

## **SUPPLEMENTARY MATERIAL**

### **Efficacy and Safety of Risankizumab for Active Psoriatic Arthritis: 100-Week Results from the Phase 3 KEEPSAKE 1 Randomized Clinical Trial**

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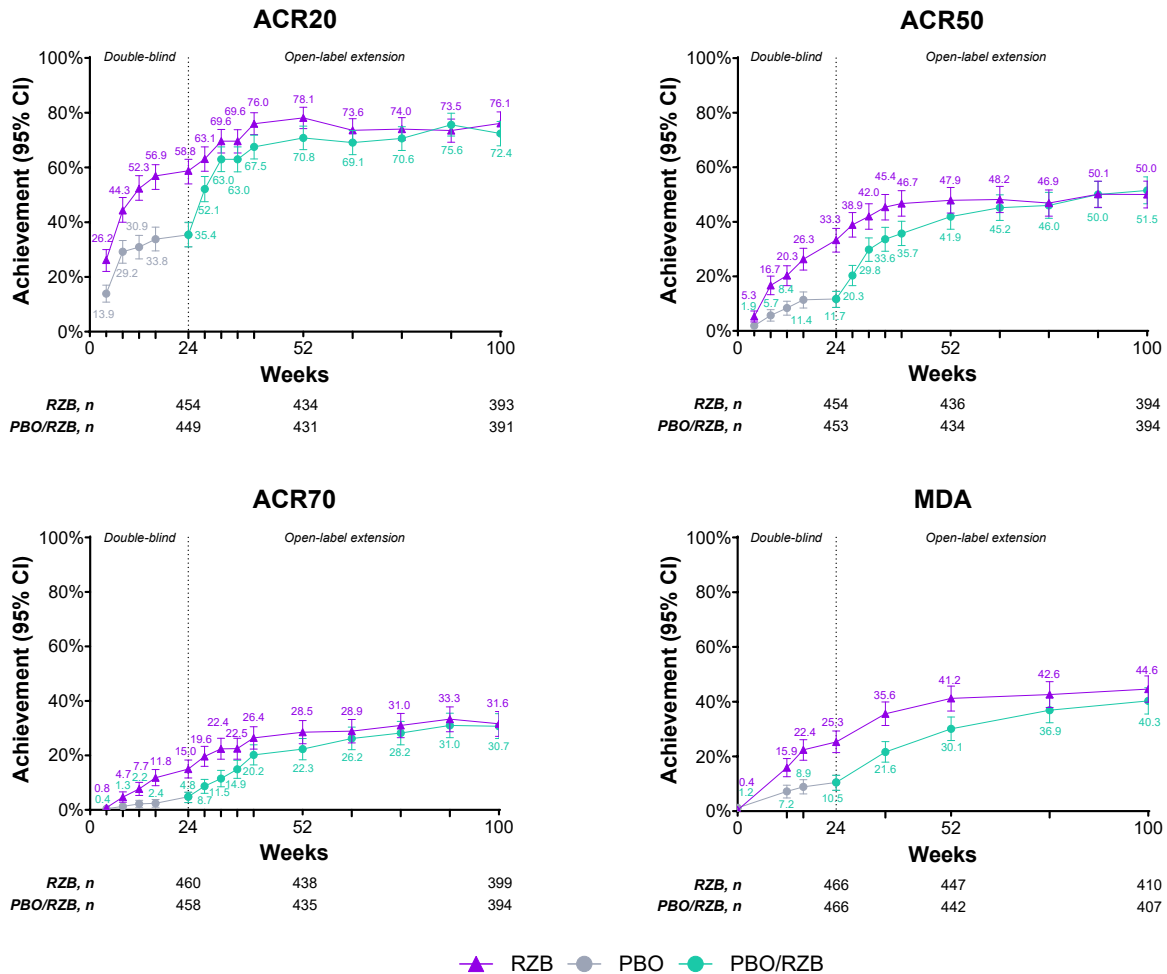
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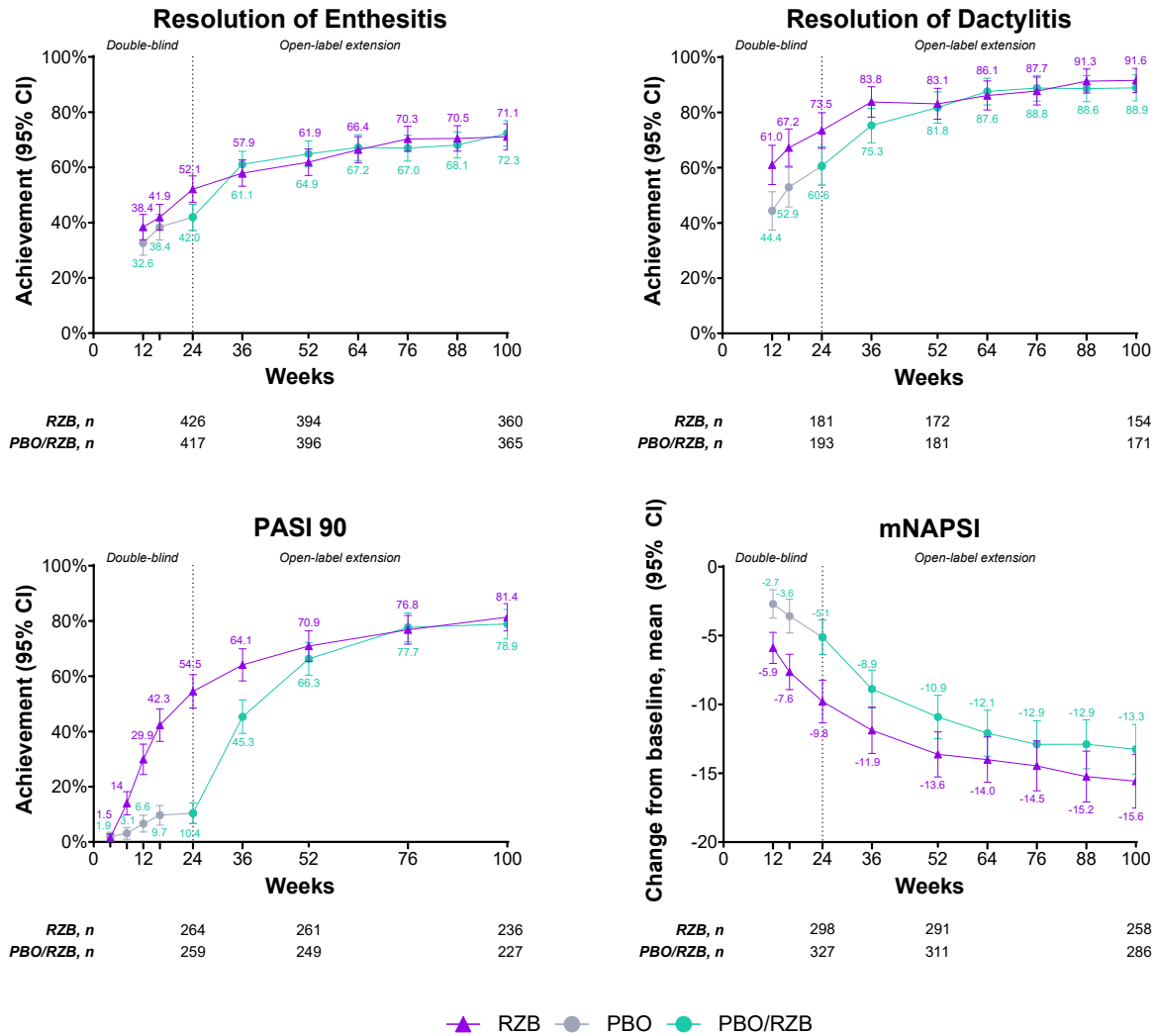
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**Supplementary Fig. 1** Achievement over time of ACR improvement endpoints and MDA (as observed).



ACR20/50/70  $\geq$  20%/ $\geq$  50%/ $\geq$  70% improvement in American College of Rheumatology criteria for symptoms of rheumatoid arthritis, *CI* confidence interval, *MDA* minimal disease activity, *PBO* placebo, *RZB* risankizumab

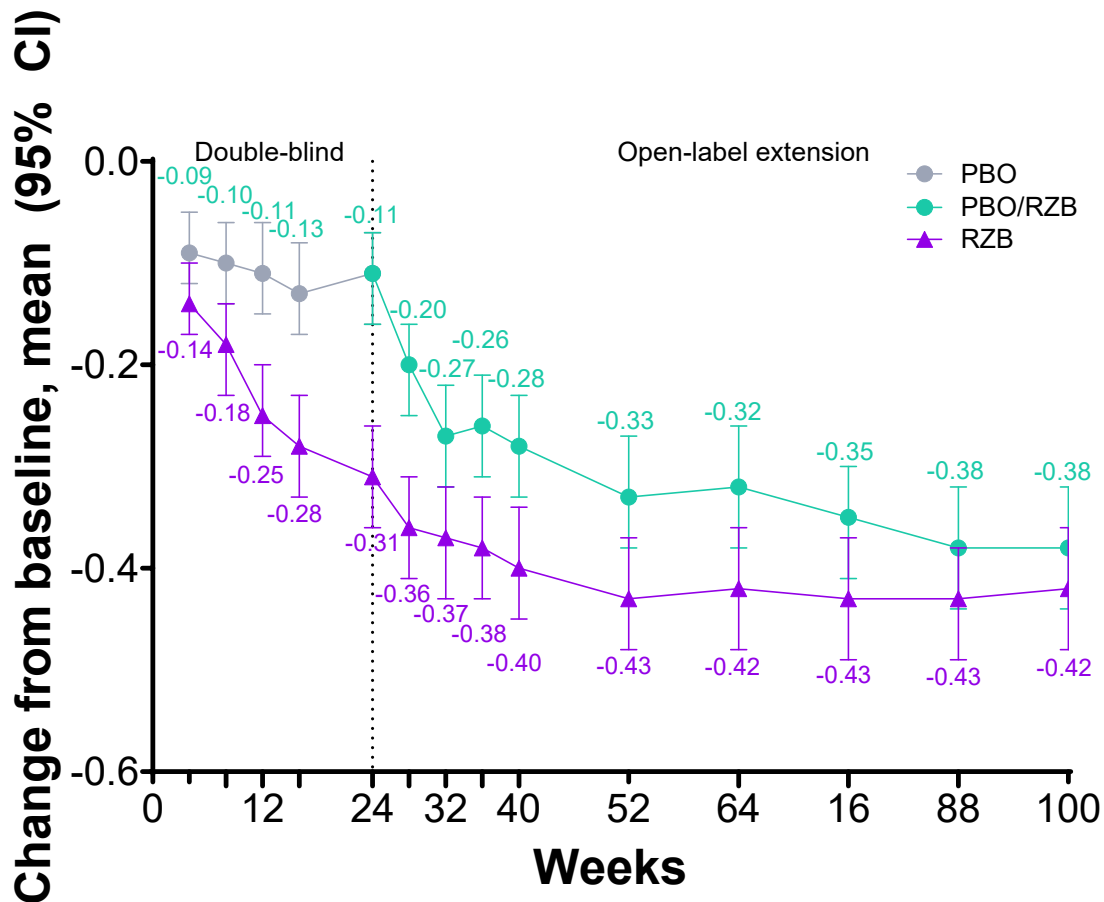
**Supplementary Fig. 2** Achievement over time of resolution of enthesitis and dactylitis, improvement in PASI 90, and reduction in mNAPSI (as observed).



PASI 90 reported only for patients with BSA affected by psoriasis  $\geq 3$  at baseline. mNAPSI reported only for patients with nail psoriasis at baseline. Resolution of enthesitis and dactylitis reported as pooled results from the KEEPSAKE 1 and 2 studies for patients with enthesitis (LEI > 0) or dactylitis (LDI > 0) at baseline.

*BSA* body surface area, *CI* confidence interval, *LDI* Leeds Dactylitis Index, *LEI* Leeds Enthesitis Index, *mNAPSI* modified Nail Psoriasis Severity Index, *PASI 90*  $\geq 90\%$  improvement from baseline in Psoriasis Area and Severity Index, *PBO* placebo, *RZB* risankizumab

Supplementary Fig. 3 Change from baseline over time in HAQ-DI (as observed).



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| <i>RZB, n</i>     | 460 | 441 | 401 |
| <i>PBO/RZB, n</i> | 458 | 438 | 398 |

CI confidence interval, HAQ-DI Health Assessment Questionnaire–Disability Index, PBO placebo, RZB risankizumab

**Supplementary Table 1** List of independent ethics committees or institutional review boards for sites that enrolled patients

| Region    | Independent Ethics Committees or Institutional Review Boards  |
|-----------|---|
| Argentina | <p>Comite Independiente de Etica para Ensayos en Farmacologia Clinica<br/> Fundacion de Estudios Farmacologicos y de Medicamentos Prof Luis M Zieher FEFyM<br/> Pte. J.E. Uriburu 774, 1st Floor<br/> Ciudad Autonoma de Buenos Aires C1027AAP, Argentina</p> <p>Comite de Etica en Farmacologia Clinica de La Fundacion CIDEA<br/> Paraguay 2041<br/> 9th floor, office H<br/> Ciudad Autonoma de Buenos Aires C1121ABE, Argentina</p> <p>Comite de Etica<br/> Dr Claude Bernard<br/> San Lorenzo 2555 - Rosario<br/> Rosario, Santa Fe S2000KPG, Argentina</p> <p>Comité Institucional de Revisión de Ensayos Clínicos CIREC<br/> Av. Luis María Campos 726 Ciudad Autonoma de Buenos, Aires<br/> C1426BOS, Argentina</p> <p>Comite de Etica Framingham<br/> calle 9 N° 431</p> |

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|                        | <p>La Plata, Buenos Aires B1902COS, Argentina</p> <p>Comité de Etica en Investigación / Comité de Docencia e Investigación del Hospital Gral. De Agudos J. M. Ramos Mejia</p> <p>Gral. Urquiza 609</p> <p>Ciudad Autonoma de Buenos Aires C1221ADC, Argentina</p> <p>Comite de Etica CAICI-CIAP Rodriguez 1198</p> <p>Rosario, Santa Fe CP2000, Argentina</p>                            |
| Australia              | <p>Monash Health Human Research Ethics Committee</p> <p>246 Clayton Rd</p> <p>Level 2, i Block, Monash Medical Centre</p> <p>Melbourne, Victoria 3168, Australia</p> <p>Bellberry Human Research Ethics Committee</p> <p>123 Glen Osmond Rd</p> <p>Eastwood, South Australia 5063, Australia</p> <p>Office of Research</p> <p>Griffith University</p> <p>Nathan, QLD 4111, Australia</p> |
| Belgium                | <p>Commissie voor Medische Ethiek Universitair Ziekenhuis Gent Corneel Heymanslaan 10</p> <p>Gent, Oost-Vlaanderen 9000, Belgium</p>   |
| Bosnia and Herzegovina | <p>Ethic Committee of the University Clinical Centre of the Republic of Sprska</p>   |



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|        | <p>Dvanaest beba bb</p> <p>Banja Luka, Republika Srpska 78000, Bosnia and Herzegovina</p> <p>Ethic Committee of Clinical Center University of Sarajevo</p> <p>Bolnicka 25</p> <p>Sarajevo, 71000, Bosnia and Herzegovina</p>  |
| Brazil | <p>Comite de Etica em Pesquisa em Seres Humanos do HC/UFPR</p> <p>Rua General Carneiro, 181, Alto da Glória</p> <p>Curitiba, Parana 80060-900, Brazil</p> <p>Comissao Nacional de Etica em Pesquisa (CONEP)</p> <p>Srtvn, Quadra 701, Lote D, Edificio PO 700, 32 andar,</p> <p>Ala Norte, Via W 5 Norte, Asa Norte</p> <p>Brasilia/OF, Brazil, 70719-040</p> <p>Comite de Etica em Pesquisa do HU-UFJF</p> <p>Rua Catulo Breviglieri, s/n</p> <p>Bairro Santa Catarina</p> <p>Juiz de Fora, Minas Gerais 36036-110, Brazil</p> <p>Comitê de Ética em Pesquisa em Seres Humanos da Santa Casa de</p> <p>São Paulo</p> <p>Rua Marquês de Itú, 381</p> <p>4º andar, Santa Cecília</p> <p>São Paulo 01221- 010, Brazil</p> |

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|          | <p>Comitê de Ética em Pesquisa do Instituto de Saúde e Bem-Estar da Mulher - ISBEM</p> <p>Rua Manoel da Nóbrega, 784 -Paraíso</p> <p>São Paulo, 04001-002, Brazil</p><br><p>Comite de Etica em Pesquisa do Sistema de Saude Mae de Deus</p> <p>Rua Grao Para, 160</p> <p>2º andar, Menino Deus</p> <p>Porto Alegre, Rio Grande do Sul 90850-170, Brazil</p><br><p>Comitê de Ética em Pesquisa Prof. Dr. Celso Figueirôa – Hospital Santa Izabel</p> <p>Praça Conselheiro Almeida Couto, 500— Nazaré</p> <p>Salvador, Bahia 40050-410, Brazil</p> |
| Bulgaria | <p>DCC XVII – Sofia EOOD</p> <p>108 Evlogi Georgiev Blvd</p> <p>Sofia, 1505, Bulgaria</p><br><p>Ethics Committee for Clinical Trials</p> <p>8. Damyan Gruev St</p> <p>Sofia 1303, Bulgaria</p><br><p>Ethics Committee at MHAT— Sofia at Military Academy</p> <p>ul. Sveti Georgi Sofiyski 3</p> <p>Sofia, 1606, Bulgaria</p>   |

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|                | <p>EC at Excelsior Medical Center</p> <p>4, Golo Burdo St</p> <p>Sofia, 1407, Bulgaria</p>   |
| Canada         | <p>Advarra</p> <p>372 Hollandview Trl, Suite 300</p> <p>Aurora, Ontario, L4G 0A5, Canada</p><br><p>Research Review Board Inc</p> <p>55 Northfield Dr East, Suite # 303</p> <p>Waterloo, Ontario N2K 3T6, Canada</p>  |
| Chile          | <p>Comité de Ética de Investigación Servicio de Salud –Metropolitano Norte</p> <p>San Jose #1053, Independencia</p> <p>Santiago, 8380755, Chile</p><br><p>Comité Ético Científico SSMC</p> <p>Victoria Subercaseaux 381</p> <p>4° Piso</p> <p>Santiago, 8320143, Chile</p> |
| Croatia        | <p>(Sredisnje eticko povjerenstvo) Central Ethics Committee</p> <p>Ksaverska cesta 4</p> <p>Zagreb, Grad Zagreb 10000, Croatia</p>   |
| Czech Republic | <p>Eticka komise Fakultni nemocnice Brno</p> <p>Jihlavska 20</p> <p>Brno, 625 00, Czech Republic</p>   |
| Denmark        | <p>Videnskabsetisk Komite Region Midtjylland</p>   |

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|         | <p>Skottenborg 26</p> <p>Viborg, 8800, Denmark</p>  |
| Estonia | <p>Research Ethics Committee of the National Institute for the Health Development</p> <p>Hiiu 42</p> <p>Tallinn, Harjumaa 11619 Estonia</p>   |
| Finland | <p>Pohjois-Savon sairaanhoitopiirin tutkimuseettinen toimikunta</p> <p>Kuopion yliopistollinen sairaala</p> <p>Puijonlaaksontie 2 PL 100</p> <p>Kuopio, 70029 KYS, Finland</p>  |
| Germany | <p>Ethik-Kommission der Medizinischen Fakultät der Ruhr- Universität Bochum</p> <p>Gesundheitscampus 33</p> <p>Bochum, Nordrhein-Westfalen 44801, Germany</p><br><p>Ethik-Kommission des Fachbereichs Medizin der Goethe- Universität Frankfurt</p> <p>Theodor-Stern-Kai 7, Haus 1</p> <p>Frankfurt Am Main, 60590, Germany</p> |
| Greece  | <p>National Organisation of Medicines (E.O.F.) National Ethics Committee (E.E.D.)</p> <p>Mesogion 284 PC 15562</p> <p>Holargos Athens, 15562, Greece</p>  |
| Israel  | <p>Rambam Medical Center</p> <p>8 Ha'Aliya street</p> <p>Haifa, 3109601, Israel</p>   |

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|           | <p>Sheba Medical Center Ethics Committee</p> <p>Dereh shiba 2</p> <p>Ramat Gan, 5262100, Israel</p> <p>Ethics Committee Barzilai Medical Center</p> <p>2 Hahistadrut St.</p> <p>Ashkelon, 78278, Israel</p>  |
| Italy     | <p>Comitato Etico per la Sperimentazione Clinica delle Province di Verona e Rovigo</p> <p>Piazzale A. Stefani 1</p> <p>C/o U.O. Farmacia Ospedale Borgo Trento</p> <p>Verona, Veneto 37126, Italy</p> <p>Comitato Etico Regionale delle Marche (C.E.R.M.)</p> <p>Via Conca, 71 - Torrette di Ancona</p> <p>Ancona, Marche 60126, Italy</p> |
| Latvia    | <p>Ethics Committee for Clinical Research at Pauls Stradins Clinical University Hospital Development Society</p> <p>Pilsonu St 13</p> <p>Riga, LV1002, Latvia</p>  |
| Lithuania | <p>Lithuanian Bioethics Committee</p> <p>Algirdo g. 31</p> <p>Vilnius, LT-03219, Lithuania</p>   |
| Malaysia  | <p>Jawatankuasa Etika &amp; Penyelidikan Perubatan Medical Research and Ethics Committee (MREC) Kementerian Kesihatan Malaysia</p>   |

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|        | <p>NIH Secretariat, Ministry of Health Malaysia, c/o Institute for Health Management, No 1 Jalan Setia Murni U13/52, Seksyen U13 Bandar Setia Alam</p> <p>Block A, Kompleks Institut Kesihatan Negara (NIH)</p> <p>Shah Alam, 40170, Malaysia</p> <p>University of Malaya Research Ethics Committee</p> <p>Pusat Perkhidmatan Penyelidikan, Tingkat 2</p> <p>Institut Pengurusan &amp; Perkhidmatan Penyelidikan (IPPP), University of Malaya</p> <p>Kuala Lumpur, 50603, Malaysia</p> <p>University of Malaya Medical Centre</p> <p>Jalan Lembah Pantai</p> <p>Kuala Lumpur, 59100, Malaysia</p> |
| Mexico | <p>Comité de Ética en Investigación de Hospital Arista</p> <p>Arista No. 1525, Colonia Artesanos</p> <p>Guadalajara, Jalisco 44200, Mexico</p> <p>Comité de Investigación de Unidad Médica de Diagnóstico y Tratamiento, SA de CV</p> <p>Arista No. 1525, Colonia Artesanos Guadalajara, Jalisco 44200, Mexico</p> <p>Comité de Ética en Investigación Unidad Clínica de Bioequivalencia S de RL de CV</p> <p>Avenida Alemania No. 1361, Colonia Moderna</p>  |

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| <p>Guadalajara, Jalisco 44190, Mexico</p> <p>Comité de Ética en Investigación Mexico Centre for Clinical Research<br/>SA de CV</p> <p>Amores No. 709, Colonia del Valle</p> <p>Ciudad De México, Mexico 03100, Mexico</p> <p>Comité de Ética en Investigación del Hospital Hispano S.A. de C.V.</p> <p>Pedro Moreno No. 934 Colonia Centro</p> <p>Guadalajara, Jalisco 44100, Mexco</p> <p>Comité Ética Investigació Investigación Biomédica para el Desarrollo<br/>de Fármacos</p> <p>Avenida Sebastián Bach No. 5257, Colonia La Estancia</p> <p>Zapopan, Jalisco 45030, Mexico</p> <p>Comite de Etica en Investigacion del Hospital la Mision S.A. de C.V</p> <p>Avenida del Hospital 112, 1° y 2° Piso, Sertoma 112</p> <p>Monterrey, Nuevo Leon 64718, Mexico</p> <p>Comité de Ética en Investigación Centro de Urologia Avanzada del<br/>Noreste SAdeCV</p> <p>Avenida Lázaro Cardenas, Col. Valle Oriente</p> <p>2660, Interior E</p> <p>San Pedro Garza García, Nuevo Leon 66269, Mexico</p> |
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|             | <p>Comité de Investigación Cardiolink SC</p> <p>Belisario Domínguez No. 2475, Colonia Obispado</p> <p>Monterrey, Nuevo Leon CP 64060, Mexico</p>   |
| Netherlands | <p>METC Erasmus MC</p> <p>Postbus 2040</p> <p>Rotterdam, Zuid-Holland 3000 CA, Netherlands</p>   |
| New Zealand | <p>Health and Disability Ethics Committees</p> <p>133 Molesworth St Ministry of Health</p> <p>Wellington, Thorndon 6011, New Zealand</p>   |
| Poland      | <p>Komisja Bioetyczna przy Okregowej Izbie Lekarskiej w Krakowie</p> <p>Ul. Krupnicza 11A</p> <p>Krakow, 31-123, Poland</p>  |
| Portugal    | <p>CEIC – Comissão de Ética para a Investigação Clínica</p> <p>Parque da Saude de Lisboa, Av. Do Brasil, 53 - Pav. 17-A</p> <p>Lisboa, 1749-004, Portugal</p>  |
| Romania     | <p>Comisia Nationala de Bioetica a Medicamentului si a Dispozitivelor<br/>Medicale</p> <p>Sos. Stefan cel Mare Nr. 19-21, Sector 2</p> <p>Bucuresti 020125, Romania</p>  |
| Russia      | <p>Local Ethics Committee of FSFSI SRI of Rheumatology</p> <p>n.a.V.A.Nasonova</p> <p>Kashirskoe shosse, 34A</p> <p>Moscow, 115522, Russia</p> <p>Central Ethics Committee at the Ministry of Health of the Russian<br/>Federation</p> |



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| <p>3, Rakhmanovsky pereulok<br/>Moscow, 127994, Russian Federation</p> <p>Local Ethics Committee of State North-Western State Medical<br/>Univserity n.a.Mechnikov<br/>Kirochnaya St. 41<br/>Saint-Petersburg, 191015, Russia</p> <p>Local Ethics Committee at the Family Outpatient Clinic #4, LLC<br/>33 Stantsionnaya St<br/>Korolev, N/A 141060, Russia</p> <p>Local Ethics Committee of State of Budgetary Education Institution of<br/>Higher Professional Education Kazan State University of the Ministry of<br/>Healthcare of the Russian Federation<br/>49 Butlerova St<br/>Kazan, Tatarstan, Respublika 420012, Russia</p> <p>Local Ethics Committee of State of Budgetary Education Institution of<br/>Healthcare of the Perm Region of the "Order Badge of Honor" Perm<br/>Regional Clinical Hospital<br/>85, Pushkina St<br/>Perm, 614099, Russia</p> <p>Local Ethics Committee of Pirogov Russian National Research Medical<br/>University<br/>Ostrovitianova St 1,</p> |
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|          | <p>Moscow, 117997, Russian Federation</p> <p>Local Ethics Committee of Ulyanovsk Regional Clinical Hospital</p> <p>7, 3 Internatsionala St</p> <p>Ulyanovsk, 432017, Russia</p> <p>LLC Medical Center-Healthy Family</p> <p>77, Kommunisticheskaya St</p> <p>Novosibirsk, 630099, Russia</p>   |
| Serbia   | <p>Ethics Committee of Serbia</p> <p>Vojvode Stepe 458</p> <p>Belgrade, 11000, Serbia</p> <p>Institute for Rheumatology</p> <p>Resavska 69</p> <p>Belgrade, Beograd 11000, Serbia</p> <p>Specijalna Bolnica za Reumatske bolesti Novi Sad</p> <p>Futoska 68</p> <p>Novi Sad, 21000, Serbia</p> |
| Slovakia | <p>Eticka komisija Trencianskeho samospravnego kraja</p> <p>K dolnej stanici 7782/20A</p> <p>Trencin 911 01, Slovakia</p> <p>Urad Trnavskeho samospravnego kraja</p> <p>P.O. Box 128</p>   |

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|              | <p>Trnava, Trnavsky kraj 917 01, Slovakia</p> <p>Urad Zilinskeho samospravného kraja</p> <p>Komenskeho 48</p> <p>Zilina, Zilinsky kraj 011 09, Slovakia</p> <p>Eticka komisia Presovskeho samospravného kraja</p> <p>Namestie mieru 1</p> <p>Presov, Presovsky kraj 080 01, Slovakia</p>  |
| Singapore    | <p>Centralised Institutional Review Board (CIRB)</p> <p>168 Jalan bukit Merah</p> <p>Singapore, 150168, Singapore</p>   |
| South Africa | <p>University of Pretoria, Faculty of Health Sciences Research Ethics Committee</p> <p>Room 4-60</p> <p>University of Pretoria and Pretoria Academic Hospital, Tswelepele Building (opposite BMW)</p> <p>Pretoria, Gauteng 0001, South Africa</p> <p>Pharma Ethics Independent Research Committee (Pty) Ltd</p> <p>123 Amcor Rd, Lyttelton Manor</p> <p>Pretoria, 0157 0002, South Africa</p> |
| South Korea  | <p>Hanyang University Seoul Hospital Institutional Review Board</p> <p>222-1, Wangsimni-ro, Seongdong-gu</p> <p>Seoul, 04763, South Korea</p>   |
| Spain        | <p>CEIC Hospital Clinico San Carlos Area 7</p>  |

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|         | <p>C/ Profesor Martin Lagos, s/n Puerta G Planta 4 Norte<br/>Madrid, 280410, Spain</p>   |
| Sweden  | <p>Regionala etikprövningsnämnden i Stockholm<br/>FE 289<br/>Stockholm, Stockholms lan 171 77, Sweden</p> <p>Etikprovningensmyndigheten<br/>Box 2110<br/>Uppsala, 750 02, Sweden</p>   |
| Taiwan  | <p>Chang Gung Medical Foundation Institutional Review Board<br/>199, Tung Hwa North Rd Taipei<br/>Taipei 10507, Taiwan</p> <p>Research Ethics Committee of the Dalin Tzuchi General Hospital No.<br/>2, Min-Sheng Rd<br/>Dalin Township, Chiayi County, 622, Taiwan</p> <p>The Institutional Review Board Chung Shan Medical University<br/>Hospital<br/>No 110, Sec.1, Chien-Kuo N Rd<br/>Taichung, 40201, Taiwan</p> |
| Ukraine | <p>Ethics Commission at Public Institution (PI) Poltava Regional Clinical<br/>Hospital n.a. M.V. Sklifosovsky Poltava City Council<br/>23, Shevchenka St<br/>Poltava, 36011, Ukraine</p>   |

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|  | <p>Ethics Commission at Public Non-Profit Enterprise (PNE) City Multifunctional Hospital #18<br/>Kharkiv City Council 104, Krasnodarska St<br/>Kharkiv, 61029, Ukraine</p> <p>Ethics Commissions at Munnicipal Non-Commeercial Enterprise "Lviv City Clinical Hospital" #4<br/>3, Sventsitskoho St<br/>Lviv, 79011, Ukraine</p> <p>Local Ethics Commission at the Government Institution (GI) National Institute of Therapy named by L.T. Malaya of National Ukrainian Academy of Medical Science<br/>2a, Lyubovi Maloy Ave<br/>Kharkiv, 61039, Ukraine</p> <p>Local Ethics Committee of Medical Centre of OK! Clinic of International Institute of Clinical Trials LLC<br/>121, Kharkivske Hwy<br/>KYIV, 02091, Ukraine</p> <p>Ethics Commission at Communal Non-Profit Enterprise (CNE)<br/>Cherkasy Regional Hospital of Cherkasy Regional Council<br/>3, Mendeleeva St<br/>Cherkasy, 18009, Ukraine</p> |
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| <p>Ethics Commission at Municipal Enterprise Kryvyi Rih City Clinical Hospital #2 of Kryvyi Rih City Council; Department of Cardiology with rheumatological beds</p> <p>30-richchia Peremogy Square, 2 Kryvyi Rih, 50056, Ukraine</p> <p>Ethics Commission at Municipal Non-Profit Enterprise (MNPE) "Chernihiv Regional Hospital" of the Chernihiv Regional Council</p> <p>25, Volkovycha St</p> <p>Chernihiv, 14029, Ukraine</p> <p>Ethics Commission at Clinic of Scientific Research Institute of Invalid Rehabilitation (Education and Scientific Medical Complex) of Vinnytsya National Medical University n.a. MI Pyrogov</p> <p>104, Khmelnytske Hwy</p> <p>Vinnytsya, 21029, Ukraine</p> <p>Ethics Committee at Communical Non-profit Enterprise City Hospital No.6 Zaporizhzhia City Council</p> <p>Therapeutic Department</p> <p>34, Stalevariv St</p> <p>Zaporizhzhia, 69035, Ukraine</p> <p>Ethics Commission of Volyn regional clinical hospital</p> <p>Rheumatology Department</p> <p>21, Presidenta Hrushevskogo Ave</p> <p>Lutsk, 43005, Ukraine</p> |
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|                | <p>Ethics Commission at Municipal Nonprofit Institution Khmelnytskyi<br/>Regional Hospital of Khmelnytskyi Regional Council<br/>1, Pilotska St<br/>Khmelnytskyi, 29000, Ukraine</p>   |
| United Kingdom | <p>London - Brighton and Sussex REC<br/>Eastern Rd<br/>Audrey Emerton Building<br/>Brighton, BN2 0AE, United Kingdom</p>  |
| United States  | <p>Quorum Institutional Review Board<br/>1501 Fourth Ave, Suite 800<br/>Seattle, Washington 98101, USA<br/><br/>Advarra- Independent Review Board<br/>6940 Columbia Gateway Dr, Suite 110<br/>Columbia, Maryland 21046, USA</p> |

**Supplementary Table 2** Efficacy results at week 100 for week 52 responders

| Parameter  | NRI-MI                         |                                | As observed                    |                                |
|--|--------------------------------|--------------------------------|--------------------------------|--------------------------------|
|  | Continuous RZB                 | PBO/RZB                        | Continuous RZB                 | PBO/RZB                        |
| ACR20, <i>n/N</i> (%)  | 275/339 (81.2)                 | 248/305 (81.2)                 | 265/304 (87.2)                 | 236/271 (87.1)                 |
| (95% CI)   | (79.6, 85.4)                   | (76.7, 85.6)                   | (83.4, 90.9)                   | (83.1, 91.1)                   |
| ACR50, <i>n/N</i> (%)  | 152/209 (72.5)                 | 145/182 (79.7)                 | 147/190 (77.4)                 | 139/166 (83.7)                 |
| (95% CI)   | (66.4, 78.6)                   | (73.6, 85.7)                   | (71.4, 83.3)                   | (78.1, 89.3)                   |
| ACR70, <i>n/N</i> (%)  | 86/125 (69.1)                  | 69/97 (71.2)                   | 85/113 (75.2)                  | 66/88 (75.0)                   |
| (95% CI)   | (61.0, 77.3)                   | (62.0, 80.4)                   | (67.3, 83.2)                   | (66.0, 84.0)                   |
| PASI 90, <sup>a</sup> <i>n/N</i> (%)   | 165/185 (89.4)                 | 147/165 (89.1)                 | 164/175 (93.7)                 | 146/159 (91.8)                 |
| (95% CI)   | (84.9, 93.8)                   | (84.3, 93.8)                   | (90.1, 97.3)                   | (87.6, 96.1)                   |
| MDA, <i>n/N</i> (%)  | 139/184 (75.5)                 | 104/133 (78.2)                 | 139/176 (79.0)                 | 104/127 (81.9)                 |
| (95% CI)   | (69.3, 81.8)                   | (71.2, 85.2)                   | (73.0, 85.0)                   | (75.2, 88.6)                   |
| Clinically meaningful change in<br>patient's assessment of pain (VAS), <sup>b</sup><br>mean (95% CI) | 252/313 (80.5)<br>(76.1, 84.9) | 235/290 (81.0)<br>(76.5, 85.5) | 252/287 (87.8)<br>(84.0, 91.6) | 235/271 (86.7)<br>(82.7, 90.8) |



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The continuous RZB cohort was randomized to RZB 150 mg (period 1) and remained on RZB (period 2). The PBO/RZB cohort was randomized to placebo (period 1) and switched to RZB 150 mg (period 2). All changes are least squares mean change from baseline. Results based on full analysis set and NRI-MI was used for binary endpoints; MMRM was used for continuous endpoints. The number of responders is calculated based on the total number of patients and estimated response rate, rounding to an integer.

<sup>a</sup>Among patients with psoriasis-affected BSA  $\geq 3\%$ .

<sup>b</sup>Improvement defined as decrease from baseline  $\geq 10$  mm in pain VAS.

*ACR20/50/70*  $\geq 20\%/ \geq 50\%/ \geq 70\%$  improvement in American College of Rheumatology criteria for symptoms of rheumatoid arthritis, *BSA* body surface area, *CI* confidence interval, *MDA* minimal disease activity, *MMRM* mixed-effect model for repeated measures, *NRI-MI* nonresponder imputation incorporating multiple imputations to handle missing data due to COVID-19 and geopolitical conflict, and all other missing data treated as nonresponders, including missing data and patients who received rescue therapy, *PBO* placebo, *RZB* Risankizumab, *VAS* Visual Analog Scale

**Supplementary Table 3** Efficacy endpoints: mean change from baseline (as observed)

| Parameter   | Week 24<br>(Period 1)          |                                | Week 52<br>(Period 1 and 2)    |                                | Week 100<br>(Period 1 and 2)   |                                |
|---|--------------------------------|--------------------------------|--------------------------------|--------------------------------|--------------------------------|--------------------------------|
|   | RZB                            | PBO                            | Continuous                     |                                | Continuous                     |                                |
|   | (n = 483)                      | (n = 481)                      | RZB<br>(n = 483)               | PBO/RZB<br>(n = 481)           | RZB<br>(n = 483)               | PBO/RZB<br>(n = 481)           |
| Change from baseline PsA-<br>mTSS, <sup>a</sup> mean (95% CI)                           | 0.23<br>(0.02, 0.43)           | 0.32<br>(0.11, 0.52)           | 0.20<br>(0.07, 0.32)           | 0.28<br>(0.12, 0.44)           | 0.33<br>(0.14, 0.52)           | 0.46<br>(0.17, 0.75)           |
| Change in PGA-F, <sup>b</sup> mean<br>[N] (95% CI)                                      | -0.8 [298]<br>(-0.9, -0.7)     | -0.4 [327]<br>(-0.5, -0.3)     | -1.2 [292]<br>(-1.4, -1.1)     | -1.1 [311]<br>(-1.2, -1.0)     | -1.5 [258]<br>(-1.7, -1.4)     | -1.3 [286]<br>(-1.5, -1.2)     |
| Clinically meaningful<br>reduction in HAQ-DI<br>(≥ 0.35), <sup>c</sup> % [n/N] (95% CI) | 53.5 [214/400]<br>(48.6, 58.4) | 31.2 [124/397]<br>(26.7, 35.8) | 62.6 [239/382]<br>(57.7, 67.4) | 50.7 [193/381]<br>(45.6, 55.7) | 63.1 [219/347]<br>(58.0, 68.2) | 56.4 [193/342]<br>(51.2, 61.7) |
| Change in patient's<br>assessment of pain VAS, <sup>d</sup><br>mean [N] (95% CI)        | -21.2 [460]<br>(-23.5, -18.9)  | -10.6 [456]<br>(-12.9, -8.3)   | -27.5 [441]<br>(-30.1, -24.9)  | -23.2 [437]<br>(-25.9, -20.6)  | -27.8 [401]<br>(-30.6, -25.1)  | -26.3 [398]<br>(-29.3, -23.2)  |

|   |                         |                         |                         |                         |                         |                         |
|---|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Change in SF-36 PCS,<br>mean [N] (95% CI)     | 6.6 [460]<br>(5.9, 7.3) | 3.0 [456]<br>(2.3, 3.7) | 8.7 [443]<br>(7.9, 9.5) | 7.4 [437]<br>(6.7, 8.2) | 8.6 [403]<br>(7.8, 9.4) | 7.8 [398]<br>(7.0, 8.6) |
| Change in FACIT-Fatigue,<br>mean [N] (95% CI) | 6.4 [460]<br>(5.5, 7.2) | 3.6 [456]<br>(2.7, 4.4) | 8.2 [443]<br>(7.2, 9.2) | 6.7 [437]<br>(5.8, 7.6) | 7.9 [403]<br>(6.8, 8.9) | 7.3 [398]<br>(6.3, 8.4) |

The continuous RZB cohort was randomized to RZB 150 mg (period 1) and remained on RZB (period 2). The PBO/RZB cohort was randomized to placebo (period 1) and switched to RZB 150 mg (period 2).

<sup>a</sup>Results for PsA-mTSS were recorded from the third reading session.

<sup>b</sup>Among patients with nail psoriasis at baseline (RZB,  $n = 309$ ; PBO/RZB,  $n = 338$ ).

<sup>c</sup>In patients with baseline HAQ-DI  $\geq 0.35$ .

<sup>d</sup>Among patients with a baseline patient's assessment of pain VAS score (RZB,  $n = 482$ ; PBO/RZB,  $n = 479$ ).

CI confidence interval, *FACIT-Fatigue* Functional Assessment of Chronic Illness Therapy–Fatigue, *HAQ-DI* Health Assessment Questionnaire–Disability Index, PASI 90

$\geq 90\%$  improvement from baseline in Psoriasis Area and Severity Index, *PBO* placebo, *PGA-F* Physician's Global Assessment of Fingernail Psoriasis, *PsA-mTSS* psoriatic arthritis-modified Total Sharp Score, *RZB* risankizumab, *SF-36 PCS* 36-item Short Form Physical Component Summary, *VAS* Visual Analog Scale.