

## Supplementary Online Content

Tachihara M, Tsujino K, Ishihara T, et al. Durvalumab plus concurrent radiotherapy for treatment of locally advanced non–small cell lung cancer: the DOLPHIN phase 2 nonrandomized controlled trial. Published online September 7, 2023. *JAMA Oncol*. doi:10.1001/jamaoncol.2023.3309

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

**Table 1. Inclusion and Key Exclusion Criteria**

|   |
|---|
| <b>Inclusion criteria</b>   |
| <b>&lt;The primary inclusion criteria&gt;</b><br>Age ≥20 years old<br>ECOG performance status of 0 or 1<br>Histologic evidence of NSCLC<br>Suspected locally advanced NSCLC (stage IIIA, B, C) or postoperative recurrence<br>With measurable lesions<br>Availability of tumor tissue for IHC<br>Adequate organ and bone marrow function<br>SpO <sub>2</sub> ≥93%<br>No history of thoracic radiation therapy and chemotherapy<br>24 weeks have passed since adjuvant chemotherapy<br>Life expectancy of ≥12 weeks<br>Body weight ≥30kg<br>Written informed consent |
| <b>&lt;The secondary inclusion criteria&gt;</b><br>Confirmed unresectable locally advanced NSCLC is curable by the radiation protocol<br>Irradiation is possible (60 Gy in 30 fractions prescribed to D95% of PTV to involved fields)   |
| PD-L1 positive of tumor cells (SP263)   |
| <b>Key Exclusion criteria</b>   |
| Active double cancer<br>Active infection, including tuberculosis, hepatitis B and C<br>Interstitial lung disease detected by chest-CT<br>Complication of active autoimmune disease<br>Prescription of more than 10mg PSL continuously   |

Abbreviations: NSCLC, non-small cell lung cancer; ECOG, Eastern Cooperative Oncology Group; PS, performance status; IHC, Immunohistochemistry; SpO<sub>2</sub>, arterial oxygen saturation of pulse oximetry; PD-L1, programmed cell death ligand-1; CT, computed tomography; PSL, prednisolone.

**eTable 2. Anti-Tumor Efficacy**

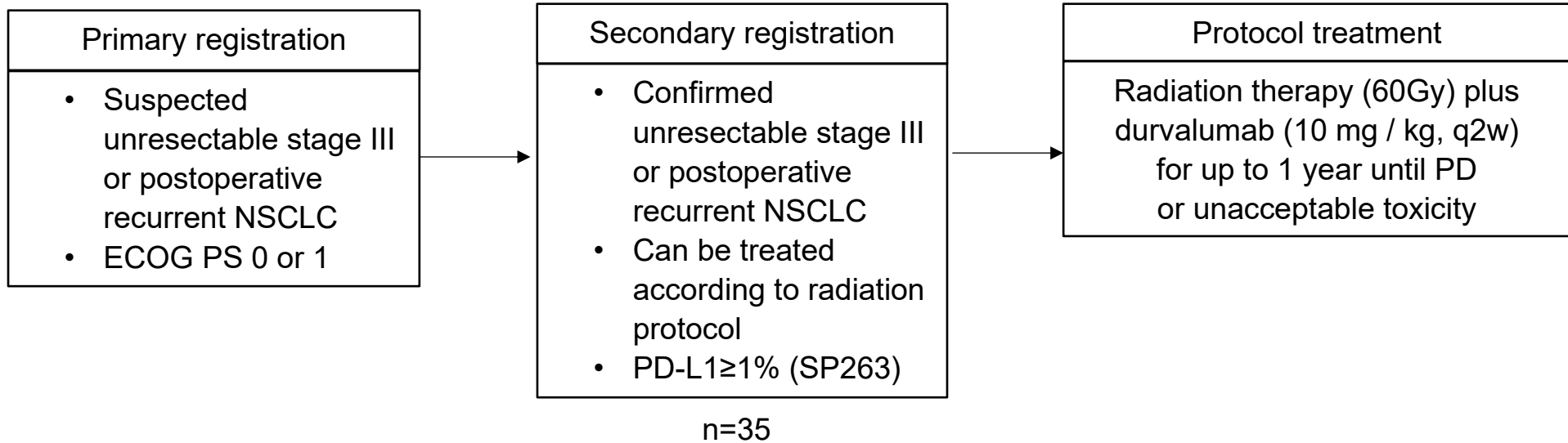
|                                       |                       |
|---------------------------------------|-----------------------|
| Anti-tumor efficacy                   | n=33                  |
| Confirmed ORR, No. %(95% CI)          | 30, 90.9% (75.7-98.1) |
| DCR, No. (% , 95% CI)                 | 33, 100% (89.4-100.0) |
| Best overall response by ICR, No. (%) |                       |
| CR                                    | 11 (33.3)             |
| PR                                    | 19 (57.6)             |
| SD                                    | 3 (9.1)               |
| PD                                    | 0 (0.0)               |
| Median DOR, months (95% CI)           | NR (14.9-NE)          |

Abbreviations: ORR, overall response rate; ICR, independent central review; CR, complete response; PR, partial response; SD, stable disease; PD, progressive disease; DCR, disease control rate; DOR, duration of response.

**eTable 3. Adverse Events of Any Cause in ≥10% of Patients**

| <b>Event</b>               | <b>Any grade</b> | <b>Grade 3 or 4</b> | <b>Grade 5</b> |
|----------------------------|------------------|---------------------|----------------|
|                            | No. (%)          |                     |                |
| Any events                 | 34 (100)         | 18 (52.9)           | 2 (5.9)        |
| Radiation dermatitis       | 15 (44.1)        | 0                   | 0              |
| Pneumonitis                | 14 (41.2)        | 4 (11.8)            | 0              |
| Constipation               | 11 (32.4)        | 0                   | 0              |
| Radiation pneumonitis      | 9 (26.5)         | 0                   | 0              |
| Esophagitis                | 9 (26.5)         | 0                   | 0              |
| Lung infection             | 8 (23.5)         | 3 (8.8)             | 1 (2.9)        |
| Dermatitis                 | 8 (23.5)         | 0                   | 0              |
| Diarrhea                   | 7 (20.6)         | 0                   | 0              |
| Hypothyroidism             | 7 (20.6)         | 0                   | 0              |
| Hyperthyroidism            | 6 (17.6)         | 0                   | 0              |
| Pyrexia                    | 6 (17.6)         | 0                   | 0              |
| Pruritus                   | 6 (17.6)         | 0                   | 0              |
| Rash                       | 8 (17.6)         | 0                   | 0              |
| Anemia                     | 6 (17.6)         | 0                   | 0              |
| Thrombocytopenia           | 6 (17.6)         | 1 (2.9)             | 0              |
| Cough                      | 5 (14.7)         | 0                   | 0              |
| Fatigue                    | 5 (14.7)         | 0                   | 0              |
| Amylase increased          | 5 (14.7)         | 1 (2.9)             | 0              |
| Lipase increased           | 5 (14.7)         | 1 (2.9)             | 0              |
| Lymphocyte count decreased | 5 (14.7)         | 5 (14.7)            | 0              |
| Nausea                     | 4 (11.8)         | 0                   | 0              |
| Decreased appetite         | 4 (11.8)         | 0                   | 0              |
| Musculoskeletal pain       | 4 (11.8)         | 0                   | 0              |
| Hyperglycemia              | 4 (11.8)         | 3 (8.8)             | 0              |
| AST increased              | 4 (11.8)         | 2 (5.9)             | 0              |
| Leukopenia                 | 4 (11.8)         | 0                   | 0              |

**eFigure 1. Study Schema**



**Primary endpoint:** 12-month PFS rate from 2<sup>nd</sup> registration (assessed by independent central review)

**Secondary endpoints:** PFS, OS, objective response rate, disease control rate, time to death or distant metastasis, treatment completion rate, and safety

**eFigure 2. Progression-Free Survival Subgroup Analyses by Characteristics**

