = 1452) [2]		
Number of patients	732	720
Number of events (%)	86 (11.7)	151 (21.0)
Estimate of IDFS hazard ratio	0.54	
99.5% CI for IDFS hazard ratio	(0.36 , 0.78)	
Unadjusted IDFS analysis (n= 1836) [3]		
Number of patients	921	915
Number of events (%)	106 (11.5)	178 (19.5)
Estimate of IDFS hazard ratio	0.58	
99.5% CI for hazard ratio	(0.41,0.82)	
Restricted mean survival time (RMST) for IDFS (n = 1836) [3]		
Number of patients	921	915
RMST ratio (olaparib/placebo) [4]	1.085	
99.5% CI for RMST ratio	(1.034,1.139)	
Chi-square: p-value	< 0.0001	
Proportionality test p-value for IDFS (n=1836)		
GT test: Identity transformation of time [5]	0.02	
GT test: Rank transformation of time [6]	0.02	

Proportionality test p-value for DDFS (n=1836)	
GT test: Identity transformation of time [5]	0.20
GT test: Rank transformation of time [6]	0.10
Proportionality test p-value for OS (n=1836)	
GT test: Identity transformation of time [5]	0.79
GT test: Rank transformation of time [6]	0.71

CI, confidence interval

[1] Patients with confirmed Myriad gBRCA-D/SD-variant, excludes 247 patients randomised in China who do not have central Myriad testing available + another 50 patients from other countries who do not have a central confirmed gBRCA-D/SD-variant result.

[2] Includes patients with both central and local hormone receptor results (see Table S5 in this Supplementary Appendix). Excludes 247 from China and 137 from non-Chinese sites. Central pathology review was performed at the European Institute of Oncology (IEO) in Milan, Italy.

[3] Includes entire intention to treat population.

[4] RMST ratio is the RMST for olaparib divided by the RMST for placebo. Numbers greater than 1.0 reflect an increase in the average months free from an IDFS event for olaparib versus placebo - ie. numbers greater than 1.0 favor olaparib. Olaparib significantly increases restricted mean survival time compared with placebo.

[5] Grambsch-Therneau test using untransformed time in the scaled Schoenfeld residual test.

[6] Grambsch-Therneau test using rank transformation of time in the scaled Schoenfeld residual.

TABLE S10: INVASIVE DISEASE FREE SURVIVAL SUBGROUP ANALYSIS

Subgroup	N Olaparib/Placebo	Events (%) Olaparib /Placebo	Hazard ratio & 95% CI [1]
Overall	**921 / 915**	**106 (11.5) / 178 (19.5)**	**0.58 (0.46, 0.74)**
Prior Chemo			
Adjuvant	461 / 455	36 (7.8) / 61 (13.4)	0.60 (0.39, 0.90)
Neoadjuvant	460 / 460	70 (15.2) / 117 (25.4)	0.56 (0.41, 0.75)
Prior Platinum			
Yes	247 / 239	34 (13.8) / 43 (18.0)	0.77 (0.49, 1.21)
No	674 / 676	72 (10.7) / 135 (20.0)	0.52 (0.39, 0.69)
HR status			
HR+/HER2- [2]	168 / 157	19 (11.3) / 25 (15.9)	0.70 (0.38, 1.27)
TNBC [3]	751 / 758	87 (11.6) / 153 (20.2)	0.56 (0.43, 0.73)
BRCA variant type [4]			
BRCA1	558 / 558	70 (12.5) / 126 (22.6)	0.52 (0.39, 0.70)
BRCA2	230 / 209	22 (9.6) / 38 (18.2)	0.52 (0.30, 0.86)
BRCA1/2	1 / 3	0 (0.0) / 0 (0.0)	
HR status by prior chemotherapy setting			
HR+/HER2- with neoadjuvant chemotherapy [2]	104 / 92	13 (12.5) / 20 (21.7)	0.52 (0.25, 1.04)
HR+/HER2- with adjuvant chemotherapy [2]	64 / 65	6 (9.4) / 5 (7.7)	1.36 (0.41, 4.71)
TNBC with neoadjuvant chemotherapy [3]	354 / 368	57 (16.1) / 97 (26.4)	0.57 (0.41, 0.79)
TNBC with adjuvant chemotherapy [3]	397 / 390	30 (7.6) / 56 (14.4)	0.54 (0.34, 0.83)
BRCA status by prior platinum therapy setting			
BRCA1 with prior platinum therapy for current breast cancer	174 / 179	27 (15.5) / 35 (19.6)	0.78 (0.47, 1.28)
BRCA1 with no prior platinum therapy for current breast cancer	384 / 379	43 (11.2) / 91 (24.0)	0.43 (0.30, 0.62)
BRCA2 with prior platinum therapy for current breast cancer	53 / 40	4 (7.5) / 8 (20.0)	
BRCA2 with no prior platinum therapy for current breast cancer	177 / 169	18 (10.2) / 30 (17.8)	0.55 (0.30, 0.98)
BRCA1/2 both with prior platinum therapy for current breast cancer	0 / 1	0 / 0 (0.0)	

BRCA1/2 both with no prior platinum therapy for current breast cancer	1 / 2	0 (0.0) / 0 (0.0)	
Prior platinum by Chemo			
Prior platinum / ACT	78 / 70	8 (10.3) / 4 (5.7)	
Prior platinum / NACT	169 / 169	26 (15.4) / 39 (23.1)	0.66 (0.40, 1.07)
No prior platinum / ACT	383 / 385	28 (7.3) / 57 (14.8)	0.51 (0.32, 0.79)
No prior platinum / NACT	291 / 291	44 (15.1) / 78 (26.8)	0.51 (0.35, 0.73)
Prior platinum by HR status			
Prior platinum / TNBC	218 / 216	28 (12.8) / 40 (18.5)	0.70 (0.43, 1.13)
Prior platinum / HR+/HER2-	28 / 23	6 (21.4) / 3 (13.0)	
No prior platinum / TNBC	533 / 542	59 (11.1) / 113 (20.8)	0.51 (0.37, 0.70)
No prior platinum / HR+/HER2-	140 / 134	13 (9.3) / 22 (16.4)	0.55 (0.27, 1.08)
Type of prior Neoadjuvant/Adjuvant chemotherapy			
Anthracycline regimen (without taxane)	7 / 13	0 (0.0) / 2 (15.4)	
Taxane regimen (without Anthracycline)	43 / 52	5 (11.6) / 8 (15.4)	0.64 (0.19, 1.93)
Anthracycline and taxane regimen	871 / 849	101 (11.6) / 168 (19.8)	0.58 (0.45, 0.74)
Type of breast surgery prior to randomisation			
Breast conservation [5]	223 / 240	20 (9.0) / 46 (19.2)	0.46 (0.27, 0.76)
Mastectomy [6]	698 / 673	86 (12.3) / 131 (19.5)	0.51 (0.33, 0.77)
Presence of at risk ovarian tissue prior to first dose of treatment			
No bilateral oophorectomy	732 / 739	92 (12.6) / 140 (18.9)	0.65 (0.50, 0.84)
Bilateral oophorectomy	189 / 176	14 (7.4) / 38 (21.6)	0.34 (0.18, 0.62)
Pathology axillary node (pN) status at surgery in the TNBC adjuvant cohort [7]			
Node negative	203 / 192	13 (6.4) / 22 (11.5)	0.61 (0.30, 1.19)
Node positive	174 / 177	15 (8.6) / 31 (17.5)	0.48 (0.25, 0.87)
CPS+EG score (for the post neoadjuvant group only)[8]			
CPS+EG score of 2, 3 or 4	398 / 387	55 (13.8) / 96 (24.8)	0.51 (0.37, 0.71)
CPS+EG score of 5 or 6	22 / 15	11 (50.0) / 10 (66.7)	0.44 (0.19, 1.06)
Age at randomisation			
Age < 50 years	699 / 673	79 (11.3) / 133 (19.8)	0.56 (0.42, 0.73)
Age 50 - 64 years	193 / 210	22 (11.4) / 41 (19.5)	0.58 (0.34, 0.96)
Age ≥65 years	29 / 32	5 (17.2) / 4 (12.5)	
Race			
White	626 / 599	75 (12.0) / 124 (20.7)	0.55 (0.41, 0.74)
Black/African-American	19 / 29	4 (21.1) / 5 (17.2)	

Asian	259 / 272	25 (9.7) / 46 (16.9)	0.59 (0.36, 0.95)
Other	17 / 15	2 (11.8) / 3 (20.0)	
Ethnicity			
Hispanic or Latino	34 / 24	7 (20.6) / 7 (29.2)	0.65 (0.22, 1.89)
Not Hispanic or Latino	805 / 812	88 (10.9) / 153 (18.8)	0.58 (0.44, 0.75)
Not known, not recorded or refused	82 / 79	11 (13.4) / 18 (22.8)	0.51 (0.24, 1.07)
Jewish descent			
Yes, of Ashkenazi descent	41 / 36	6 (14.6) / 9 (25.0)	0.49 (0.16, 1.35)
No, not of Ashkenazi descent [9]	880 / 876	100 (11.4) / 169 (19.3)	0.58 (0.45, 0.74)
Primary Study Database			
Breast International Group (BIG)	810 / 806	95 (11.7) / 160 (19.9)	0.58 (0.45, 0.75)
NRG Oncology (US)	111 / 109	11 (9.9) / 18 (16.5)	0.57 (0.26, 1.18)
Geographic region			
North America	122 / 132	11 (9.0) / 23 (17.4)	0.48 (0.23, 0.97)
South America	16 / 12	3 (18.8) / 5 (41.7)	
Europe	481 / 452	62 (12.9) / 95 (21.0)	0.59 (0.43, 0.81)
Asia Pacific and South Africa	302 / 319	30 (9.9) / 55 (17.2)	0.59 (0.37, 0.91)

Hazard ratios are provided only if at least 5 IDFS events have occurred in each of the two treatment groups.

Even without correcting for multiple comparisons none of the tests for heterogeneity reached statistical significance

[1] The Cox model included factors for treatment group, subgroup factor and the treatment-by-subgroup interaction. All patients with non-missing subgroup data were included in the model. A hazard ratio <1 favors olaparib 300 mg bd. The CI was calculated using a profile likelihood approach. These analyses are not inferential. Statistics are provided only if at least 5 IDFS events have occurred in each of the two treatment groups.

[2] HR+ is defined as ER positive and/or PgR positive.

[3] Two patients are excluded from the summary of the TNBC subset because they do not have locally confirmed negative HER2 status.

[4] According to central Myriad testing.

[5] Breast conservation defined as partial mastectomy / breast quadrantectomy / breast segmentectomy / breast lumpectomy and breast re-excision of margins.

[6] Mastectomy defined as modified radical mastectomy, radical mastectomy (Halsted) or simple mastectomy, or bilateral mastectomy.

[7] TNBC, adjuvant patients only, with sentinel node sampling or axillary node dissection.

[8] Pre-specified subgroup analysis. Includes patients that received neoadjuvant chemotherapy, whether they had hormone receptor positive or triple negative disease.

[9] Not Ashkenazi Jewish can mean that the patient self identifies as either Jewish but not Ashkenazi Jewish, not Jewish or descent recorded as unknown.

TABLE S11: EXPOSURE TO STUDY TREATMENT (SAFETY ANALYSIS SET)

	Olaparib 300 mg bd (N=911)	Placebo (N=904)
Total intended exposure (days) [1]		
Mean	306.5	322.4
SD	114.80	97.54
Median	364.0	364.0
Min	1	2
Max	492	414
Actual treatment exposure (days) [2]		
Mean	294.4	315.1
SD	113.90	97.59
Median	350.0	358.0
Min	1	2
Max	420	404
Number of days on 300 mg treatment bd [3]		
Mean	245.2	306.3
SD	141.68	107.51
Median	338.0	358.0
Min	1	2
Max	420	404

Patients with partial treatment end dates are excluded.

[1] Total intended exposure in days = (last dose date - first dose date + 1); does not take account of dose interruptions.

[2] Actual treatment exposure = intended exposure - total duration of dose interruptions, where intended exposure will be calculated as above.

[3] Number of days on 300mg olaparib/placebo bd (actual exposure for the assigned starting dose).

TABLE S12: DOSE INTENSITY (SAFETY ANALYSIS SET)

	Olaparib 300 mg bd (N=911)	Placebo (N=904)
Relative dose intensity (RDI) [1,2]		
No. patients	910	903
Mean	91.9	96.7
SD	12.57	8.12
Median	99.6	100.0
Min	10	38
Q1	87	97
Q3	100	100
Max	103	100
Percentage intended dose (PID) [1,3]		
No. patients	910	903
Mean	81.1	92.0
SD	27.51	17.87
Median	94.8	98.9
Min	0	1
Q1	75	94
Q3	100	100
Max	100	100

Patients with partial treatment end dates are excluded.

[1] Treatment up to one year or until the date of invasive disease (whichever is earliest).

[2] Relative dose intensity (RDI) is the percentage of the actual total dose delivered relative to the intended total dose through to treatment discontinuation.

[3] Percentage intended dose (PID) is the percentage of the actual total dose delivered relative to the intended total dose through to invasive disease.

Due to the eCRF design, the actual cumulative dose does not capture all missed or forgotten doses within an individual day. This will be recorded as if the patient took a full daily dose, which could lead to an overestimation of RDI and PID.

TABLE S13 OF CUMULATIVE EXPOSURE OVER TIME IN MONTHS (SAFETY ANALYSIS SET)

Cumulative exposure over time (months) [1]	Olaparib 300 mg bd (N=911)	Placebo (N=904)
	no. of patients (%)	
> 0 months	910 (99.9)	903 (99.9)
≥ 1 month	848 (93.1)	872 (96.5)
≥ 2 months	824 (90.5)	847 (93.7)
≥ 3 months	801 (87.9)	836 (92.5)
≥ 4 months	782 (85.8)	821 (90.8)
≥ 5 months	769 (84.4)	805 (89.0)
≥ 6 months	757 (83.1)	794 (87.8)
≥ 7 months	752 (82.5)	782 (86.5)
≥ 8 months	739 (81.1)	771 (85.3)
≥ 9 months	719 (78.9)	758 (83.8)
≥ 10 months	706 (77.5)	753 (83.3)
≥ 11 months	685 (75.2)	733 (81.1)

Patients with partial treatment end dates are excluded.

[1] Rows are cumulative and subjects are included if they have taken treatment up to and including that day.

TABLE S14A: BLOOD TRANSFUSIONS (SAFETY ANALYSIS SET)

	Olaparib 300 mg bd (N=911)	**Placebo (N=904)**
	no. of patients (%)	
Patients with at least one blood transfusion	53 (5.8)	8 (0.9)
With ≥ grade 3 anemia on treatment	42 (4.6)	2 (0.2)
With < grade 3 anemia on treatment	9 (1.0)	2 (0.2)
No anemia reported on treatment	2 (0.2)	4 (0.4)
Number of patients with only 1 transfusion	37 (4.1)	6 (0.7)
Number of patients with 2 transfusions	13 (1.4)	2 (0.2)
Number of patients with 3 transfusions	2 (0.2)	0 (0.0)
Number of patients with 5 transfusions	1 (0.1)	0 (0.0)

Includes blood transfusions up to and including 30 days following the date of last dose date.

TABLE S14B: BLOOD TRANSFUSIONS OVER TIME (SAFETY ANALYSIS SET)

	Olaparib 300 mg bd (N=911)		**Placebo (N=904)**	
	no. of patients (%)	*Total no. of transfusions*	*no. of patients (%)*	*Total no. of transfusions*
Treatment month during which blood transfusion is given[1]				
Up to month 1	2 (0.2)	2	0 (0.0)	0
>=1 - 2 months	2 (0.2)	2	1 (0.1)	2
>=2 - 3 months	21 (2.3)	22	0 (0.0)	0
>=3 - 4 months	8 (0.9)	10	1 (0.1)	1
>=4 - 5 months	5 (0.5)	5	1 (0.1)	1
>=5 - 6 months	7 (0.8)	8	1 (0.1)	1
>=6 - 7 months	4 (0.4)	4	0 (0.0)	0
>=7 - 8 months	8 (0.9)	8	0 (0.0)	0
>=8 - 9 months	3 (0.3)	3	0 (0.0)	0
>=9 - 10 months	2 (0.2)	2	1 (0.1)	1
>=10 - 11 months	3 (0.3)	3	1 (0.1)	1
>=11 months	5 (0.5)	5	2 (0.2)	3

Includes blood transfusions up to and including 30 days following the date of last dose date.

[1] Patients with multiple transfusions within the same monthly period are counted once for that period.

TABLE S15: TREATMENT DOSE REDUCTIONS (SAFETY ANALYSIS SET)[1]

	Olaparib 300 mg bd (N=911)	Placebo (N=904)
Patients with no dose reduction (%)	683 (75.0)	857 (94.8)
Patients with a dose reduction (%)	228 (25.0)	47 (5.2)
Total number of dose reductions	287	54
Number of patients with a dose reduction		
1 dose reduction (%)	170 (18.7)	40 (4.4)
2 dose reductions (%)	57 (6.3)	7 (0.8)
3 or more dose reductions (%)	1 (0.1)	0 (0.0)
Reason for reduction [2]		
Adverse event (%)	222 (24.4)	35 (3.9)
Dosing error (%)	6 (0.7)	10 (1.1)
Administrative reasons (%)	2 (0.2)	1 (0.1)
Other (%)	0 (0.0)	1 (0.1)

[1] Dose reductions are based on investigator initiated decisions, reductions due to 'Subject non-compliance' are omitted.

[2] Reasons for dose reductions are not mutually exclusive for patients with multiple reductions although are counted only once per category.

TABLE S16: MOST COMMON AES LEADING TO PERMANENT DISCONTINUATION OF TREATMENT (SAFETY ANALYSIS SET)

Preferred Term	Olaparib 300 mg bd (N=911)	Placebo (N=904)
	no. of patients (%)	
Any AE leading to permanent discontinuation	90 (9.9)	38 (4.2)
Nausea	18 (2.0)	3 (0.3)
Anaemia	16 (1.8)	0 (0.0)
Fatigue	12 (1.3)	4 (0.4)
Neutrophil count decreased	9 (1.0)	1 (0.1)
Headache	7 (0.8)	2 (0.2)
Vomiting	7 (0.8)	0 (0.0)
White blood cell count decreased	6 (0.7)	1 (0.1)
Dizziness	2 (0.2)	3 (0.3)
Decreased appetite	2 (0.2)	2 (0.2)
Diarrhoea	3 (0.3)	1 (0.1)
Breast cancer	1 (0.1)	2 (0.2)
Drug hypersensitivity	3 (0.3)	0 (0.0)
Pruritus	3 (0.3)	0 (0.0)
Abdominal pain upper	1 (0.1)	1 (0.1)
Arthralgia	1 (0.1)	1 (0.1)

Table shows the number and percentage of patients with that adverse event

Includes AEs with an onset from date of first dose up to 30 days following date of last dose.

TABLE S17: ANY CONCURRENT HORMONE THERAPY FOR PRIMARY BREAST CANCER IN THE HR+/HER2- SUBGROUP

	Olaparib 300 mg bd (N=921)	Placebo (N=915)	Overall (N=1836)
		no. of patients (%)	
All HR+/HER2- patients [1]	**168 (100.0)**	**157 (100.0)**	**325 (100.0)**
Any concurrent hormone therapy [2]	**146 (86.9)**	**142 (90.4)**	**288 (88.6)**
Endocrine therapy	146 (86.9)	142 (90.4)	288 (88.6)
Anti-estrogens	72 (42.9)	61 (38.9)	133 (40.9)
Tamoxifen	72 (42.9)	59 (37.6)	131 (40.3)
Toremifene	0 (0.0)	2 (1.3)	2 (0.6)
Aromatase inhibitors	83 (49.4)	85 (54.1)	168 (51.7)
Anastrozole	25 (14.9)	30 (19.1)	55 (16.9)
Exemestane	23 (13.7)	23 (14.6)	46 (14.2)
Letrozole	41 (24.4)	37 (23.6)	78 (24.0)
Pituitary and hypothalamic hormones and analogues	39 (23.2)	33 (21.0)	72 (23.7)

Each treatment will be counted a maximum of once per patient. Percentages presented are based on those patients that have hormone receptor positive breast cancer.

Of the 325 patients with hormone-receptor positive disease, 147 had oophorectomy either before (n=74) or following (n=73) randomization. These numbers for olaparib are: 42, and 33; and for placebo are: 32 and 40.

[1] HR+ is defined as ER positive and/or PgR positive based on a cut-off for positivity of ≥ 1% of cells stained positive.

[2] NB. The protocol defines hormone-receptor positivity as ≥ 1% of cells stained positive but use of adjuvant endocrine therapy was determined by institutional and/ or national guidelines, which may not recommend endocrine therapy for patients with tumors with 1-9% staining of cells for estrogen receptor explaining the lack of endocrine therapy use in 11.4% of patients balanced between treatment arms.

TABLE S18: IMPORTANT PROTOCOL DEVIATIONS

Important protocol deviations (IPD)s are a concise list of pre-defined protocol deviations which have a very high likelihood of influencing the primary efficacy and/or the secondary safety results. IPD's are also distinct from simple protocol deviations.

	Olaparib 300 mg bd (N=921)	**Placebo (N=915)**	**Overall (N=1836)**
	no. of patients (%)		
Number of patients with at least one important protocol deviation triggering a sensitivity analysis [1]	16 (1.7)	14 (1.5)	30 (1.6)
No histologically confirmed non-metastatic primary invasive adenocarcinoma of the breast [2]	3 (0.3)	0 (0.0)	3 (0.2)
No documented germline pathogenic /likely pathogenic variant in *BRCA1* or *BRCA2* [2]	3 (0.3)	3 (0.3)	6 (0.3)
Randomized but did not receive any study treatment [2]	10 (1.1)	11 (1.2)	21 (1.1)
Number of patients with at least one important protocol deviation excl. important GCP violations [3]	130 (14.1)	122 (13.3)	252 (13.7)
No histologically confirmed non-metastatic primary invasive adenocarcinoma of the breast [2]	3 (0.3)	0 (0.0)	3 (0.2)
No documented germline pathogenic /likely pathogenic variant in *BRCA1* or *BRCA2* [2]	3 (0.3)	3 (0.3)	6 (0.3)
Randomized but did not receive any study treatment [2]	10 (1.1)	11 (1.2)	21 (1.1)
Not fulfilling criteria for high risk disease	25 (2.7)	12 (1.3)	37 (2.0)
Inadequate breast surgery and/or radiotherapy	7 (0.8)	8 (0.9)	15 (0.8)
Inadequate axilla surgery	5 (0.5)	1 (0.1)	6 (0.3)
Completed less than 6 cycles of neoadjuvant or adjuvant chemotherapy containing anthracyclines, taxanes or the combination of both	7 (0.8)	15 (1.6)	22 (1.2)
Peri-operative chemotherapy (patients who had both neoadjuvant and adjuvant therapy; 'unquantifiable risk of disease relapse')	4 (0.4)	6 (0.7)	10 (0.5)
Evidence of metastatic disease (to include only those patients who had suspicion or confirmation of recurrence prior to randomisation)	2 (0.2)	4 (0.4)	6 (0.3)
No staging or insufficient staging	67 (7.3)	66 (7.2)	133 (7.2)
Prior PARP inhibitor use	0 (0.0)	0 (0.0)	0 (0.0)
Prior cancer < 5 years ago including MDS/t-AML	0 (0.0)	2 (0.2)	2 (0.1)

Received no study treatment whatsoever for a period of more than 7 days due to errors in dispensing of medication	5 (0.5)	4 (0.4)	9 (0.5)
Received an alternative study treatment to that which they were randomized	0 (0.0)	0 (0.0)	0 (0.0)
Received prohibited concomitant medication	10 (1.1)	12 (1.3)	22 (1.2)
Received additional anti-cancer therapy prior to IDFS event [4]	0 (0.0)	0 (0.0)	0 (0.0)
Received other investigational agent prior to IDFS event	0 (0.0)	0 (0.0)	0 (0.0)
Lack of confirmatory exams for events that count towards the analysis end points, efficacy and safety	0 (0.0)	1 (0.1)	1 (0.1)

[1] Statistical Analysis Plan specified that a sensitivity analysis for primary efficacy be conducted if >10% of the full analysis set did not have the intended disease or indication or did not receive any study medication. This is shown in Table S9.

[2] An important protocol deviation (IPD) that triggers a sensitivity analysis

[3] The same patient may have had more than one important protocol deviation. Important protocol deviations are those that could have a strong influence on the interpretation of the efficacy or safety results.

[4] Other than hormone therapy or adjuvant bisphosphonates permitted in the protocol.

TABLE S19: SUMMARY OF ADVERSE EVENTS IN THE SAFETY ANALYSIS SET [1]

Adverse Event — no. of patients (%)	Olaparib (N=911)	Placebo (N=904)
Any adverse event	835 (91.7)	753 (83.3)
Serious adverse event	79 (8.7)	76 (8.4)
Adverse event of special interest [2]	30 (3.3)	46 (5.1)
MDS/AML	2 (0.2)	3 (0.3)
Pneumonitis [3]	9 (1.0)	11 (1.2)
New primary cancer [4]	19 (2.1)	32 (3.5)
New primary invasive breast cancer	7	8
New primary ductal carcinoma in situ	3	4
New primary ovarian malignancy [5]	1	4
New primary fallopian tube cancer	1	4
New primary lung cancer	1	2
Malignant melanoma	1	3
Non-melanoma skin cancer	3	2
Other [6]	3	6
Grade ≥3 adverse event	221 (24.3)	102 (11.3)
Grade 4 adverse event [7]	17 (1.9)	4 (0.4)
Decreased neutrophil count	5	0
Anemia	4	0
Decreased lymphocyte count	3	0
Depression	0	2
Other [8]	6	2
Adverse event leading to permanent discontinuation of treatment [9]	90 (9.9)	38 (4.2)
Adverse event leading to death [10]	1 (0.1)	2 (0.2)

[1] Included are adverse events with an onset date on or after the date of the first dose and up to and including 30 days after the date of the last dose of olaparib or placebo. The safety analysis set excludes patients who did not receive any olaparib or placebo. AML denotes acute myeloid leukemia, and MDS myelodysplastic syndrome.

[2] Included are adverse events of special interest with an onset at any date after the first dose of olaparib or placebo. One patient in the olaparib group had both pneumonitis and a nonmelanoma skin cancer and is counted in both the pneumonitis and new primary cancer categories.

[3] In the olaparib group, seven patients had pneumonitis, and two patients had radiation pneumonitis. In the placebo group, eight patients had pneumonitis, and three patients had radiation pneumonitis.

[4] In the olaparib group, nineteen patients had twenty new primary cancers: one patient had both new primary breast cancer and new primary lung cancer and is counted in both categories. In the placebo group, thirty-two patients had thirty-three new primary cancers: one patient had new primary breast cancer and new serous tubular intraepithelial carcinoma, and is counted in both new primary invasive breast cancer and the ‘other’ categories.

[5] In the olaparib group, one patient had new primary ovarian cancer (a possible recurrence of ovarian cancer > 5 years before randomization).

[6] In the olaparib group, one patient each in the 'other' category had colorectal cancer, endometrial adenocarcinoma, and meningioma. In the placebo group, one patient each in the 'other' category had cervical carcinoma, endometrial adenocarcinoma, pancreatic carcinoma, rectal carcinoma, transitional-cell carcinoma, and new serous tubular intraepithelial carcinoma (in a patient who also had new primary invasive breast cancer).

[7] A total of 18 grade 4 adverse events were reported in 17 patients who received olaparib; one patient had both grade 4 anemia and decreased neutrophil count and is counted in both of anemia and decreased neutrophil count categories.

[8] In the olaparib group, one patient each in the 'other' category had AML, bipolar disorder, fatigue, febrile neutropenia, abnormal hepatic function, and a suicide attempt. In the placebo group, one patient each in the 'other' category had increased aspartate aminotransferase level and acute cholecystitis.

[9] The most common adverse events, occurring in at least 1% of the patients, that led to discontinuation of olaparib were nausea (2.0%), anemia (1.8%), fatigue (1.3%), and decreased neutrophil count (1.0%); there were no adverse events that occurred in at least 1% of patients that led to discontinuation of placebo.

[10] In the olaparib group, cardiac arrest led to death in one patient. In the placebo group, AML and ovarian cancer led to death in one patient each.

6. REFERENCE

1. Mittendorf EA, Jeruss JS, Tucker SL, et al. Validation of a novel staging system for disease-specific survival in patients with breast cancer treated with neoadjuvant chemotherapy. J Clin Oncol 2011;29:1956–62.