

Supplementary Materials

Safety, Efficacy and Pharmacokinetics of AZD7442 (Tixagevimab/Cilgavimab) for Treatment of Mild-to-Moderate COVID-19: 15-Month Final Analysis of the TACKLE Trial

F.D. Richard Hobbs¹, Hugh Montgomery², Francisco Padilla³, Jesus Abraham Simón-Campos⁴, Douglas Arbetter⁵, Seth Seegobin⁶, Alexandre Kiazand⁷, Katie Streicher⁸, Nuria Martinez-Alier^{6*}, Taylor S. Cohen⁸, Mark T. Esser⁸

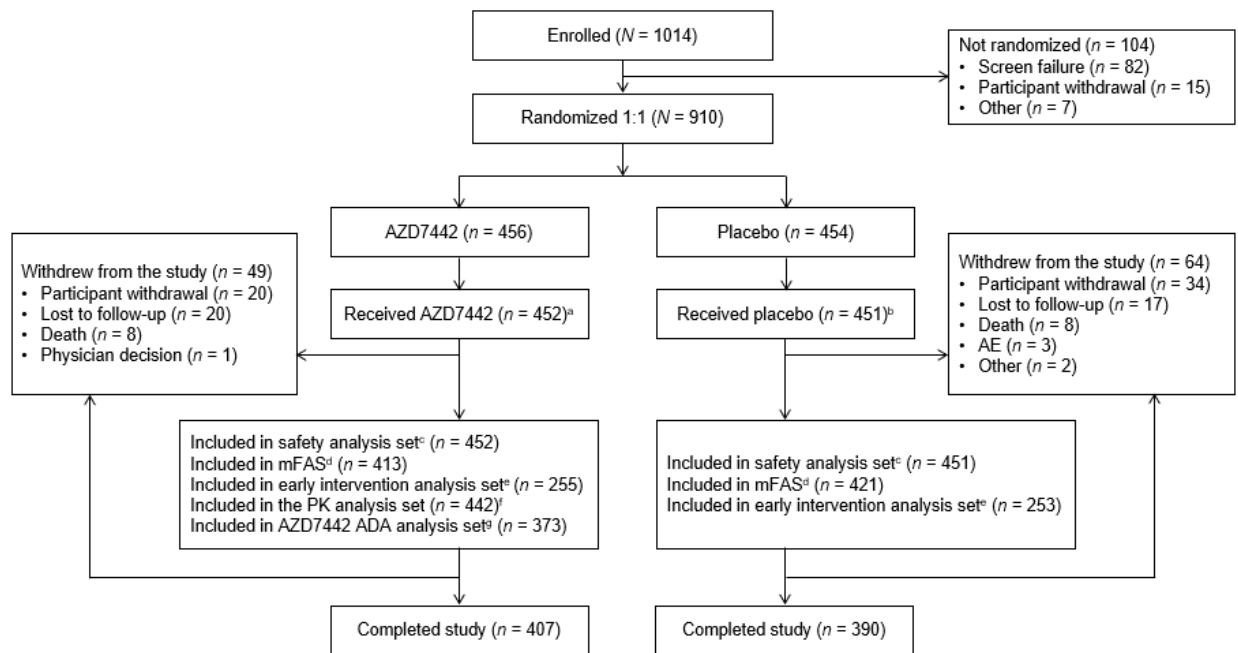
¹Nuffield Department of Primary Care Health Sciences, University of Oxford, Oxford, UK; ²Department of Medicine, University College London, London, UK; ³Centro de Investigación en Cardiología y Metabolismo, Guadalajara, Jalisco, Mexico; ⁴Köhler & Milstein Research/Méchnikov Project, and Universidad Autonoma de Yucatan, Mérida, Yucatán, Mexico; ⁵Vaccines & Immune Therapies, BioPharmaceuticals R&D, AstraZeneca, Boston, MA, USA; ⁶Vaccines & Immune Therapies, BioPharmaceuticals R&D, AstraZeneca, Cambridge, UK; ⁷Patient Safety, Chief Medical Office, R&D and Vaccines and Immune Therapies, AstraZeneca, Gaithersburg, MD, USA; ⁸Vaccines & Immune Therapies, BioPharmaceuticals R&D, AstraZeneca, Gaithersburg, MD, USA

**Affiliation at the time of this analysis.*

Correspondence to: Mark T. Esser

Email: mark.esser@astrazeneca.com

Fig. S1. Patient flow through the TACKLE study



ADA antidrug antibody, AE adverse event, mFAS modified full analysis set

^aFour participants did not receive AZD7442 due to participant withdrawal ($n = 3$) or physician decision ($n = 1$)

^bThree participants did not receive placebo due to participant withdrawal ($n = 1$) or other reasons ($n = 2$)

^cComprising all participants who received study drug regardless of baseline hospitalization status

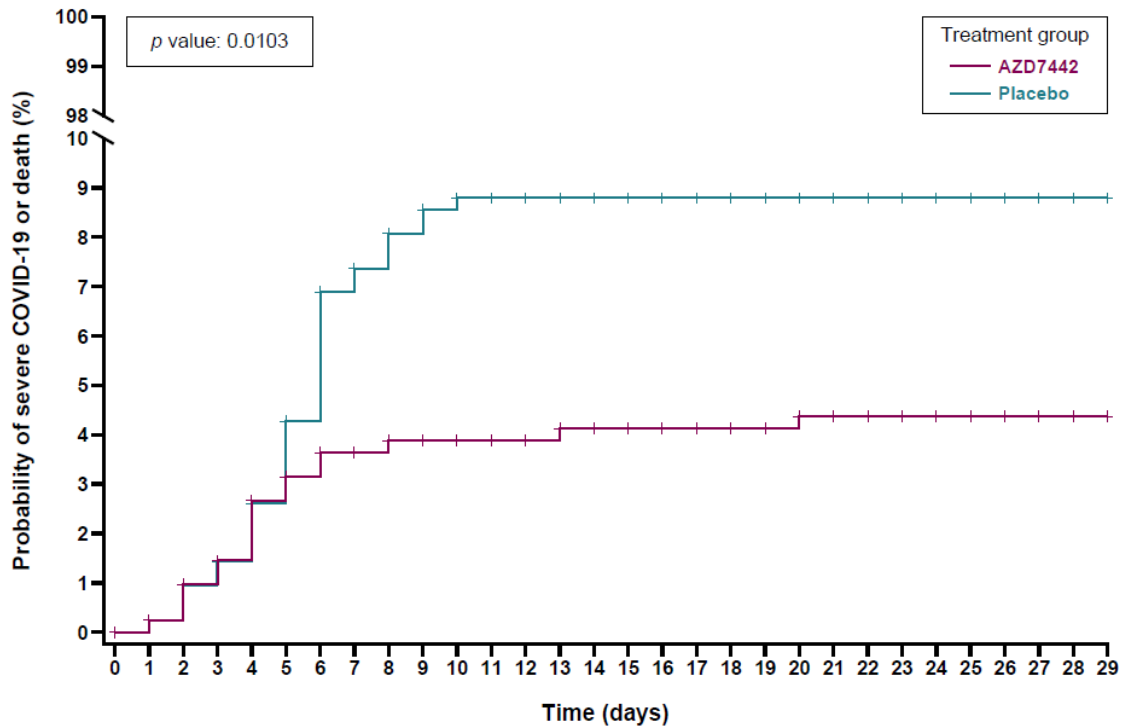
^dComprising all participants who received study drug within 7 days of symptom onset and were not hospitalized at baseline (day 1) for isolation purposes (hospitalization was allowed for isolation purposes in Japan and Russia due to local requirements)

^eComprising all participants in the mFAS who received study drug within 5 days of symptom onset

^fComprising all participants who received AZD7442 and had at least one quantifiable serum pharmacokinetic observation post-dose

^gComprising all participants in the safety analysis set who received AZD7442 and were assessed for ADAs at baseline and at least one post-baseline visit

Fig. S2. Kaplan–Meier analysis of the primary efficacy endpoint (time to severe COVID-19 or death from any cause through day 29)



Number of participants at risk

AZD7442	413	412	409	407	402	399	396	396	394	394	394	394	392	392	391	391	390	390	389	389	389	389	389	388	386	385	376	0	
Placebo	421	420	417	415	410	403	391	389	386	383	381	381	381	381	380	379	379	379	378	378	378	377	377	377	376	375	370	365	0

The p value is based on log-rank test stratified by time from symptom onset (≤ 5 versus > 5 days) and risk of progression to severe COVID-19 (high versus low)

COVID-19 coronavirus disease 2019

Table S1. List of study sites and IRB approvals

Country	Centre no.	Name and address of IEC/IRB	Chairman of IEC/IRB	Date of Approval	Approval ID
Argentina	202	CEI Centro de Investigaciones Médicas Mar del Plata Av. Colón 3083 5th Floor, Mar del Plata, Buenos Aires, 7600	Martin Donadio	25-Mar-21	VV-TMF-005864214
Argentina	203	Comité de Ética Independiente de la Clínica Privada Independencia, Luis María Drago 5681, Munro, Buenos Aires, 1605	Marcelo Baggio	05-Apr-21	VV-TMF-006058052
Argentina	205	Comité Independiente de Ética Prof. Dr. Luis J. E. Uriburu 774 1st floor, Buenos Aires, Caba, C1027AAP	Luis Zieher	10-Apr-21	VV-TMF-005938003
Argentina	206	Comité Independiente de Ética Prof. Dr. Luis J. E. Uriburu 774 1st floor, Buenos Aires, Caba, C1027AAP	Luis Zieher	20-Apr-21	VV-TMF-005970977

Brazil	702	Comitê de Ética em Pesquisa do Hospital das Clínicas da Faculdade de Medicina de Ribeirão Preto da Universidade de São Paulo Campus Universitário, SN, Prédio Central, Subsolo Ribeirão Preto/SP 14048-900	Dra. Mariana Guimarães Villanova	29-Apr-21	4.679.639
Brazil	704	Comitê de Ética em Pesquisa do Instituto de Saúde e Bem Estar da Mulher Manoel da Nóbrega Street, 784 São Paulo/SP 04001-002	Valdinéia Agnelo Pires da Silva	06-May-21	4.696.784
Brazil	706	Comitê de Ética em Pesquisa INVESTIGA - Institutos de Pesquisa Dr. Romeu Tórtima Avenue, 739 Campinas/SP 13084-791	Cristiana Madjarof	12-May-21	4.707.118

Brazil	707	Comitê de Ética em Pesquisa em Seres Humanos CEPH da Fundação Universidade Regional de Blumenau Antonio da Veiga Street, 140 Bloco A 2 nd Floor Blumenau/SC 89030-903	Professor Márcio Cristiano de Souza Rastelli	12-May-21	4.707.536
Brazil	709	Comitê de Ética em Pesquisa do Hospital das Clínicas de Porto Alegre Ramiro Barcelos Street, 2350 Room 2229 Porto Alegre/RS 90035-903	Têmis Maria Félix	05-May-21	4.692.755
Czech Republic	1901	Eticka komise Cesky Tesin Hrabinska 895/50, Cesky Tesin, 737 01	Mgr. Petr Papuga	29-Mar-21	1/2021
Czech Republic	Central: 1901	Eticka komise Fakultni nemocnice Ostrava 17. listopadu 1790/5, Ostrava – Poruba, 708 52	Doc. MUDr. Karol Zelenik, Ph.D., MBA	25-Mar-21	255/2021

Czech Republic	1902	Etická komise Oblastní nemocnice Kolin, a.s. Zizkova 146, Kolin 280 02	Martin Novacek	26-Mar-21	KO-016/2021
Czech Republic	Central: 1902	Etická komise Fakultní nemocnice Ostrava 17. listopadu 1790/5, Ostrava – Poruba, 708 52	Doc. MUDr. Karol Zelenik, Ph.D., MBA	25-Mar-21	255/2021
Czech Republic	1903	Etická komise pro Pardubickou a Svitavskou nemocnici Kyjevská 44, Pardubice, 532 02	MUDr. David Stuchlik	09-Apr-21	638/9.4.2021
Czech Republic	Central: 1903	Etická komise Fakultní nemocnice Ostrava 17. listopadu 1790/5, Ostrava – Poruba, 708 52	Doc. MUDr. Karol Zelenik, Ph.D., MBA	25-Mar-21	255/2021
Germany	2602	Ethikkommission (EC) der Landesärztekammer Hessen	Prof. Dr. med. Sebastian Harder	03-Feb-21	Nr. 9545_AMG_M_2021

		Hanauer Landstraße 152, Frankfurt, 60314			
Germany	2603	<u>Ethikkommission der Landesärztekammer Rheinland-Pfalz,</u> Deutschhausplatz 3, Mainz, 55116	Univ.-Prof. Dr. med. Dipl. Ing. Stephan Letzel	03-Feb-21	Nr. 9545_AMG_M_2021
Germany	2604	<u>EC Landesamt für Gesundheit und Soziales (LAGeSo)</u> Geschäftsstelle der Ethik-Kommission des Landes Berlin, Turmstraße 21, Haus A Berlin, 10559	Prof. Dr. med. K. Thomas Moesta	03-Feb-21	Nr. 9545_AMG_M_2021
Germany	2605	<u>EC Landesamt für Gesundheit und Soziales (LAGeSo)</u> Geschäftsstelle der Ethik-Kommission des Landes Berlin, Turmstraße 21, Haus A Berlin,	Prof. Dr. med. K. Thomas Moesta	01-Mar-21	Nr. 9545_AMG_M_2021

		10559			
Germany	2606	<u>Ethik-Kommission der Medizinischen Fakultät der LMU</u> Pettenkoferstr. 8a München, 80336	Prof. Dr. Wolfgang Eisenmenger	03-Feb-21	Nr. 9545_AMG_M_2021
Germany	2607	<u>Ethikkommission (EC) der Ärztekammer Nordrhein</u> Tersteegenstraße 9 Düsseldorf 40474	Prof. Dr. Kurt Racké	03-Feb-21	Nr. 9545_AMG_M_2021
Germany	2608	<u>EC Landesamt für Gesundheit und Soziales (LAGeSo)</u> Geschäftsstelle der Ethik-Kommission des Landes Berlin, Turmstraße 21, Haus A Berlin, 10559	Prof. Dr. med. K. Thomas Moesta	03-Feb-21	Nr. 9545_AMG_M_2021
Germany	2609	EC Ethik-Kommission der Ärztekammer Hamburg, Weidestrasse 122b	Prof. Dr. med. Rolf Stahl	03-Feb-21	Nr. 9545_AMG_M_2021

		Hamburg, 22083			
Germany	2610	EC Bayerische Landesärztekammer Muehlbaurstraße 16 München 81677	Prof. Dr. med. Hasford	01-Mar-21	Nr. 9545_AMG_M_2021
Germany	2612	Landesärztekammer Rheinland-Pfalz EC Deutschhausplatz 3 Mainz 55116	Univ.-Prof. Dr. med. Dipl. Ing. Stephan Letzel	22-Apr-21	Nr. 9545_AMG_M_2021
Hungary	Central: 3302	Ethics Committee of Hungary – Central Egészségügyi Tudományos Tanács / Medical Research Council Klinikai Farmakológiai Etikai Bizottság/Ethics Committee for Clinical Pharmacology Alkotmány u. 25. Budapest 1054	Prof. Dr. Bitter István	01-Mar-21	OGYEI/5496-8/2021

Hungary	Central: 3305	Ethics Committee of Hungary - Central Egészségügyi Tudományos Tanács / Medical Research Council Klinikai Farmakológiai Etikai Bizottság/Ethics Committee for Clinical Pharmacology Budapest 1054	Prof. Dr. Bitter István	01-Mar-21	OGYEI/5496-8/2021
Italy	4101	INMI 'L.Spallanzani' - IRCCS Via Portuense 292 Roma, RM 149	Cinzia Caporale	09-Feb-21	VV-TMF-005801409
Italy	4102	Comitato Etico dell'Ospedale San Raffaele Via Olgettina 60 Milano 20132	Elisabetta Riva	25-Feb-21	VV-TMF-005845206
Italy	4104	Comitato Etico Dell'Area Vasta Emilia Nord – Sede di Reggio Emilia Viale Umberto I Reggio Emilia	Roberto Giuseppe Grilli	02-Mar-21	NA (receipt of CEC approval)

		43123			
Italy	4105	Comitato Etico Dell'Area Vasta Emilia Nord – Sede di Piacenza Via Giuseppe Taverna 49 Piacenza 29100	Roberto Giuseppe Grilli	02-Mar-21	NA (receipt of CEC approval)
Italy	4108	Azienda Ospedaliero – Universitaria Pisana via A. Cocchi, 7/9 Pisa 56121	Romano Danesi	25-Feb-21	NA (receipt of CEC approval)
Japan	4301	Institutional Review Board of Tohoku Medical and Pharmaceutical University Hospital 1-12-1 Fukumuro, Miyagino-ku Sendai-shi Miyagi 983-8512	Kazuhiro Murakami	08-Mar-21	NA
Japan	4303	Maebashi Red Cross Hospital Institutional Review Board 389-1 Asakura-machi	Yutaka Uehara	22-Feb-21	NA

		Maebashi-Shi Gunma 371-0811			
Japan	4304	Saitama Medical University Hospital Institutional Review Board 38 Morohongo Moroyama-machi Iruma-Gun Saitama-Ken 350-0495	Keiji Yamamoto	02-Mar-21	NA
Japan	4305	Showa University Hospital Institutional Review Board 1-5-8, Hatanodai Shinagawa-ku Tokyo 142-8666	Takaaki Matsuyama	08-Mar-21	NA
Japan	4306	Tokyo Medical University Hachioji Medical Center Institutional Review Board 1163, Tatemachi Hachioji-shi Tokyo 193-0998	Hiroyuki Jimbo	25-Mar-21	NA

Japan	4307	Institutional Review Board of International University of Health and Welfare 1-24-1 Minami-Aoyama Amity Nogizaka Bldg. Minato-ku , Tokyo 107-0062	Tsutomu Yamazaki	25-Feb-21	NA
Japan	4308	Center Hospital of the National Center for Global Health and Medicine IRB 1-21-1 Toyama Shinjuku-ku Tokyo 162-8655	Takeshi Tamaki	03-Mar-21	NA
Japan	4309	Chiba Aoba Municipal Hospital Institutional Review Board 1273-2, Aobacho Chuo-ku Chiba-shi, Chiba 260-0852	Tomoyuki Rokkaku	24-Feb-21	NA
Japan	4310	Institutional Review Board of Tokyo Shinagawa Hospital 6-3 22 Higashioi Shinagawa-ku, Tokyo	Masaharu Shinkai	24-Feb-21	NA

		140-8522			
Japan	4312	Rakuwakai Otowa Hospital Institutional Review Board 2 Otowachinji-cho Yamashina-ku Kyoto-shi Kyoto 607-8062	Yuko Wada	18-Feb-21	NA
Mexico	Central: 4901	Comité de Etica en Investigación del Instituto Jalisciense de Investigación Clínica Penitenciaria #20 Colonia Centro, Guadalajara, Jalisco 44100	Mtra. Bertha Alicia Ochoa Sanchez Dr. Liliana Faviola de la Cerda Trujillo Dr. Luis Enrique Colunga Lozano	06-Jan-21	CEI-000001
Mexico	Central: 4902	Comité de Etica en Investigación del Instituto Jalisciense de Investigación Clínica Penitenciaria #20 Colonia Centro, Guadalajara, Jalisco 44100	Mtra. Bertha Alicia Ochoa Sanchez Dr. Liliana Faviola de la Cerda Trujillo Dr. Luis Enrique Colunga Lozano	06-Jan-21	CEI-000001
Mexico	Central:	Comité de Etica en Investigación del Instituto Jalisciense de Investigación Clínica Penitenciaria #20	Mtra. Bertha Alicia Ochoa Sanchez	06-Jan-21	CEI-000001

	4903	Colonia Centro, Guadalajara, Jalisco 44100	Dr. Liliana Faviola de la Cerda Trujillo Dr. Luis Enrique Colunga Lozano		
Mexico	Central: 4904	Comité de Etica en Investigación del Instituto Jalisciense de Investigación Clínica Penitenciaria #20 Colonia Centro, Guadalajara, Jalisco 44100	Mtra. Bertha Alicia Ochoa Sanchez Dr. Liliana Faviola de la Cerda Trujillo Dr. Luis Enrique Colunga Lozano	06-Jan-21	CEI-000001
Mexico	4905	Comité de Etica en Investigación de Médica Sur S.A.B de C.V Puente de Piedra No. 150 Colonia Toriello Guerra Tlalpan Ciudad de México 14050	Dr. Norberto Carlos Chávez Tapia Dra. Varenka Julieta Barbero Becerra Dra. Eva Juarez Hernandez	18-Jan-21	01-2021-CEI-30
Mexico	4906	Comité de Etica en Investigación del Hospital Universitario "Dr. José Eleuterio González" Francisco Ignacio Madero y Avenida Gonzalitos S/N Colonia Mitras Centro Monterrey , Nuevo León 64460	José Gerardo Garza Leal Dr. C. Guillermo Elizondo Riojas Dr. Mario Alberto Campos Coy	07-Jan-21	PI21-00005

Mexico	4907	Comité de Etica en Investigación del Instituto Nacional de Enfermedades Respiratorias Ismael Cosío Villegas Calzada de Tlalpan #4502 Colonia Sección XVI Tlalpan Ciudad de México 14080	Lic. Adriana Espinosa Jove Dra. en C. Blanca Margarita Bazán Perkins Dr. Edgar Enrique Sevilla Reyes	05-Jan-21	INER/CEI/083/2021
Mexico	Central: 4908	Comité de Etica en Investigación del Instituto Jalisciense de Investigación Clínica Penitenciaria #20 Colonia Centro, Guadalajara, Jalisco 44100	Mtra. Bertha Alicia Ochoa Sanchez Dr. Liliana Faviola de la Cerda Trujillo Dr. Luis Enrique Colunga Lozano	06-Jan-21	CEI-000001
Mexico	Central: 4909	Comité de Etica en Investigación del Instituto Jalisciense de Investigación Clínica Penitenciaria #20 Colonia Centro, Guadalajara, Jalisco 44100	Mtra. Bertha Alicia Ochoa Sanchez Dr. Liliana Faviola de la Cerda Trujillo Dr. Luis Enrique Colunga Lozano	06-Jan-21	CEI-000001

Mexico	Central: 4910	Comité de Etica en Investigación del Instituto Jalisciense de Investigación Clínica Penitenciaria #20 Colonia Centro, Guadalajara, Jalisco 44100	Mtra. Bertha Alicia Ochoa Sanchez Dr. Liliana Faviola de la Cerda Trujillo Dr. Luis Enrique Colunga Lozano	06-Jan-21	CEI-000001
Mexico	Central: 4911	Comité de Etica en Investigación del Instituto Jalisciense de Investigación Clínica Penitenciaria #20 Colonia Centro, Guadalajara, Jalisco 44100	Mtra. Bertha Alicia Ochoa Sanchez Dr. Liliana Faviola de la Cerda Trujillo Dr. Luis Enrique Colunga Lozano	06-Jan-21	CEI-000001
Poland	Central: 5704	Komisja Bioetyczna przy Dolnoslaskiej Izbie Lekarskiej Kazimierza Wielkiego 45 Wroclaw 50-077	Dr n. med. Włodzimierz Bednorz	08-Apr-21	Resolution no. 22/04/2021
Poland	Central: 5706	Komisja Bioetyczna przy Dolnoslaskiej Izbie Lekarskiej Kazimierza Wielkiego 45 Wroclaw 50-077	Dr n. med. Włodzimierz Bednorz	08-Apr-21	Resolution no. 22/04/2021

Russian Federation	6201	LEC of "Medical Research Institute" Legal: 25A Koli Tomchaka Str. Location:148D Moskovsky prosp. Saint Petersburg 196084	Yuhno Mihail	24-Feb-21	VV-TMF-005749760
Russian Federation	6202	St. Pt. State Institution of Health "City polyclinic No 109, Oleko Dundicha Street, 8 building 2 Saint-Petersburg 192283	Zhagrin Valeri	24-Feb-21	VV-TMF-005749962
Russian Federation	6205	Independent Ethics Committee at Joint- Stock Company "Group of Companies Medsi" 16, Krasnaya Presnya str. Moscow 123242	Igor Abramov	05-Mar-21	VV-TMF-005842991
Russian Federation	6206	Ethics committee, Pokrovskiy Hosp 85, Bolshoy prospect V.O. St.-Petersburg 199106	Balyabin Aleksandr	24-Feb-21	VV-TMF-005791088
Russian Federation	6208	IEC of LLC Clinic OsNova	Daria Adiatullina	01-Apr-21	VV-TMF-005969985

		Serebristiy boulevard, 20 Saint-Petersburg 197227			
Russian Federation	6209	IEC Bayandin Murmansk Regional Clinical Hospital 6 Pavlova ul. Murmansk 183047	Viktorina Dolina	09-Mar-21	VV-TMF-005793049
Russian Federation	6210	LEC of Ltd "Astarta" Nakhimova Street, 11 Saint-Petersburg 199226	Stroyev Yuri	01-Mar-21	VV-TMF-005796218
Spain	Central: 7001	CEIM Provincial de Malaga Ethic Committee Provincial de Málaga Ethic Committee Provincial de Málaga Avda. Carlos Haya s/n Malaga 29010	Dr. Manuel Herrera Gutiérrez	12 Apr 2021	NA: There is no approval ID itself
Spain	Central: 7003	CEIM Provincial de Malaga Ethic Committee Provincial de Málaga Ethic Committee Provincial de Málaga Avda. Carlos Haya s/n	Dr. Manuel Herrera Gutiérrez	12 Apr 2021	NA: There is no approval ID itself

		Malaga 29010			
Spain	Central: 7004	CEIM Provincial de Malaga Ethic Commitee Provincial de Málaga Ethic Commitee Provincial de Málaga Avda. Carlos Haya s/n Malaga 29010	Dr. Manuel Herrera Gutiérrez	12 Apr 2021	NA: There is no approval ID itself
Ukraine	7705	EC of "Central city clinical hospital of Ivano-Frankivsk city council"114, Mazepy str. Ivano-Frankivsk 78018	O.V. Tsikhon	18-May-21	Nr 59
Ukraine	7706	EC of Communal Non-profit Enterprise 'Kherson City Clinical Hospital n.a. Ye.Ye. Karabelesh'22/1, Ushakova Str. Kherson, 73000	O. I. Demediuk	13-May-21	Nr 10-СП
Ukraine	7707	EC of ME Dnipro Multifield Clinical Hospital #4, 31, Blyzhnya street	M.D. Shynkarenko	13-May-21	Nr 11

		Dnipro 49102			
United Kingdom	Central: 2804	The Old Chapel Royal Standard Place, Nottingham NG1 6FS	Professor Catherine Urch	06-Jan-21	REC Ref: 20/HRA/5769 IRAS Project ID: 291930
United Kingdom	Central: 2816	The Old Chapel Royal Standard Place, Nottingham NG1 6FS	Professor Catherine Urch	06-Jan-21	REC Ref: 20/HRA/5769 IRAS Project ID: 291930
United Kingdom	Central: 2817	The Old Chapel Royal Standard Place, Nottingham NG1 6FS	Professor Catherine Urch	06-Jan-21	REC Ref: 20/HRA/5769 IRAS Project ID: 291930
United Kingdom	Central: 2819	The Old Chapel Royal Standard Place, Nottingham NG1 6FS	Professor Catherine Urch	06-Jan-21	REC Ref: 20/HRA/5769 IRAS Project ID: 291930
United Kingdom	Central: 2821	The Old Chapel Royal Standard Place, Nottingham NG1 6FS	Professor Catherine Urch	06-Jan-21	REC Ref: 20/HRA/5769 IRAS Project ID: 291930
United Kingdom	Central:	The Old Chapel	Professor Catherine Urch	06-Jan-21	

	2823	Royal Standard Place, Nottingham NG1 6FS			REC Ref: 20/HRA/5769 IRAS Project ID: 291930
United States of America	Central: 7801	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA
United States of America	Central: 7802	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA
United States of America	Central: 7805	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA
United States of America	Central: 7806	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA
United States of America	Central: 7807	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA
	Central:	Advarra		07-Jan-21	NA

United States of America	7810	6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB		
United States of America	Central: 7811	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA
United States of America	Central: 7812	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA
United States of America	Central: 7814	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA
United States of America	Central: 7815	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA
United States of America	Central: 7816	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA
	Central:	Advarra		07-Jan-21	NA

United States of America	7818	6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB		
United States of America	Central: 7821	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA
United States of America	Central: 7825	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA
United States of America	Central: 7826	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA
United States of America	Central: 7827	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA
United States of America	Central: 7829	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB	07-Jan-21	NA
	Central:	Advarra		07-Jan-21	NA

United States of America	7831	6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinias, PhD, MAR, AB		
United States of America	Central: 7833	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinias, PhD, MAR, AB	07-Jan-21	NA
United States of America	Central: 7834	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinias, PhD, MAR, AB	07-Jan-21	NA
United States of America	Central: 7835	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinias, PhD, MAR, AB	07-Jan-21	NA
United States of America	Central: 7836	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinias, PhD, MAR, AB	07-Jan-21	NA
United States of America	Central: 7837	Advarra 6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinias, PhD, MAR, AB	07-Jan-21	NA
	Central:	Advarra		07-Jan-21	NA

United States of America	7838	6100 Merriweather Dr., Suite 600 Columbia, MD 21044	Susan Ebert, MS, CIP Luke Gelinas, PhD, MAR, AB		
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IEC Independent Ethics Committee; *IRB* Institutional Review Board

Table S2. AEs

Event	AZD7442 (N = 452)	Placebo (N = 451)
Participants with at least one AE, n (%)	251 (55.5)	252 (55.9)
AEs by Preferred Term		
COVID-19	51 (11.3)	51 (11.3)
Post-acute COVID-19 syndrome	38 (8.4)	29 (6.4)
COVID-19 pneumonia	26 (5.8)	49 (10.9)
Fatigue	16 (3.5)	15 (3.3)
Hypertension	16 (3.5)	18 (4.0)
Headache	13 (2.9)	11 (2.4)
Vaccination complication	13 (2.9)	13 (2.9)
Diarrhea	11 (2.4)	6 (1.3)
Back pain	10 (2.2)	10 (2.2)
Urinary tract infection	10 (2.2)	9 (2.0)
Arthralgia	9 (2.0)	8 (1.8)
Type 2 diabetes mellitus	9 (2.0)	7 (1.6)
Anosmia	8 (1.8)	3 (0.7)
Asthenia	8 (1.8)	9 (2.0)
Cough	8 (1.8)	4 (0.9)
Dizziness	8 (1.8)	1 (0.2)
Injection site pain	8 (1.8)	11 (2.4)
Diabetes mellitus inadequate control	7 (1.5)	4 (0.9)
Insomnia	7 (1.5)	2 (0.4)
Myalgia	7 (1.5)	4 (0.9)
Gastroenteritis	6 (1.3)	2 (0.4)
Alopecia	5 (1.1)	7 (1.6)
Depression	5 (1.1)	5 (1.1)
Nausea	5 (1.1)	3 (0.7)

Nasopharyngitis	4 (0.9)	8 (1.8)
Dyslipidemia	3 (0.7)	5 (1.1)
Dyspnea	3 (0.7)	11 (2.4)
Ligament sprain	1 (0.2)	5 (1.1)
Sinusitis	1 (0.2)	6 (1.3)

AE adverse event, COVID 19 coronavirus disease 2019

Table S3. SAEs

Event	AZD7442 (N = 452)	Placebo (N = 451)
Participants with at least one SAE, n (%)	46 (10.2)	65 (14.4)
AE by System Organ Class, n (%)		
AE by Preferred Term, n (%)		
Blood and lymphatic system disorders	1 (0.2)	1 (0.2)
Anemia of malignant disease	1 (0.2)	0
Blood loss anemia	0	1 (0.2)
Cardiac disorders	5 (1.1)	5 (1.1)
Acute myocardial infarction	2 (0.4)	1 (0.2)
Arrhythmia	0	2 (0.4)
Acute coronary syndrome	1 (0.2)	0
Acute left ventricular failure	1 (0.2)	0
Atrial fibrillation	1 (0.2)	0
Cardiac arrest	0	1 (0.2)
Cardiac failure	0	1 (0.2)
Myocardial ischemia	1 (0.2)	0
Supraventricular extrasystoles	1 (0.2)	0
Eye disorders	0	1 (0.2)
Diabetic retinopathy	0	1 (0.2)
Gastrointestinal disorders	0	3 (0.7)
Gastritis erosive	0	1 (0.2)
Gastrointestinal hemorrhage	0	1 (0.2)
Esophageal varices hemorrhage	0	1 (0.2)
Varices esophageal	0	1 (0.2)
General disorders and administration site conditions	1 (0.2)	1 (0.2)
Death	0	1 (0.2)
Sudden cardiac death	1 (0.2)	0

Hepatobiliary disorders	3 (0.7)	2 (0.4)
Cholecystitis chronic	2 (0.4)	0
Biliary colic	0	1 (0.2)
Cholecystitis	1 (0.2)	0
Portal vein thrombosis	0	1 (0.2)
Infections and infestations	29 (6.4)	49 (10.9)
COVID-19 pneumonia	23 (5.1)	37 (8.2)
COVID-19	2 (0.4)	9 (2.0)
Appendicitis	1 (0.2)	0
Bacterial diarrhea	0	1 (0.2)
Cellulitis	1 (0.2)	0
Disseminated tuberculosis	0	1 (0.2)
Gastroenteritis viral	1 (0.2)	0
Pneumonia bacterial	1 (0.2)	0
Post-acute COVID-19 syndrome	0	1 (0.2)
Pseudomonas infection	0	1 (0.2)
Sepsis	1 (0.2)	0
Septic shock	0	1 (0.2)
Sinusitis	0	1 (0.2)
Superinfection bacterial	0	1 (0.2)
Injury, poisoning, and procedural complications	2 (0.4)	3 (0.7)
Forearm fracture	0	1 (0.2)
Foreign body in gastrointestinal tract	0	1 (0.2)
Hip fracture	1 (0.2)	0
Jaw fracture	0	1 (0.2)
Road traffic accident	1 (0.2)	0
Musculoskeletal and connective tissue disorders	1 (0.2)	1 (0.2)
Immobilization syndrome	1 (0.2)	0

Intervertebral disc protrusion	0	1 (0.2)
Neoplasms benign, malignant, and unspecified (incl. cysts and polyps)	2 (0.4)	0
Colorectal cancer metastatic	1 (0.2)	0
Gastric cancer	1 (0.2)	0
Nervous system disorders	2 (0.4)	3 (0.7)
Loss of consciousness	0	1 (0.2)
Optic neuritis	0	1 (0.2)
Presyncope	1 (0.2)	0
Superior sagittal sinus thrombosis	0	1 (0.2)
Syncope	1 (0.2)	0
Pregnancy, puerperium, and perinatal conditions	0	2 (0.4)
Abortion spontaneous	0	2 (0.4)
Psychiatric disorders	1 (0.2)	1 (0.2)
Bipolar disorder	1 (0.2)	0
Disorientation	0	1 (0.2)
Renal and urinary disorders	2 (0.4)	1 (0.2)
Nephrolithiasis	1 (0.2)	1 (0.2)
Chronic kidney disease	1 (0.2)	0
Ureteric obstruction	0	1 (0.2)
Reproductive system and breast disorders	0	1 (0.2)
Adenomyosis	0	1 (0.2)
Respiratory, thoracic, and mediastinal disorders	1 (0.2)	2 (0.4)
Acute pulmonary oedema	0	1 (0.2)
Pneumothorax	0	1 (0.2)
Pulmonary embolism	1 (0.2)	0
Skin and subcutaneous tissue disorders	0	1 (0.2)
Actinic keratosis	0	1 (0.2)

Vascular disorders	2 (0.4)	1 (0.2)
Hypertensive crisis	1 (0.2)	0
Hypertensive emergency	0	1 (0.2)
Peripheral artery thrombosis	1 (0.2)	0

COVID 19 coronavirus disease 2019, SAE serious adverse event

Table S4. AESIs

Event	AZD7442 (N = 452)	Placebo (N = 451)
Participants with at least one AESI, n (%)	19 (4.2)	17 (3.8)
AE by System Organ Class, n (%)		
AE by Preferred Term, n (%)		
Cardiac disorders	2 (0.4)	1 (0.2)
Acute coronary syndrome	1 (0.2)	0
Acute myocardial infarction	0	1 (0.2)
Myocardial ischemia	1 (0.2)	0
General disorders and administration site conditions	14 (3.1)	13 (2.9)
Injection site pain	8 (1.8)	11 (2.4)
Injection site erythema	2 (0.4)	2 (0.4)
Injection site discomfort	2 (0.4)	1 (0.2)
Injection site bruising	1 (0.2)	1 (0.2)
Injection site hematoma	1 (0.2)	1 (0.2)
Injection site induration	1 (0.2)	0
Injection site inflammation	1 (0.2)	0
Injection site nodule	1 (0.2)	0
Injection site warmth	0	1 (0.2)
Nervous system disorders	1 (0.2)	0
Cerebral hypoperfusion	1 (0.2)	0
Skin and subcutaneous tissue disorders	2 (0.4)	2 (0.4)
Rash	1 (0.2)	1 (0.2)
Dermatitis allergic	0	1 (0.2)
Erythema	1 (0.2)	0
Vascular disorders	0	2 (0.4)
Hypertensive emergency	0	1 (0.2)
Thrombophlebitis	0	1 (0.2)

AES adverse event of special interest

Table S5. Summary of TE-ADAs to AZD7442 and its constituent monoclonal antibodies

	Tixagevimab^a (N = 372)	Cilgavimab^b (N = 363)	AZD7442^{c,d} (N = 373)
Participants with TE-ADAs, n (%)	27 (7.3)	46 (12.7)	54 (14.5)
Median of maximum ADA titer (range)	320.0 (160–1280)	160.0 (80–2560)	160.0 (80–2560)

ADA antidrug antibody, N number of ADA-evaluable participants, n number of participants with a positive result in the specific ADA category, TEADA treatment-emergent ADA

^aAssay limit of detection = 80

^bAssay limit of detection = 40

^cTE-ADA positivity to AZD7442 was defined as being TE-ADA positive to tixagevimab and/or cilgavimab

^dTE-ADA positivity was defined as either ADA negative at baseline and ADA positive at ≥ 1 post-baseline assessments with ADA titers ≥ 2 times the assay limit (≥ 160 for tixagevimab or ≥ 80 for cilgavimab), or baseline-positive ADA titer that was boosted ≥ 4 -fold during the study period. The N for the AZD7442 ADA-evaluable set comprises all participants with an ADA-evaluable sample for either tixagevimab or cilgavimab