

SUPPLEMENTARY DATA

Note to the editor: For the main section of the manuscript, we have focused on the key efficacy and safety results of the clinical trial. In the interest of transparency, we have provided these supplementary materials, which include study site information and patient disposition data.

SUPPLEMENTARY DATA

Supplementary Table 1

Country	Site Number	Site Name	Subjects Screened	Subjects Randomized	Subjects Completed
Czech Republic	1002	ResTrial s.r.o.	8	6	6
Czech Republic	1001	Fakultní Nemocnice v Motole	3	1	1
Czech Republic	1006	Nemocnice Slaný	2	1	1
Czech Republic	1003	DIKa centrum s.r.o.	13	5	4
Germany	1208	Gemeinschaftspraxis Dres. Ulrich-Michael Aigner und Anna Bartnik-Mikuta	7	4	4
Germany	1201	Praxis Dr. Julia Chevts	6	3	3
Germany	1211	Praxis Dr. Rolf Göbel	3	3	3
Germany	1207	Gemeinschaftspraxis Dres Josef und Wilma Großkopf	3	1	1
Germany	1209	Diabetologische Schwerpunktpraxis Pirna	2	1	1
Germany	1205	Pro scientia med im MARE Klinikum	6	1	1
Germany	1202	Praxis Dr. Sauter	2	1	0
Germany	1210	Gemeinschaftspraxis Unterm Heilig Kreuz	1	1	1
Germany	1206	Gemeinschaftspraxis für Innere Medizin und Diabetologie	7	5	5
Hungary	1303	DRC Gyógyszervizsgáló Központ Kft.	4	3	3
Hungary	1304	CRU Hungary Egészségügyi és Szolgáltató Kft.	18	10	8
Hungary	1306	Markhot Ferenc Oktatókórház és Rendelointézet	3	2	2
Hungary	1305	Kanizsai Dorottya Kórház	1	1	1
Hungary	1302	Zala Megyei Kórház	4	3	3
Hungary	1308	Clin Fan Szolgáltató Kft.	4	2	1
Hungary	1309	Szegedi Tudományegyetem Szent-Györgyi Albert Klinikai Központ	2	1	1
South Korea	1402	CHA Bundang Medical Center, CHA University	1	0	0
South Korea	1406	Seoul National University Hospital	1	1	1
South Korea	1401	Seoul Saint Mary's Hospital	2	2	2
Spain	1605	Hospital Moncloa	17	1	0

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Spain	1606	Hospital Universitario Nuestra Señora de Valme	17	6	5
Spain	1603	CM Avances Medicos	3	1	1
Spain	1607	Hospital Virgen de la Macarena	15	10	7
Spain	1608	HU Girona Dr Trueta	1	1	1
Spain	1601	Complejo Hospitalario Universitario La Coruña	6	4	4
Spain	1609	Hospital Clínico Universitario Virgen de la Victoria	3	1	0
Sweden	1704	Medect Clinical Trials	5	1	1
Sweden	1701	Pharmasite Research, Inc.	13	6	3
Sweden	1702	S3 Clinical Research Centers	3	2	2
USA	1834	Sunstone Medical Research, LLC	3	0	0
USA	1826	Universal Research Group	18	2	2
USA	1819	Rainier Clinical Research Center, Inc.	9	3	3
USA	1820	John Muir Physician Network Clinical Research Center	5	1	1
USA	1810	Clinical Research Partners, LLC	23	11	8
USA	1833	Gulf Coast Diabetes & Endocrine Center	8	3	2
USA	1814	National Research Institute	16	10	5
USA	1804	Metabolic Research Institute, Inc.	10	4	2
USA	1805	Aurora Advanced Healthcare, Inc.	5	1	1
USA	1836	ClinSearch, LLC	5	2	2
USA	1831	Mercy Medical Research Institute	4	1	0
USA	1806	Encompass Clinical Research	8	5	5
USA	1827	Desert Endocrinology Clinical Research Center	8	3	3
USA	1813	Diabetes & Endocrinology Consultants	17	7	6
USA	1832	West Broadway Clinic	6	1	1
USA	1807	Catalina Research Institute, LLC	58	28	22
USA	1835	Mountain View Clinical Research, Inc.	13	8	6
USA	1803	Kentucky Diabetes Endocrinology Center	6	4	4

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USA	1815	Valley Research	6	4	4
USA	1812	Upstate Pharmaceutical Research	5	1	0
USA	1837	Torrance Clinical Research Institute, Inc.	33	9	9
USA	1830	Northridge Clinical Research Inc	13	8	8
USA	1811	Endocrine and Metabolic Consultants	14	2	2
USA	1808	Dallas Diabetes and Endocrine Center	13	4	4
USA	1841	Miami Dade Medical Research Institute, LLC	9	4	3
USA	1809	Infosphere Clinical Research	35	17	14
USA	1838	Cedar Crosse Research Center	12	5	4
USA	1839	Juno Research, LLC	6	4	4
USA	1821	Rocky Mountain Diabetes and Osteoporosis Center, PA	6	4	4
USA	1818	Atlanta Center for Clinical Research	1	1	1
USA	1802	Progressive Clinical Research, LLC	5	1	1
USA	1824	Crescent City Clinical Research	11	5	3
Totals			577	254	211

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Supplementary Table 2

Country	Institutional Review Boards and Independent Ethics Committees
Czech Republic	
	Etická Komise pro Multicentricka Klinicka Hodnoceni, Fakultní Nemocnice Motol, V Úvalu 84, Praha 5, Prague, 150 06
	Lokální Etická Komise ResTrial s.r.o., V Sadech 15/4, Praha 6, Prague, 160 00
	Etická Komise Uherskohradištské Nemocnice, J.E. Purkyne 365, Uherské Hradište, 686 68
	Lokální Etická Komise Nemocnice Slaný, Politických Veznu 576, Slaný, 274 01
Germany	
	Ethik-Kommission der Landesärztekammer Baden-Württemberg, Jahnstraße 40, Stuttgart, Baden-Wuerttemberg, 70573
	Ethik-Kommission der Ärztekommision Westfalen-Lippe und der Medizinischen Fakultät der Westfälischen Wilhelms Universität Münster, Gartenstraße 210–214, Münster, Nordrhein-Westfalen, 48147
	Ethik-Kommission der Landesärztekammer Rheinland-Pfalz, Deutschhausplatz 3, Mainz, Rheinland-Pfalz, 55116
	Ethik-Kommission der Ärztekammer Schleswig-Holstein, Bismarckallee 8–12, Bad Segeberg, Schleswig-Holstein, 23795
	Ethik-Kommission der Ärztekammer Hamburg, Weidestraße 122b, Hamburg, 22083
	Ethik-Kommission der Bayerischen Landesärztekammer, Muehlbaurstraße 16, München, Bayern, 81677
	Ethik-Kommission bei der Sächsischen Landesärztekammer, Schützenhohe 16, Dresden, Sachsen, 01099
	Ethik-Kommission der Landesärztekammer Hessen, Im Vogelsgesang 3, Frankfurt, Hessen, 60488
Hungary	
	Egészségügyi Tudományos Tanács Klinikai Farmakológiai Etikai Bizottsága, Arany János Utca 6-8, Budapest, H-1051
The Netherlands	
	METC Brabant, Hilvarenbeekseweg 60, p/a St. Elisabeth Ziekenhuis, Route 84 Kamer 0.9, Tilburg, North Brabant, 5000 LC
South Korea	
	Seoul Saint Mary's Hospital, 222 Banpo-daero, Seocho-Gu, Seoul, 137-701
	CHA Bundang Medical Center, CHA University, 59, Yatap-ro, Bundang-gu, Seongnam-si, Gyeonggi-do, 463-712
	Samsung Medical Center, 81 Irwon-ro, Gangnam-gu, Seoul, 135-710
	Yeungnam University, 214-1 Dae-Dong, Gyeongsan-si, Daegu, 712-2036
	Wonju Severance Christian Hospital, 20 Ilsan-ro, Wonju-si, Gangwon-do, 220-701
	Seoul National University Hospital, 101 Daehak-ro, Jongno-gu, Seoul, 110-744

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	Chonbuk National University, 20 Geonjiro, Deokjin-gu, Jeonju-si, Jeollabuk-do, 561-712
	Pusan National University Hospital, 179 Gudeok-ro, Seo-gu, Busan, Gyeongsangnam-do, 602-739
	Severance Hospital Institutional Review Board (Yonsei University College of Medicine), 50-1 Yonsei-ro, Seodaemun-gu, Seoul, NA, 120-752
Spain	
	Comité Ético de Investigación Clínica de Galicia-SERGAS Div. de Farmacia y Productos Sanitarios, Calle San Lázaro s/n, Edificio de la Conselleria de Sanidad, Santiago de Compostela, La Coruña, 15703
	Hospital Universitario Vall d'Hebron, Passeig de la Vall d'Hebrón 119-129, Barcelona, 08035
	Vall d'Hebrón Institut de Recerca (VHIR), Passeig Vall d'Hebron, 119-129, Edificio Hospital Maternoinfantil, Planta 13, Barcelona, 08035
	Hospital Clínico San Cecilio de Granada, Avenida Doctor Olóriz 16, 5º planta, Granada, 18012
	Comité Ético de Investigación Clínica Hospital Puerta de Hierro Majadahonda, C/ Joaquín Rodrigo, 2, Entrada por Laboratorios-Banco de Sangre, Planta 1ª (peines 6-7), Majadahonda, Madrid, 28222
	Comité Ético de Investigación Clínica Complejo Hospitalario Nuestra Señora de Valme, Carretera Cadiz-Bellavista, km 548.9, Planta Baja, Secretaría Administrativa/Dirección Económico-Administrativa, Sevilla, 41041
	Comité Ético de Investigación Clínica Hospital Universitario Virgen Macarena, Avenida Dr. Fedriani 3, Planta 2 - Unidad de Investigación, Sevilla, 41009
	Comité Ético de Investigación Clínica CEIC Hospital de Girona Dr Josep Trueta, Avenida de França s/n, 9ª Planta A, Girona, 17007
	Comité Ético de Investigación Clínica del Hospital Clínico Universitario Virgen de la Victoria, Unidad de Garantía de Calidad, Campus Universitario de Teatinos s/n, 1ª Planta, Málaga, 29010
	Hospital Universitario La Princesa, Calle Diego de León 62, Madrid, 28006
Sweden	
	Regionala Etikprövningsnämnden i Lund, Östra Vallgatan 14, Lund, Skane, 223 61
	Regionala Etikprövningsnämnden i Lund, Stora Algatan 4, Lund, Skane, 223 50
USA	
	Quorum Review Institutional Review Board, 1501 Fourth Avenue, Suite 800, Seattle, WA, 98101
	Saint Luke's-Roosevelt Hospital Center, 1000 10th Avenue, Suite 11-C, New York, NY, 10019
	UCLA Office of Protection for Research Subjects, 11000 Kinross Avenue, Suite 102, Los Angeles, CA, 90095
	Saint John's Institutional Review Board, 1235 East Cherokee Street, Springfield, MO, 65804

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Supplementary Figure – Patient disposition. *Two of these patients randomized to treatment did not receive at least one dose of study drug and were not included in the full analysis or safety data sets. q.d., once daily; SAE, serious adverse event.

