List of the Compassionate Use programs of the Paul-Ehrlich Institut

Last update 25.03.2025

Medicinal Product: Daromun (L19IL2/L19TNF)

Active substance	L19IL2 (antibody L19 conjugated to human IL-2 in diabody format) and L19TNF (antibody L19 conjugated to human TNFα in homotrimer format)
Pharmaceutical Form	Solution for injection
Application	Intralesional injection
Dosing	One weekly administration of mixture of 13 Mio IU of L19IL2 and 400 ug L19TNF among all injectable tumor lesions for 4 weeks
Indication	Neoadjuvant treatment of adult patients with locally advanced fully resectable melanoma who are not amenable to adjuvant systemic therapy
Date of Confirmed Notification	12.09.2024
Duration of Compassionate Use Programme	11.09.2025
Responsible Person (Company), Contact Person	Responsible Person: Philogen S.p.A. Loc. Bellaria 35 53018 Sovicille (Siena) Italy Legal Representative: Sun Pharma France SAS 31 rue des Poissonniers 92200 Neuilly sur Seine France Contact Person: Dr. Ainhara Aguado Barandiaran EU Medical Manager Sun Pharmaceuticals Germany GmbH Hemmelrather Weg 201 51377 Leverkusen Ainhara.Aguado@sunpharma.com +49 1622499222

Medicinal Product: Teplizumab

Active substance	Teplizumab is a CD3-directed monoclonal antibody (humanised IgG1 kappa)
Pharmaceutical Form	Concentrate for solution for infusion
Application	Intravenous use after dilution
Dosing	by intravenous infusion (over a minimum of 30 minutes), using a body surface area-based dosing (BSA), once daily for 14 consecutive days as follows: • day 1: 65 µg/m^2 • day 2: 125 µg/m^2 • day 3: 250 µg/m^2 • day 4: 500 µg/m^2 days 5 to 14: 1.030 µg/m^2
Indication	Teplizumab is indicated to delay the onset of Stage 3 type 1 diabetes (T1D) in adult and paediatric patients 8 to 65 years of age with Stage 2 T1D
Date of Confirmed Notification	24.09.2024
Duration of Compassionate Use Programme	23.09.2025
Responsible Person (Company), Contact Person	Sanofi-Aventis Deutschland GmbH Industriepark Höchst, K703 65926 Frankfurt Germany **Contact Information** Medical Information Sanofi Germany E-Mail: medinfo.de@sanofi.com Phone: 0800 52 52 010 https://www.sanofi.de/de/kontakt

Medicinal Product: Belantamab Mafodotin

Active substance	Belantamab Mafodotin
Pharmaceutical Form	Powder for concentrate for solution for infusion
Application	For intravenous infusion after reconstitution and dilution.
Dosing	With bortezomib and dexamethasone (BVd): 2.5 mg/kg belantamab mafodotin once every 3 weeks. Bortezomib and dexamethasone are administered for the first 8 cycles; belantamab mafodotin is administered from cycle 1 until completion of treatment. With pomalidomide and dexamethasone (BPd): Cycle 1: 2.5mg/kg belantamab mafodotin administered once. Cycle 2 onwards: 1.9 mg/kg belantamab mafodotin administered once every 4 weeks.

	For the recommended dosing of bortezomib, dexamethasone or pomalidomide, refer to the corresponding Summary of Product Characteristics.
Indication	In combination with bortezomib/dexamethasone or pomalidomide/dexamethasone for the Treatment in Adult Patients with relapsed or refractory Multiple Myeloma who have received at least one prior therapy including an anti-CD38 antibody, an immunomodulatory agent and a proteasome inhibitor and who cannot receive a CAR-T therapy.
Date of Confirmed Notification	28.11.2024
Duration of Compassionate Use Programme	27.11.2025
Responsible Person (Company), Contact Person	GSK Research & Development Limited, 79 New Oxford Street, London, WC1A 1DG, United Kingdom Contact: Customer Care Center, GlaxoSmithKline Services GmbH & Co. KG E-mail: service.info@gsk.com

Medicinal Product: Riliprubart

Active substance	Riliprubart
Pharmaceutical Form	Concentrate for solution for injection
Application	intravenous (IV) and subcutaneous (SC) administration
Dosing	IV Dose: 3500 mg (3 vials of 1200 mg/8 mL each) SC Dose: 600 mg (1 vial of 1200 mg/8 mL)
Indication	Treating Patients with Cold Agglutinin Disease (CAD)
Date of Confirmed Notification	06.02.2025
Duration of Compassionate Use Programme	05.02.2026
Responsible Person (Company), Contact Person	**Responsible Person** Sanofi-Aventis Deutschland GmbH Frankfurt am Main Germany **Contact details:** Antoine Robert ptaoffice@sanofi.com

Medicinal Product: Zanidatamab

Active substance	Zanidatamab
Pharmaceutical Form	Lyophilized powder for concentrate for solution for infusion in a single dose vial
Application	Intravenous infusion
Dosing	Zanidatamab drug product is 20 mg/kg administered as an intravenous infusion once every 2 weeks
Indication	Adults with previously treated, unresectable, locally advanced or metastatic HER2-positive (IHC3+) biliary tract cancer (BTC)
Date of Confirmed Notification	10.02.2025
Duration of Compassionate Use Programme	09.02.2026
Responsible Person (Company), Contact Person	Jazz Pharmaceuticals Ireland Limited 5th Floor, Waterloo Exchange, Waterloo Road, Dublin 4, D04 E5W7, Ireland EarlyAccess@jazzpharma.com Michael Jeglitsch, Jazz Pharmaceuticals Medical Director Germany Phone number: +49 171 5327752

Medicinal Product: Teprotumumab

Active substance	Teprotumumab is a fully human IgG1 monoclonal antibody which binds to IGF-1R.
Pharmaceutical Form	Powder for concentrate for solution for infusion
Application	For intravenous use after reconstitution and dilution
Dosing	Dosing is based on the patient's actual body weight. The recommended dose is 10 mg/kg of body weight for the initial dose followed by 20 mg/kg of body weight for 7 additional doses given once every three weeks as an intravenous infusion.
Indication	Moderate to severe Thyroid Eye Disease (TED)
Date of Confirmed Notification	24.03.2025
Duration of Compassionate Use Programme	23.03.2026
Responsible Person (Company), Contact Person	**Responsible Person:** Amgen GmbH Riesstraße 24

	80992 Munich Germany **Contact information:** Medical Information Amgen GmbH 0800 – 264 36 44 medinfo.amgen.de

Kontakt: ct@pei.de