

Supplemental Materials

Injection Site Reactions with Long-term Pegcetacoplan Use in Patients with Paroxysmal Nocturnal Hemoglobinuria: A Brief Report

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Table S1. List of IRBs and/or IECs

Central IRBs/IECs	Site number(s)
Advarra 6940 Columbia Gateway Drive Suite 110 Columbia, MD 21046, USA	01016
	01021
	01003
	01001
	01025
	01026
	01002
	01011
South West and Overseas Persons Protection Committee IV- CPPSOOM4 Cabanis Haut ESQUIROL Hospital Center 15 rue du Docteur Marcland Limoges cedex 87025, France	06005
	06008
	06007
	06006
	06001
	06009
	06003
	06010
Ethnics Committee of the University of Duisburg-Essen Robert-Koch-Str. 9-11 Essen 45147, Germany	05001
University and Polytechnic Hospital Faith Medicines Research Ethics Committee	09002

Avenida Fernando Abril Martorell, nº 106, Torre A planta 7ª 4 Valencia 6026, Spain	09001
Western IRB 1019 South East 39 th Avenue Suite 120 Puyallup, WA 98374, USA	01019
Delta General Hospital Medical Ethics Committee Oude Leielaan 6 Menen 8930, Belgium	07001
Saint-Luc University Hospital-Faculty Ethics Committee Promenade de l'Alma 51 bte 1.43.03 Bruxelles 1200, Belgium	07002
Duke Health IRB 2424 Erwin Road Suite 405 Durham, NC 27705, USA	01009
Ethics Committee of Pavlov First Saint Petersburg State Medical University L'va Tolstogo Street, 6/8 Saint Petersburg, 197022, Russia	11006

Ethics Committee at the Medical University of RWTH Aachen University Universitätsklinikum Aachen Pauwelsstraße 30 52074 Aachen, Germany	05002
Ethics Committee of the Hamburg Medical Association Weidestraße 122b 22083 Hamburg, Germany	05004
Ethics Committee of the University of Ulm Helmholtzstraße 20 89081 Ulm, Germany	05003
Health Research Ethics Board University of Alberta 308 Campus Towers Edmonton, Alberta T6G 1K8, Canada	10001
IRB of Chungnam National University Hospital 2F, Research Center for Biomedical Convergence Munwha-ro 282, Jung-gu Daejeon, 35015, South Korea	13002
IRB of Medical Corporation Ohryokukai, Nihonbashi Sakura Clinic Inamura Building 5F, 1-9-2, Nihonbashi Kayaba-cho Chuo-ku, Tokyo 103-0025, Japan	03006
IRB of Japanese Red Cross Nagoya Daiichi Hospital 3-35 Michishita-cho, Nakamura-ku	03008

Nagoya, Aichi, 453-8511, Japan	
IRB of Japanese Red Cross Nagoya Daini Hospital 2-9 Myoken-cho, Showa-ku Nagoya, Aichi, 466-8650, Japan	03009
IRB of Juntendo University Hospital 3-1-3 Hongo Bunkyo-ku, Tokyo 113-8431, Japan	03003
IRB of Okayama University Hospital 2-5-1 Shikata-cho, Kita-ku Okayama-city, Okayama, 700-8558, Japan	03010
IRB of Shinshu University Hospital 3-1-1 Asahi, Matsumoto Nagano, 390-8621, Japan	03007
Melbourne Health Human Research Ethics Committee The Royal Melbourne Hospital 300 Grattan Street Parkville, Victoria 3050, Australia	02001
Northwestern University IRB 750 North Lake Shore Drive 7 th Floor Chicago, IL 60611, USA	01012

<p>NTT Medical Center Tokyo IRB 5-9-22 Higashi-Gotanda Shinagawa-ku, Tokyo 141-8625, Japan</p>	03001
<p>Pharmnadzor, LLC Komendantsky prospect 4 liter A Office 618 Saint Petersburg, 197227, Russia</p>	11005
<p>Research Ethics Committee Yorkshire and the Humber–Leeds East Health Research Authority National Health Service Blood and Transplant Newcastle Blood Donor Center Holland Drive Newcastle upon Tyne, NE2 4NQ, United Kingdom</p>	04001
<p>Roswell Park IRB Roswell Park Cancer Institute 665 Elm Street Buffalo, New York 14263, USA</p>	01013
<p>Samaritan Health Services Regional IRB Samaritan Health Services Research Institute 2300 North West Walnut Boulevard Corvallis, OR 97330, USA</p>	01014
<p>University Health Network Research Ethics Board 700 University Avenue 10th Floor, Room 1056</p>	10002

Toronto, Ontario, M5G 1Z5, Canada	
University of Southern California IRB 1640 Marengo Street Suite 700 Los Angeles, CA, 90033, USA	01010

IEC institutional ethics committee, *IRB* institutional review board.

Table S2. MedDRA SOC and PTs classified as plain language terms

SOC	PT	Plain language term ^{17,18}
General disorders and administration site conditions	Administration site discoloration	Change in color, not the color it normally is, and/or odd color
	Administration site swelling	Abnormal enlargement
	Infusion site bruising	Injury involving rupture of small blood vessels and discoloration without a break in the overlying skin
	Infusion site erythema	Redness
	Infusion site induration	Thickening or hardening
	Infusion site reaction	Response at the injection site
	Infusion site swelling	Abnormal enlargement
	Infusion site urticaria	Hives, itch, and/or rash on the skin
	Injection site bruising	Injury involving rupture of small blood vessels and discoloration without a break in the overlying skin
	Injection site discoloration	Change in color, not the color it normally is, and/or odd color
	Injection site erythema	Redness
	Injection site hematoma	Pooling of blood due to a larger blood vessel leakage
	Injection site hemorrhage	Bleeding
	Injection site induration	Thickening or hardening

	Injection site mass	Palpable, firm, discrete, or well-demarcated lump
	Injection site pain	Physical suffering or discomfort
	Injection site pruritus	Itchy skin
	Injection site rash	Red itchy swelling on skin
	ISR	Response at the injection site
	Injection site swelling	Abnormal enlargement
	Vaccination site erythema	Redness
	Vaccination site pain	Physical suffering or discomfort
	Vaccination site swelling	Abnormal enlargement
Injury, poisoning, and procedural complications	Infusion-related reaction	Response at the infusion site
Skin lesion and subcutaneous tissue disorders	Skin lesion	Cut, injury, wound, and/or sore on the skin

ISR injection site reaction, *MedDRA* Medical Dictionary for Regulatory Activities, *PT* Preferred Term, *SOC* System Organ Class.