Lista lekova za retke bolesti - 14.10.2026.

EU br.	Proizvod / aktivna supstanca	Indikacija	Sponzor	Datum dodele statusa	Trgovački naziv – EU broj proizvoda – Datum primene
EU/3/17/1863	Autologous T lymphocyte-enriched population of cells transdukovane pomoću a lentivirusni vektor encoding a Himerno antigen receptor targeting humani B cell maturation antigen with 4-1BB and CD3-zeta intracellular signalling domains	Lečenje multiplog mijeloma	Bristol-Myers Squibb Pharma EEIG	20 Apr 2017	Abecma - EU/1/21/1539 - 19 Aug 2021
EU/3/08/588	Rekombinantni humani ADAMTS-13	Lečenje trombotične trombocitopenične purpure	Takeda Manufacturing Austria AG	03 Dec 2008	ADZYNMA - EU/1/24/1837 - 02 Aug 2024
EU/3/14/1309	17α,21-dihydroxy-16α-methyl-pregna-1,4,9(11)-triene-3,20-dione	Lečenje Duchenneove mišićne distrofije	Santhera Pharmaceuticals (Deutschland) GmbH	22 Aug 2014	AGAMREE - EU/1/23/1776 - 15 Dec 2023
EU/3/07/498	Polihexanide	Lečenje Acanthamoeba keratitisa	S.I.F.I. Società Industria Farmaceutica Italiana S.p.A.	14 Nov 2007	AKANTIOR - EU/1/24/1840 - 23 Aug 2024
EU/3/07/453	Rekombinantni fuzioni protein koji se sastoji od humani faktor koagulacije IX attached to the Fc domain of humani IgG1	Lečenje hemofilije B (urođenog nedostatka faktora IX)	Swedish Orphan Biovitrum AB (publ)	08 Jun 2007	ALPROLIX - EU/1/16/1098 - 13 May 2016
EU/3/19/2176	Rekombinantni humani faktor koagulacije VIII Fc - von Willebrand faktor - XTEN fusion protein	Lečenje hemofilije A	Swedish Orphan Biovitrum AB (publ)	28 Jun 2019	ALTUVOCT - EU/1/24/1824 - 18 Jun 2024

EU/3/21/2527	(14S)-8-[3-(2-{dispiro[2.0.24.13]heptan-7-yl}ethoxy)-1H-pyrazol-1-yl]-12,12-dimethyl-2lamba6-thia-3,9,11,18,23-penta-azatetracyclo[17.3.1.111,14.05,10]tetracosa-1(22),5,7,9,19(23),20-hexaene-2,2,4-trione calcium salt hydrate, deutivacaftor, tezacaftor	Lečenje cistične fibroze	Vertex Pharmaceuticals (Ireland) Limited	12 Nov 2021	Alyftrek - EU/1/25/1943 - 01 Jul 2025
EU/3/15/1589	Glibenclamide	Lečenje neonatalnog dijabetesa	AMMTeK	15 Jan 2016	AMGLIDIA - EU/1/18/1279 - 28 May 2018
EU/3/18/2026	Sintetički dvolančani siRNA oligonukleotid usmeren protiv transthyretin mRNA, with six phosphorothioate linkages in the backbone, and nine 2'-fluoro and thirty-five 2'-O-methyl nucleoside residues in the sequence, which is kovalentno vezan via a phosphodiester group to a ligand koji sadrži three N-acetylgalactosamine residues	Lečenje amiloidoze posredovane transtiretinom	Alnylam Netherlands B.V.	25 May 2018	Amvuttra - EU/1/22/1681 - 16 Sep 2022
EU/3/17/1848	Acetylleucine	Lečenje Niemann-Pickove bolesti	IntraBio Ireland Ltd	20 Mar 2017	Aqneursa - EU/1/25/1928 - 20 Jan 2026
EU/3/14/1259	Amikacin sulfate	Lečenje plućne bolesti izazvane netuberkuloznim mikobakterijama	Insmed Netherlands B.V.	08 Apr 2014	ARIKAYCE liposomal - EU/1/20/1469 - 28 Oct 2020

EU/3/20/2251	Artesunate	Lečenje malarije	Amivas Ireland Limited	28 Feb 2020	Artesunate Amivas - EU/1/21/1582 - 24 Nov 2021
EU/3/17/1873	Poly(oxy-1,2-ethanediyl), .alfa.-hydro-.omega.-hydroxy-,15,15'-diester with N-acetyl-L-isoleucyl-L-cysteinyl-L-valyl-1-methyl-L-tryptophyl-L-glutaminyl-L-.alfa.-aspartyl-L-tryptophylglycyl-L-alanyl-L-histidyl-L-arginyl-L-cysteinyl-L-threonyl-2-[2-(2-aminoethoxy)ethoxy]acetyl-N6-carboxy-L-lysinamide cyclic (2.fwdarw.12)-(disulfide); where two identical synthetic peptide domains are kovalentno vezan at the ends of the polyethylene glycol chain	Lečenje paroksizmalne noćne hemoglobinurije	Swedish Orphan Biovitrum AB (publ)	22 May 2017	ASPAVELI - EU/1/21/1595 - 14 Dec 2021
EU/3/22/2716	Pegcetacoplan	Lečenje C3 glomerulopatije sa imunskim kompleksima ili bez njih	Swedish Orphan Biovitrum AB (publ)	10 Nov 2022	ASPAVELI - EU/1/21/1595 - 16 Jan 2026
EU/3/17/1889	(S)-1-(4-fluorophenyl)-1-(2-(4-(6-(1-methyl-1H-pyrazol-4-yl)pyrrolo[2,1-f][1,2,4]triazin-4-yl)piperazin-yl)pyrimidin-5-yl)ethan-1-amine	Lečenje gastrointestinalnih stromalnih tumora	Blueprint Medicines (Netherlands) B.V.	17 Jul 2017	AYVAKYT - EU/1/20/1473 - 25 Sep 2020
EU/3/18/2074	Avapritinib	Lečenje mastocitoze	Blueprint Medicines (Netherlands) B.V.	26 Oct 2018	AYVAKYT - EU/1/20/1473 - 25 Mar 2022

EU/3/13/1127	Inotuzumab ozogamicin	Lečenje akutne B-limfoblastne leukemije	Pfizer Europe MA EEIG	07 Jun 2013	Besponsa - EU/1/17/1200 - 03 Jul 2017
EU/3/09/650	Blinatumomab	Lečenje akutne limfoblastne leukemije	Amgen Europe B.V.	24 Jul 2009	BLINCYTO - EU/1/15/1047 - 25 Nov 2015
EU/3/13/1118	Rekombinantni humani tripeptidyl-peptidase 1	Lečenje neuronske ceroidne lipofuscinoze tipa 2	BioMarin International Limited	12 Mar 2013	Brineura - EU/1/17/1192 - 01 Jun 2017
EU/3/12/1028	(2S)-2-{[(2R)-2-[({[3,3-dibutyl-7-(methylthio)-1,1-dioxido-5-phenyl-2,3,4,5-tetrahydro- 1,2,5-benzothiadiazepin-8-yl]oxy}acetyl)amino]-2-(4-hydroxyphenyl)acetyl]amino}butanoic acid	Lečenje progresivne porodične intrahepatične holestaze	Ipsen Pharma	17 Jul 2012	Bylvay - EU/1/21/1566 - 19 Jul 2021
EU/3/09/629	Nanobody directed towards the humani A1 domain of von Willebrand faktor	Lečenje trombotične trombocitopenične purpure	Ablynx N.V.	30 Apr 2009	Cablivi - EU/1/18/1305 - 04 Sep 2018
EU/3/20/2252	Autologne humane ćelije T cells genetically modifikovan ex-vivo with a lentivirusni vektor encoding a Himerno antigen receptor for B-cell maturation antigen	Lečenje multiplog mijeloma	Janssen-Cilag International NV	28 Feb 2020	CARVYKTI - EU/1/22/1648 - 30 May 2022
EU/3/19/2210	Autologous CD34+ hematopoetske matične ćelije with a CRISPR-edited erythroid enhancer region of the BCL11A gen	Lečenje beta-talasemije intermedije i major	Vertex Pharmaceuticals (Ireland) Limited	17 Oct 2019	Casgevy - EU/1/23/1787 - 12 Feb 2024

EU/3/19/2242	Autologous CD34+ hematopoetske matične ćelije with a CRISPR-edited erythroid enhancer region of the BCL11A gen	Lečenje bolesti srpastih ćelija	Vertex Pharmaceuticals (Ireland) Limited	09 Jan 2020	Casgevy - EU/1/23/1787 - 12 Feb 2024
EU/3/07/514	(1R, 2R)-Octanoic acid [2-(2',3'-dihydro-benzo [1,4] dioxin-6'-yl)-2-hydroxy-1-pyrrolidin-1-ylmethyl-ethyl]-amide-L-tartaric acid salt	Lečenje Gaucherove bolesti	Sanofi B.V.	04 Dec 2007	Cerdelga - EU/1/14/974 - 21 Jan 2015
EU/3/14/1406	Chenodeoxycholic acid	Lečenje urođenih poremećaja primarne sinteze žučnih kiselina	Leadiant Biosciences Ireland Limited	16 Dec 2014	Chenodeoxycholic acid Leadiant - EU/1/16/1110 - 12 Apr 2017
EU/3/07/471	humani faktor koagulacije X	Lečenje naslednog nedostatka faktora X	Kedrion S.p.A.	17 Sep 2007	Coagadex - EU/1/16/1087 - 18 Mar 2016
EU/3/14/1276	Isavuconazonium sulfate	Lečenje mukormikoze	Basilea Pharmaceutica Deutschland GmbH	04 Jun 2014	Cresemba - EU/1/15/1036 - 19 Oct 2015
EU/3/14/1284	Isavuconazonium sulfate	Lečenje invazivne aspergiloze	Basilea Pharmaceutica Deutschland GmbH	04 Jul 2014	Cresemba - EU/1/15/1036 - 19 Oct 2015
EU/3/14/1351	Rekombinantni humani monoclonal IgG1 antitelo for fibroblast growth faktor 23	Lečenje X-vezane hipofosfatemije	Kyowa Kirin Holdings B.V.	15 Oct 2014	CRYSVITA - EU/1/17/1262 - 21 Feb 2018
EU/3/18/2011	Burosumab	Lečenje fosfaturnog mezenhimalnog tumora	Kyowa Kirin Holdings B.V.	16 Apr 2018	CRYSVITA - EU/1/17/1262 - 28 Jul 2022
EU/3/08/578	Cysteamine hydrochloride	Lečenje cistinoze	Recordati Rare Diseases	07 Nov 2008	Cystadrops - EU/1/15/1049 - 23 Jan 2017

EU/3/17/1923	Glasdegib maleate	Lečenje akutne mijeloidne leukemije	Pfizer Europe MA EEIG	16 Oct 2017	Daurismo - EU/1/20/1451 - 29 Jun 2020
EU/3/15/1534	Glycyl-L-2-methylprolyl-L-glutamic acid	Lečenje Rettovog sindroma	Acadia Pharmaceuticals (Netherlands) B.V.	10 Aug 2015	Daybu - EU/1/26/2045 - 21 Aug 2026
EU/3/07/513	(S)-2-nitro-6-(4-(trifluoromethoxy)benzyloxy)-6,7-dihydro-5H-imidazo[2,1-b][1,3]oxazine	Lečenje tuberkuloze	Mylan IRE Healthcare Ltd	29 Nov 2007	Dovprela - EU/1/20/1437 - 04 Aug 2020
EU/3/12/1009	Givinostat	Lečenje Duchenneove mišićne distrofije	Italfarmaco S.p.A.	04 Jul 2012	DUVYZAT - EU/1/25/1930 - 06 Jun 2025
EU/3/16/1627	Allogeneic Epstein-Barr virus specific cytotoxic T lymphocytes	Lečenje posttransplantacionog limfoproliferativnog poremećaja	Pierre Fabre Medicament	21 Mar 2016	Ebvallo - EU/1/22/1700 - 16 Dec 2022
EU/3/22/2625	Sebetralstat	Lečenje naslednog angioedema	Kalvista Pharmaceuticals (Ireland) Limited	21 Jun 2022	Ekterly - EU/1/25/1975 - 18 Sep 2025
EU/3/15/1458	Humanizovano anti-folate receptor 1 monoklonsko antitelo conjugated to maytansinoid DM4	Lečenje karcinoma jajnika	AbbVie Deutschland GmbH & Co. KG	19 Mar 2015	ELAHERE - EU/1/24/1866 - 15 Nov 2024
EU/3/15/1567	Rekombinantni humani interleukin-3 truncated diphtheria toxin fusion protein	Lečenje blastne neoplazme plazmacitoidnih dendritskih ćelija	Stemline Therapeutics B.V.	11 Nov 2015	ELZONRIS - EU/1/20/1504 - 13 Jan 2021
EU/3/17/1945	Tiratricol	Lečenje Allan-Herndon-Dudleyjevog sindroma	Rare Thyroid Therapeutics International AB	08 Nov 2017	Emcitate - EU/1/24/1897 - 17 Feb 2025

EU/3/16/1609	Humanizovano IgG4 monoklonsko antitelo against total complement component 1, subcomponent s	Lečenje autoimune hemolitičke anemije	Recordati Rare Diseases	17 Feb 2016	Enjaymo - EU/1/22/1687 - 23 Nov 2022
EU/3/16/1680	Humanizovano anti-IL-6 receptor monoklonsko antitelo	Lečenje poremećaja spektra optičkog neuromijelitisa	Roche Registration GmbH	27 Jun 2016	Enspryng - EU/1/21/1559 - 29 Jun 2021
EU/3/14/1339	Cannabidiol	Lečenje Dravetovog sindroma	Jazz Pharmaceuticals Ireland Limited	15 Oct 2014	Epidyolex - EU/1/19/1389 - 23 Sep 2019
EU/3/17/1855	Cannabidiol	Lečenje Lennox-Gastautovog sindroma	Jazz Pharmaceuticals Ireland Limited	20 Mar 2017	Epidyolex - EU/1/19/1389 - 23 Sep 2019
EU/3/17/1959	Cannabidiol	Lečenje tuberozne skleroze	Jazz Pharmaceuticals Ireland Limited	17 Jan 2018	Epidyolex - EU/1/19/1389 - 20 Apr 2021
EU/3/19/2184	N-((R)-2,3-dihydroxypropoxyl)-3,4-difluro-2-(2-fluoro-4-iodo-phenylamino)-benzamide	Lečenje neurofibromatoze tipa 1	Merck Europe B.V.	25 Jul 2019	Ezmekly - EU/1/25/1950 - 18 Jul 2025
EU/3/18/2104	(4-{(2S,4S)-4-ethoxy-1-[(5-methoxy-7-methyl-1H-indol-4-yl)methyl]piperidin-2-yl}benzoic acid-hydrogen chloride(1/1))	Lečenje C3 glomerulopatije	Novartis Europharm Limited	14 Dec 2018	FABHALTA - EU/1/24/1802 - 01 Apr 2025
EU/3/20/2281	(4-{(2S,4S)-4-ethoxy-1-[(5-methoxy-7-methyl-1H-indol-4-yl)methyl]piperidin-2-yl}benzoic acid-hydrogen chloride(1/1))	Lečenje paroksizmalne noćne hemoglobinurije	Novartis Europharm Limited	04 Jun 2020	FABHALTA - EU/1/24/1802 - 21 May 2024
EU/3/20/2345	Sparsentan	Lečenje primarne IgA nefropatije	Vifor France S.A.	19 Oct 2020	Filspari - EU/1/23/1788 - 23 Apr 2024

EU/3/10/845	Dry extract from birch bark (DER 5-10 : 1), extraction solvent n-heptane 95% (w/w)	Lečenje bulozne epidermolize	Chiesi Farmaceutici S.p.A.	23 Feb 2011	Filsuvez - EU/1/22/1652 - 23 Jun 2022
EU/3/20/2372	Dabrafenib mesylate	Lečenje glioma	Novartis Europharm Limited	09 Dec 2020	Finlee - EU/1/23/1767 - 16 Nov 2023
EU/3/13/1219	Fenfluramine hydrochloride	Lečenje Dravetovog sindroma	UCB Pharma	18 Dec 2013	Fintepla - EU/1/20/1491 - 21 Dec 2020
EU/3/17/1836	Fenfluramine hydrochloride	Lečenje Lennox-Gastautovog sindroma	UCB Pharma	27 Feb 2017	Fintepla - EU/1/20/1491 - 31 Jan 2023
EU/3/16/1731	Sintetički dvolančani siRNA oligonukleotid usmeren protiv delta-aminolevulinic acid synthase 1 mRNA kovalentno vezan to a ligand koji sadrži three N-acetylgalactosamine residues	Lečenje akutne hepatične porfirije	Alnylam Netherlands B.V.	29 Aug 2016	Givlaari - EU/1/20/1428 - 04 Mar 2020
EU/3/18/1999	Recombinant adeno-associated virusni vektor koji sadrži a codon-optimized Padua derivative of humani faktor koagulacije IX cDNA	Lečenje hemofilije B	CSL Behring GmbH	21 Mar 2018	Hemgenix - EU/1/22/1715 - 23 Feb 2023
EU/3/15/1500	Synthetic 47-amino-acid N-myristoylated lipopeptide, izveden from the preS region of hepatitis B virus	Lečenje infekcije virusom hepatitisa delta	Gilead Sciences Ireland Unlimited Company	19 Jun 2015	Hepcludex - EU/1/20/1446 - 05 Aug 2020
EU/3/08/579	Ex-vivo expanded Autologne humane ćelije corneal epithelium koji sadrži matične ćelije	Lečenje lezija rožnjače sa nedostatkom limbalnih matičnih ćelija usled opekotina oka	Holostem S.r.l.	07 Nov 2008	Holoclar - EU/1/14/987 - 19 Feb 2015

EU/3/17/1910	Sirolimus	Lečenje tuberozne skleroze	Plusultra Pharma GmbH	23 Aug 2017	Hyftor - EU/1/23/1723 - 26 May 2023
EU/3/16/1826	Recombinant IgG degrading enzim of Streptococcus pyogenes	sprečavanje odbacivanja transplantata nakon transplantacije solidnog organa	Hansa Biopharma AB	12 Jan 2017	Idefirix - EU/1/20/1471 - 01 Sep 2020
EU/3/09/723	Rekombinantni fuzioni protein linking humani faktor koagulacije IX with humani albumin	Lečenje hemofilije B	CSL Behring GmbH	04 Feb 2010	IDELVION - EU/1/16/1095 - 13 May 2016
EU/3/16/1703	Setmelanotide	Lečenje nedostatka proopiomelanokortina	Rhythm Pharmaceuticals Netherlands B.V.	14 Jul 2016	Imcivree - EU/1/21/1564 - 19 Jul 2021
EU/3/18/2101	Setmelanotide	Lečenje nedostatka receptora leptina	Rhythm Pharmaceuticals Netherlands B.V.	19 Nov 2018	Imcivree - EU/1/21/1564 - 19 Jul 2021
EU/3/19/2192	Setmelanotide	Lečenje Bardet-Biedlovog sindroma	Rhythm Pharmaceuticals Netherlands B.V.	21 Aug 2019	Imcivree - EU/1/21/1564 - 05 Sep 2022
EU/3/23/2833	Setmelanotide	Lečenje stečene hipotalamičke gojaznosti	Rhythm Pharmaceuticals Netherlands B.V.	13 Oct 2023	Imcivree - EU/1/21/1564 - 05 May 2026
EU/3/23/2876	Tarlatamab	Lečenje plućnog neuroendokrinog karcinoma (prvobitno: mikrocelularni karcinom pluća)	Amgen Europe B.V.	12 Jan 2024	IMDYLLTRA - EU/1/26/2033 - 01 Jun 2026

EU/3/10/794	N-tert-butyl-3-[(5-methyl-2-{[4-(2-pyrrolidin-1-ylethoxy)phenyl]amino}pyrimidin-4-yl)amino] benzenesulfonamide dihydrochloride monohydrate	Lečenje primarne mijelofibroze	Bristol-Myers Squibb Pharma EEIG	01 Oct 2010	Inrebic - EU/1/20/1514 - 09 Feb 2021
EU/3/10/810	N-tert-butyl-3-[(5-methyl-2-{[4-(2-pyrrolidin-1-ylethoxy)phenyl]amino}pyrimidin-4-yl)amino] benzenesulfonamide dihydrochloride monohydrate	Lečenje mijelofibroze nakon esencijalne trombocitemije	Bristol-Myers Squibb Pharma EEIG	26 Nov 2010	Inrebic - EU/1/20/1514 - 09 Feb 2021
EU/3/10/811	N-tert-butyl-3-[(5-methyl-2-{[4-(2-pyrrolidin-1-ylethoxy)phenyl]amino}pyrimidin-4-yl)amino] benzenesulfonamide dihydrochloride monohydrate	Lečenje mijelofibroze nakon policitemije vere	Bristol-Myers Squibb Pharma EEIG	26 Nov 2010	Inrebic - EU/1/20/1514 - 09 Feb 2021
EU/3/19/2182	Elafibranor	Lečenje primarnog bilijarnog holangitisa	Ipsen Pharma	25 Jul 2019	Iqirvo - EU/1/24/1855 - 23 Sep 2024
EU/3/14/1345	Osilodrostat	Lečenje Cushingovog sindroma	Recordati Rare Diseases	15 Oct 2014	Isturisa - EU/1/19/1407 - 13 Jan 2020
EU/3/20/2339	Leniolisib	Lečenje sindroma aktivirane fosfoinozitid 3-kinaze delta	Pharming Technologies B.V.	19 Oct 2020	Joenja - EU/1/26/2034 - 22 May 2026
EU/3/13/1181	Budesonide	Lečenje eozinofilnog ezofagitisa	Dr Falk Pharma GmbH	05 Aug 2013	Jorveza - EU/1/17/1254 - 10 Jan 2018

EU/3/18/2116	Ivacaftor, N-(1,3-dimethyl-1H-pyrazole-4-sulfonyl)-6-[3-(3,3,3-trifluoro-2,2-dimethylpropoxy)-1H-pyrazol-1-yl]-2-[(4S)-2,2,4-trimethylpyrrolidin-1-yl]pyridine-3-carboxamide, tezacaftor	Lečenje cistične fibroze	Vertex Pharmaceuticals (Ireland) Limited	14 Dec 2018	Kaftrio - EU/1/20/1468 - 21 Aug 2020
EU/3/10/827	Rekombinantni humani lysosomal acid lipase	Lečenje nedostatka lizozomalne kisele lipaze	Alexion Europe SAS	17 Dec 2010	Kanuma - EU/1/15/1033 - 01 Sep 2015
EU/3/21/2397	Tebentafusp	Lečenje uvealnog melanoma	Immunocore Ireland Limited	19 Feb 2021	KIMMTRAK - EU/1/22/1630 - 06 Apr 2022
EU/3/16/1778	Budesonide	Lečenje primarne IgA nefropatije	STADA Arzneimittel AG	18 Nov 2016	Kinpeygo - EU/1/22/1657 - 18 Jul 2022
EU/3/18/2050	Selumetinib	Lečenje neurofibromatoze tipa 1	AstraZeneca AB	31 Jul 2018	Koselugo - EU/1/21/1552 - 19 Jun 2021
EU/3/17/1870	Thymidine and deoxycytidine	Lečenje sindroma deplecije mitohondrijalne DNK, miopatski oblik	UCB Pharma	20 Apr 2017	KYGEVVI - EU/1/25/2013 - 27 Mar 2026
EU/3/14/1266	Autologne T ćelije transdukovane pomoću lentivirusni vektor koji sadrži a Himerno antigen receptor usmeren protiv CD19	Lečenje B-limfoblastne leukemije/limfoma	Novartis Europharm Limited	29 Apr 2014	Kymriah - EU/1/18/1297 - 27 Aug 2018
EU/3/16/1745	Autologne T ćelije transdukovane pomoću lentivirusni vektor koji sadrži a Himerno antigen receptor usmeren protiv CD19	Lečenje difuznog B-krupnoćelijskog limfoma	Novartis Europharm Limited	14 Oct 2016	Kymriah - EU/1/18/1297 - 27 Aug 2018

EU/3/21/2464	Tisagenlecleucel	Lečenje folikularnog limfoma	Novartis Europharm Limited	19 Jul 2021	Kymriah - EU/1/18/1297 - 03 May 2022
EU/3/04/260	Rekombinantni humani α-Mannosidase	Lečenje α-manozidoze	Chiesi Farmaceutici S.p.A.	26 Jan 2005	Lamzede - EU/1/17/1258 - 27 Mar 2018
EU/3/12/963	Chlormethine	Lečenje kožnog T-ćelijskog limfoma	Helsinn Birex Pharmaceuticals Ltd	22 May 2012	Ledaga - EU/1/16/1171 - 07 Mar 2017
EU/3/07/446	Autologous CD34+ cells transfektovane pomoću lentivirusni vektor koji sadrži the humani arylsulfatase A cDNA	Lečenje metahromatske leukodistrofije	Orchard Therapeutics (Netherlands) B.V.	13 Apr 2007	Libmeldy - EU/1/20/1493 - 18 Dec 2020
EU/3/13/1214	(4R,5R)-1-[[4-[[4-[3,3-dibutyl-7-(dimethylamino)-2,3,4,5-tetrahydro-4-hydroxy-1,1-dioxido-1-benzothiepin-5-yl]phenoxy]methyl]phenyl]methyl]-4-aza-1-azoniabicyclo[2.2.2]octane chloride	Lečenje Alagilleovog sindroma	Mirum Pharmaceuticals International B.V.	18 Dec 2013	Livmarli - EU/1/22/1704 - 12 Dec 2022
EU/3/13/1216	(4R,5R)-1-[[4-[[4-[3,3-dibutyl-7-(dimethylamino)-2,3,4,5-tetrahydro-4-hydroxy-1,1-dioxido-1-benzothiepin-5-yl]phenoxy]methyl]phenyl]methyl]-4-aza-1-azoniabicyclo[2.2.2]octane chloride	Lečenje progresivne porodične intrahepatične holestaze	Mirum Pharmaceuticals International B.V.	18 Dec 2013	Livmarli - EU/1/22/1704 - 01 Jul 2024

EU/3/07/519	Maribavir	prevencija bolesti izazvane citomegalovirusom (CMV) kod rizičnih pacijenata sa oslabljenim ćelijskim imunitetom	Takeda Pharmaceuticals International AG Ireland Branch	18 Dec 2007	LIVTENCITY - EU/1/22/1672 - 10 Nov 2022
EU/3/13/1133	Maribavir	Lečenje citomegalovirusne bolesti kod pacijenata sa oslabljenim ćelijskim imunitetom	Takeda Pharmaceuticals International AG Ireland Branch	07 Jun 2013	LIVTENCITY - EU/1/22/1672 - 10 Nov 2022
EU/3/16/1701	Poly(oxy-1,2-ethanediyl), alfa-(carboxymethyl)-omega-methoxy-,amide with arginase 1 [cobalt cofactor] (synthetic humani) (1:10), trimer	Lečenje hiperargininemije	Immedica Pharma AB	14 Jul 2016	Loargys - EU/1/23/1774 - 18 Dec 2023
EU/3/21/2517	Mosunetuzumab	Lečenje folikularnog limfoma	Roche Registration GmbH	12 Nov 2021	Lunsumio - EU/1/22/1649 - 07 Jun 2022
EU/3/07/523	Lutetium (177Lu)-N-[(4,7,10-Tricarboxymethyl-1,4,7,10-tetraazacyclododec-1-yl)acetyl]-D-phenylalanyl-L-cysteinyl-L-tyrosyl-D-tryptophanyl-L-lysyl-L-threoninyl-L-cysteinyl-L-threonine-cyclic(2-7)disulfide	Lečenje gastroenteropankreatičnih neuroendokrinih tumora	Novartis Europharm Limited	31 Jan 2008	Lutathera - EU/1/17/1226 - 28 Sep 2017
EU/3/12/981	Adenovirus associated virusni vektor serotype 2 koji sadrži the humani RPE65 gen	Lečenje naslednih distrofija mrežnjače (prvobitno: Leberova kongenitalna amauroza)	Novartis Europharm Limited	02 Apr 2012	Luxturna - EU/1/18/1331 - 05 Dec 2018

EU/3/15/1518	Adenovirus-associated virusni vektor serotype 2 koji sadrži the humani RPE65 gen	Lečenje naslednih distrofija mrežnjače (prvobitno: retinitis pigmentosa)	Novartis Europharm Limited	28 Jul 2015	Luxturna - EU/1/18/1331 - 05 Dec 2018
EU/3/17/1930	Seladelpar	Lečenje primarnog bilijarnog holangitisa	Gilead Sciences Ireland UC	16 Oct 2017	Lyvdelzi - EU/1/24/1898 - 21 Feb 2025
EU/3/18/2076	Glycine, L-alanine, L-arginine, L-aspartic acid, L-cysteine, L-glutamic acid, L-histidine, L-lysine monohydrate, L-methionine, L-phenylalanine, L-proline, L-serine, L-threonine, L-tryptophan, L-tyrosine, taurine	Lečenje bolesti urina sa mirisom javorovog sirupa	Recordati Rare Diseases	26 Oct 2018	Maapliv - EU/1/25/1955 - 29 Jul 2025
EU/3/12/973	Rekombinantni humani beta-glucuronidase	Lečenje mukopolisaharidoze tipa VII (Slyjev sindrom)	Ultragenyx Germany GmbH	21 Mar 2012	Mepsevii - EU/1/18/1301 - 27 Aug 2018
EU/3/14/1424	Humanizovano Fc engineered monoklonsko antitelo against CD19	Lečenje difuznog B-krupnoćelijskog limfoma	Incyte Biosciences Distribution B.V.	15 Jan 2015	Minjuvi - EU/1/21/1570 - 01 Sep 2021
EU/3/25/3027	Tafasitamab	Lečenje folikularnog limfoma	Incyte Biosciences Distribution B.V.	26 Feb 2025	Minjuvi - EU/1/21/1570 - 16 Dec 2025
EU/3/12/1022	Metreleptin	Lečenje porodične parcijalne lipodistrofije	Chiesi Farmaceutici S.p.A.	17 Jul 2012	Myalepta - EU/1/18/1276 - 01 Aug 2018
EU/3/12/1023	Metreleptin	Lečenje Barraquer-Simonsovog sindroma	Chiesi Farmaceutici S.p.A.	17 Jul 2012	Myalepta - EU/1/18/1276 - 01 Aug 2018
EU/3/12/1024	Metreleptin	Lečenje Lawrenceovog sindroma	Chiesi Farmaceutici S.p.A.	17 Jul 2012	Myalepta - EU/1/18/1276 - 01 Aug 2018

EU/3/12/1025	Metreleptin	Lečenje Berardinelli-Seipovog sindroma	Chiesi Farmaceutici S.p.A.	17 Jul 2012	Myalepta - EU/1/18/1276 - 01 Aug 2018
EU/3/00/005	Gemtuzumab Ozogamicin	Lečenje akutne mijeloidne leukemije	Pfizer Europe MA EEIG	18 Oct 2000	Mylotarg - EU/1/18/1277 - 23 Apr 2018
EU/3/14/1353	Mexiletine hydrochloride	Lečenje miotoničnih poremećaja	Lupin Europe GmbH	19 Nov 2014	Namuscla - EU/1/18/1325 - 20 Dec 2018
EU/3/13/1210	Rekombinantni humani parathyroid hormone	Lečenje hipoparatireoidizma	Takeda Pharmaceuticals International AG Ireland Branch	18 Dec 2013	Natpar - EU/1/15/1078 - 26 Apr 2017
EU/3/16/1770	5-[4-[2-(5-(1-hydroxyethyl)-2-pyridinyl)ethoxy]benzyl]-2,4-thiazolidinedione hydrochloride	Lečenje adrenoleukodistrofije	Minoryx Therapeutics S.L.	18 Nov 2016	Nezglyal - EU/1/26/2060 - 22 Sep 2026
EU/3/12/1087	Recombinant modifikovan humani growth hormone	Lečenje nedostatka hormona rasta	Pfizer Europe MA EEIG	24 Jan 2013	Ngenla - EU/1/21/1617 - 15 Feb 2022
EU/3/11/899	2,2'-{2-[(1R)-1-({[(2,5-dichlorobenzoyl)amino]acetyl}amino)-3-methylbutyl]-5-oxo-1,3,2-dioxaborolane-4,4-diyl}diacetic acid	Lečenje multiplog mijeloma	Takeda Pharma A/S	27 Sep 2011	Ninlaro - EU/1/16/1094 - 23 Nov 2016
EU/3/10/777	Cyclic pyranopterin monophosphate	Lečenje nedostatka molibdenskog kofaktora tipa A	Integral Pharma Solutions EU Limited	20 Sep 2010	NULIBRY - EU/1/22/1684 - 16 Sep 2022
EU/3/19/2214	Nirogacestat	Lečenje sarkoma mekih tkiva	Merck Europe B.V.	17 Oct 2019	Ogsiveo - EU/1/25/1932 - 18 Aug 2025

EU/3/21/2434	6-Amino-5-chloro-N-((1R)-1-(5-(((5-chloro-4-(trifluoromethyl)-2-pyridinyl)amino)carbonyl)-2-thiazolyl)ethyl)-4-pyrimidinecarboxamide	Lečenje glioma	Ipsen Pharma	20 May 2021	Ojemda - EU/1/26/2025 - 21 Apr 2026
EU/3/11/886	N-(cyanomethyl)-4-(2-{[4-(morpholin-4-yl)phenyl]amino}pyrimidin-4-yl)benzamide, dihydrochloride salt	Lečenje mijelofibroze nakon policitemije vere	GlaxoSmithKline Trading Services Limited	05 Aug 2011	Omjjara - EU/1/23/1782 - 26 Jan 2024
EU/3/11/887	N-(cyanomethyl)-4-(2-{[4-(morpholin-4-yl)phenyl]amino}pyrimidin-4-yl)benzamide, dihydrochloride salt	Lečenje mijelofibroze nakon esencijalne trombocitemije	GlaxoSmithKline Trading Services Limited	05 Aug 2011	Omjjara - EU/1/23/1782 - 26 Jan 2024
EU/3/11/888	N-(cyanomethyl)-4-(2-{[4-(morpholin-4-yl)phenyl]amino}pyrimidin-4-yl)benzamide, dihydrochloride salt	Lečenje primarne mijelofibroze	GlaxoSmithKline Trading Services Limited	05 Aug 2011	Omjjara - EU/1/23/1782 - 26 Jan 2024
EU/3/11/933	Nanoliposomal irinotecan	Lečenje karcinoma pankreasa	Les Laboratoires Servier	09 Dec 2011	Onivyde pegylated liposomal - EU/1/16/1130 - 18 Oct 2016
EU/3/11/857	Sintetički dvolančani siRNA oligonukleotid usmeren protiv transthyretin mRNA	Lečenje amiloidoze posredovane transtiretinom	Alnylam Netherlands B.V.	15 Apr 2011	Onpattro - EU/1/18/1320 - 29 Aug 2018
EU/3/16/1769	2-hydroxy-6-((2-(1-isopropyl-1H-pyrazol-5-yl)pyridin-3-yl)methoxy)benzaldehyde	Lečenje bolesti srpastih ćelija	Pfizer Europe MA EEIG	18 Nov 2016	Oxbryta - EU/1/21/1622 - 15 Feb 2022

EU/3/15/1586	Rekombinantni humani nerve growth faktor	Lečenje neurotrofičnog keratitisa	Dompé farmaceutici S.p.A.	14 Dec 2015	OXERVATE - EU/1/17/1197 - 10 Jul 2017
EU/3/16/1637	Sintetički dvolančani siRNA oligonukleotid usmeren protiv hydroxyacid oxidase 1 mRNA and kovalentno vezan to a ligand koji sadrži three N-acetylgalactosamine residues	Lečenje primarne hiperoksalurije	Alnylam Netherlands B.V.	21 Mar 2016	Oxlumo - EU/1/20/1496 - 23 Nov 2020
EU/3/25/3035	Paltusotine	Lečenje akromegalije	Crinetics Pharmaceuticals Europe GmbH	26 Feb 2025	Palsonify - EU/1/26/2021 - 27 Apr 2026
EU/3/09/708	Pegylated recombinant phenylalanine ammonia lyase	Lečenje hiperfenilalaninemije	BioMarin International Limited	28 Jan 2010	Palynziq - EU/1/19/1362 - 08 May 2019
EU/3/18/2066	Pemigatinib	Lečenje karcinoma bilijarnog trakta	Incyte Biosciences Distribution B.V.	24 Aug 2018	Pemazyre - EU/1/21/1535 - 29 Mar 2021
EU/3/18/2013	Polatuzumab vedotin	Lečenje difuznog B-krupnoćelijskog limfoma	Roche Registration GmbH	16 Apr 2018	Polivy - EU/1/19/1388 - 20 Jan 2020
EU/3/16/1756	Mogamulizumab	Lečenje kožnog T-ćelijskog limfoma	Kyowa Kirin Holdings B.V.	14 Oct 2016	Poteligeo - EU/1/18/1335 - 26 Nov 2018
EU/3/11/849	(S)-{8-fluoro-2-2[4-(3-methoxyphenyl)-1-piperazinyl]-3-[2-methoxy-5-(trifluoromethyl)-phenyl]-3,4-dihydro-4-quinazolinyl} acetic acid	prevencija citomegalovirusne bolesti kod rizičnih pacijenata sa oslabljenim ćelijskim imunitetom	Merck Sharp & Dohme B.V.	15 Apr 2011	PREVYMIS - EU/1/17/1245 - 10 Jan 2018
EU/3/20/2270	Mitapivat sulfate	Lečenje nedostatka piruvat-kinaze	Agios Netherlands B.V.	22 Apr 2020	Pyrukynd - EU/1/22/1662 - 10 Nov 2022

EU/3/23/2827	Mitapivat sulfat	Lečenje talasemije intermedije i major (prvobitno: beta-talasemija intermedija i major)	Agios Netherlands B.V.	13 Oct 2023	Pyrukynd - EU/1/22/1662 - 22 May 2026
EU/3/23/2889	Mitapivat sulfate	Lečenje talasemije intermedije i major (prvobitno: beta-talasemija intermedija i major)	Agios Netherlands B.V.	12 Jan 2024	Pyrukynd - EU/1/22/1662 - 22 May 2026
EU/3/16/1732	Sintetički oligonukleotid ribonukleinske kiseline usmeren protiv superoxide dismutase 1 messenger ribonucleic acid	Lečenje amiotrofične lateralne skleroze	Biogen Netherlands B.V.	29 Aug 2016	Qalsody - EU/1/23/1783 - 03 Jun 2024
EU/3/12/1062	Himerno monoklonsko antitelo against GD2	Lečenje neuroblastoma	Recordati Netherlands B.V.	08 Nov 2012	Qarziba - EU/1/17/1191 - 11 May 2017
EU/3/17/1936	1-[4-bromo-5-[1-ethyl-7-(methylamino)-2-oxo-1,2-dihydro-1,6-naphthyridin-3-yl]-2-fluorophenyl]-3-phenylurea	Lečenje gastrointestinalnih stromalnih tumora	Deciphera Pharmaceuticals (Netherlands) B.V.	08 Nov 2017	QINLOCK - EU/1/21/1569 - 24 Nov 2021
EU/3/10/733	Glyceryl tri-(4-phenylbutyrate)	Lečenje nedostatka karbamoil-fosfat sintetaze 1	Immedica Pharma AB	10 Jun 2010	Ravicti - EU/1/15/1062 - 01 Dec 2015
EU/3/10/734	Glyceryl tri-(4-phenylbutyrate)	Lečenje nedostatka ornitin-karbamoiltransferaze	Immedica Pharma AB	10 Jun 2010	Ravicti - EU/1/15/1062 - 01 Dec 2015
EU/3/10/735	Glyceryl tri-(4-phenylbutyrate)	Lečenje citrulinemije tipa 1	Immedica Pharma AB	10 Jun 2010	Ravicti - EU/1/15/1062 - 01 Dec 2015

EU/3/10/736	Glyceryl tri-(4-phenylbutyrate)	Lečenje argininosukcinske acidurije	Immedica Pharma AB	10 Jun 2010	Ravicti - EU/1/15/1062 - 01 Dec 2015
EU/3/10/737	Glyceryl tri-(4-phenylbutyrate)	Lečenje hiperargininemije	Immedica Pharma AB	10 Jun 2010	Ravicti - EU/1/15/1062 - 01 Dec 2015
EU/3/10/738	Glyceryl tri-(4-phenylbutyrate)	Lečenje nedostatka ornitin-translokaze (HHH sindrom)	Immedica Pharma AB	10 Jun 2010	Ravicti - EU/1/15/1062 - 01 Dec 2015
EU/3/14/1300	Rekombinantni fuzioni protein koji se sastoji od a modifikovan form of the extracellular domain of humani activin receptor IIB povezan sa the humani IgG1 Fc domain	Lečenje beta-talasemije intermedije i major	Bristol-Myers Squibb Pharma EEIG	29 Jul 2014	Reblozyl - EU/1/20/1452 - 26 Jun 2020
EU/3/14/1331	Rekombinantni fuzioni protein koji se sastoji od a modifikovan form of the extracellular domain of humani activin receptor IIB povezan sa the humani IgG1 Fc domain	Lečenje mijelodisplastičnih sindroma	Bristol-Myers Squibb Pharma EEIG	22 Aug 2014	Reblozyl - EU/1/20/1452 - 26 Jun 2020
EU/3/21/2459	Sintetički dvolančani siRNA oligonukleotid usmeren protiv apolipoprotein C-III mRNA and kovalentno vezan to a ligand koji sadrži three N-acetylgalactosamine residues	Lečenje sindroma porodične hilomikronemije	Arrowhead Pharmaceuticals Ireland Limited	19 Jul 2021	Redemplo - EU/1/26/2041 - 22 Jun 2026
EU/3/19/2205	2-(3-(4-(1H-indazol-5-ylamino)quinazolin-2-yl)phenoxy)-N-isopropylacetamide-methane sulfonic acid salt	Lečenje bolesti kalem protiv domaćina	Sanofi Winthrop Industrie	17 Oct 2019	REZUROCK - EU/1/26/2015 - 25 Mar 2026

EU/3/20/2385	Rezafungin acetate	Lečenje invazivne kandidijaze	Mundipharma GmbH	06 Jan 2021	Rezzayo - EU/1/23/1775 - 22 Dec 2023
EU/3/16/1622	Adeno-associated virusni vektor serotype 5 koji sadrži a B-domain deleted variant of humani faktor koagulacije VIII gen	Lečenje hemofilije A	BioMarin International Limited	21 Mar 2016	Roctavian - EU/1/22/1668 - 25 Aug 2022
EU/3/19/2227	2-(isopropylamino)-3-methyl-5-(6-methyl-5-((2-(1-methyl-1H-pyrazol-4-yl)pyridin-4-yl)oxy)pyridin-2-yl)pyrimidin-4(3H)-one	Lečenje tenosinovijalnog tumora džinovskih ćelija, lokalizovanog i difuznog tipa	Deciphera Pharmaceuticals (Netherlands) B.V.	16 Dec 2019	ROMVIMZA - EU/1/25/1968 - 24 Sep 2025
EU/3/04/214	Midostaurin	Lečenje akutne mijeloidne leukemije	Novartis Europharm Limited	29 Jul 2004	Rydapt - EU/1/17/1218 - 20 Sep 2017
EU/3/10/765	Midostaurin	Lečenje mastocitoze	Novartis Europharm Limited	04 Aug 2010	Rydapt - EU/1/17/1218 - 20 Sep 2017
EU/3/20/2272	Rozanolixizumab	Lečenje miastenije gravis	UCB Pharma	22 Apr 2020	Rystiggo - EU/1/23/1780 - 08 Jan 2024
EU/3/20/2305	Imetelstat sodium	Lečenje mijelodisplastičnih sindroma	Geron Netherlands B.V.	27 Jul 2020	Rytelo - EU/1/24/1894 - 11 Mar 2025
EU/3/20/2261	Asciminib	Lečenje hronične mijeloidne leukemije	Novartis Europharm Limited	24 Mar 2020	Scemblix - EU/1/22/1670 - 26 Aug 2022
EU/3/21/2435	(S)-2-amino-6-(2-hydroxypropanoyl)-7,8-dihydropteridin-4(3H)-one	Lečenje hiperfenilalaninemije	PTC Therapeutics International Limited	20 May 2021	Sephience - EU/1/25/1939 - 25 Jun 2025
EU/3/18/2037	Omaveloxolone	Lečenje Friedreichove ataksije	Biogen Netherlands B.V.	27 Jun 2018	Skyclarys - EU/1/23/1786 - 12 Feb 2024

EU/3/19/2213	Lonapegsomatropin	Lečenje nedostatka hormona rasta	Ascendis Pharma Endocrinology Division A/S	17 Oct 2019	Skytrofa - EU/1/21/1607 - 17 Jan 2022
EU/3/13/1185	Eculizumab	Lečenje poremećaja spektra optičkog neuromijelitisa	Alexion Europe SAS	05 Aug 2013	Soliris - EU/1/07/393 - 28 Aug 2019
EU/3/14/1304	Eculizumab	Lečenje miastenije gravis	Alexion Europe SAS	29 Jul 2014	Soliris - EU/1/07/393 - 17 Aug 2017
EU/3/15/1450	Gallium (68Ga)-edotreotide	dijagnostika gastroenteropankreatičnih neuroendokrinih tumora	Novartis Europharm Limited	19 Mar 2015	SomaKit TOC - EU/1/16/1141 - 12 Dec 2016
EU/3/20/2374	Trametinib dimethyl sulfoxide	Lečenje glioma	Novartis Europharm Limited	09 Dec 2020	Spexotras - EU/1/23/1781 - 08 Jan 2024
EU/3/12/976	Antisense oligonucleotide targeted to the SMN2 gen	Lečenje 5q spinalne mišićne atrofije	Biogen Netherlands B.V.	02 Apr 2012	Spinraza - EU/1/17/1188 - 01 Jun 2017
EU/3/08/594	Rekombinantni humani tissue non-specific alkaline phosphatase - Fc - deca-aspartate fusion protein	Lečenje hipofosfatazije	Alexion Europe SAS	03 Dec 2008	Strensiq - EU/1/15/1015 - 01 Sep 2015
EU/3/05/313	Autologous CD34+ cells transfektovane pomoću retrovirusni vektor koji sadrži adenosine deaminase gen	Lečenje teške kombinovane imunodeficijencije (SCID) usled nedostatka adenozin-deaminaze (ADA)	Fondazione Telethon Ets	26 Aug 2005	Strimvelis - EU/1/16/1097 - 30 May 2016

EU/3/17/1828	1-(2,2-difluoro-2H-1,3-benzodioxol-5-yl)-N-{1-[(2R)-2,3-dihydroxypropyl]-6-fluoro-2-(1-hydroxy-2-methylpropan-2-yl)-1H-indol-5-yl}cyclopropane-1-carboxamide and ivacaftor	Lečenje cistične fibroze	Vertex Pharmaceuticals (Ireland) Limited	27 Feb 2017	Symkevi - EU/1/18/1306 - 06 Nov 2018
EU/3/15/1551	Rekombinantni humani IgG1 kappa light chain monoklonsko antitelo targeting plasma kallikrein	Lečenje naslednog angioedema	Takeda Pharmaceuticals International AG Ireland Branch	09 Oct 2015	TAKHZYRO - EU/1/18/1340 - 26 Nov 2018
EU/3/21/2486	Talquetamab	Lečenje multiplog mijeloma	Janssen-Cilag International N.V.	20 Aug 2021	TALVEY - EU/1/23/1748 - 22 Aug 2023
EU/3/19/2220	Autologne T ćelije periferne krvi CD4 and CD8 selected and CD3 and CD28 activated transdukovane pomoću retrovirusni vektor koji eksprimira anti CD19 CD28/CD3-zeta Himerno antigen receptor and cultured	Lečenje limfoma ćelija plašta	Kite Pharma EU B.V.	13 Nov 2019	Tecartus - EU/1/20/1492 - 15 Dec 2020
EU/3/20/2344	Autologne T ćelije periferne krvi CD4 and CD 8 selected and CD 3 and CD 28 activated transdukovane pomoću retrovirusni vektor koji eksprimira anti- CD 19 CD 28/ CD 3-zeta Himerno antigen receptor and cultured	Lečenje akutne limfoblastne leukemije	Kite Pharma EU B.V.	19 Oct 2020	Tecartus - EU/1/20/1492 - 05 Sep 2022
EU/3/14/1250	Phosphorothioate oligonucleotide targeted to transthyretin	Lečenje ATTR amiloidoze	Akcea Therapeutics Ireland Limited	26 Mar 2014	Tegsedi - EU/1/18/1296 - 10 Jul 2018

EU/3/16/1802	Ivosidenib	Lečenje akutne mijeloidne leukemije	Les Laboratoires Servier	12 Dec 2016	Tibsovo - EU/1/23/1728 - 08 May 2023
EU/3/18/1994	Ivosidenib	Lečenje karcinoma bilijarnog trakta	Les Laboratoires Servier	21 Mar 2018	Tibsovo - EU/1/23/1728 - 08 May 2023
EU/3/04/186	Treosulfan	pripremna terapija pre transplantacije hematopoetskih progenitorskih ćelija	medac Gesellschaft für klinische Spezialpräparate mbH	23 Feb 2004	Trecondi - EU/1/18/1351 - 24 Jun 2019
EU/3/13/1103	Treprostinil sodium	Lečenje hronične tromboembolijske plućne hipertenzije	SciPharm Sàrl	08 Feb 2013	Trepulmix - EU/1/19/1419 - 07 Apr 2020
EU/3/24/2973	Olezarsen sodium	Lečenje sindroma porodične hilomikronemije	Swedish Orphan Biovitrum AB (publ)	21 Aug 2024	Tryngolza - EU/1/25/1969 - 18 Sep 2025
EU/3/16/1786	Recombinant adeno-associated virusni vektor serotype 2 carrying the gen for the humani aromatic L-amino acid decarboxylase protein	Lečenje nedostatka dekarboksilaze aromatičnih L-amino-kiselina	PTC Therapeutics International Limited	18 Nov 2016	Upstaza - EU/1/22/1653 - 22 Jul 2022
EU/3/06/360	Ciclosporin	Lečenje vernalnog keratokonjunktivitisa	Santen Oy	06 Apr 2006	Verkazia - EU/1/17/1219 - 10 Jul 2018
EU/3/21/2420	Alpelisib	Lečenje spektra prekomernog rasta povezanog sa PIK3CA	Novartis Europharm Limited	26 Mar 2021	Vijoice - EU/1/26/2042 - 16 Jul 2026
EU/3/22/2737	Vorasidenib hemicitrate hemihydrate	Lečenje glioma	Les Laboratoires Servier	13 Jan 2023	Voranigo - EU/1/25/1912 - 19 Sep 2025

EU/3/02/128	Carboxypeptidase G2	pomoćno lečenje pacijenata sa rizikom od toksičnosti metotreksata	Serb	03 Feb 2003	Voraxaze - EU/1/21/1586 - 13 Jan 2022
EU/3/12/1094	modifikovan Rekombinantni humani C-type natriuretic peptide	Lečenje ahondroplazije	BioMarin International Limited	24 Jan 2013	Voxzogo - EU/1/21/1577 - 01 Sep 2021
EU/3/17/1946	(2S,4R)-1-(2-(3-acetyl-5-(2-methylpyrimidine-5-yl)-1H-indazol-1-yl)acetyl)-N-(6-bromopyridine-2-yl)-4-fluoropyrrolidine-2-carboxamide	Lečenje paroksizmalne noćne hemoglobinurije	Alexion Europe SAS	12 Dec 2017	Voydeya - EU/1/24/1792 - 25 Apr 2024
EU/3/18/2012	Genetically modifikovan replication-incompetent herpes simplex virus-1 koji eksprimira collagen VII	Lečenje bulozne epidermolize	Krystal Biotech Netherlands B.V.	16 Apr 2018	Vyjuvek - EU/1/25/1918 - 24 Apr 2025
EU/3/10/803	Himerno monoklonsko antitelo against claudin-18 splice variant 2	Lečenje karcinoma želuca	Astellas Pharma Europe B.V.	26 Nov 2010	Vyloy - EU/1/24/1856 - 25 Sep 2024
EU/3/12/1066	tafamidis	Lečenje senilne sistemske amiloidoze	Pfizer Europe MA EEIG	08 Nov 2012	Vyndaqel - EU/1/11/717 - 19 Feb 2020
EU/3/18/1992	Efgartigimod alfa	Lečenje miastenije gravis	Argenx	21 Mar 2018	Vyvgart - EU/1/22/1674 - 11 Aug 2022
EU/3/21/2555	Efgartigimod alfa	Lečenje hronične inflamatorne demijelinizacione polineuropatije	Argenx	14 Jan 2022	Vyvgart - EU/1/22/1674 - 20 Jun 2025
EU/3/11/942	Liposomal combination of cytarabine and daunorubicin	Lečenje akutne mijeloidne leukemije	Jazz Pharmaceuticals Ireland Ltd	11 Jan 2012	Vyxeos liposomal - EU/1/18/1308 - 27 Aug 2018

EU/3/07/459	1-{3-[3-(4-chlorophenyl)propoxy]propyl}piperidine, hydrochloride	Lečenje narkolepsije	Bioprojet Pharma	10 Jul 2007	Wakix - EU/1/15/1068 - 04 Apr 2016
EU/3/12/998	Autologous CD34+ cells transfektovane pomoću lentivirusni vektor koji sadrži the Wiskott-Aldrich syndrome protein gen	Lečenje Wiskott-Aldrichovog sindroma	Fondazione Telethon Ets	06 Jun 2012	Waskyra - EU/1/25/1996 - 12 Jan 2026
EU/3/14/1249	Phosphorothioate oligonucleotide targeted to apolipoprotein C-III	Lečenje sindroma porodične hilomikronemije	Akcea Therapeutics Ireland Limited	19 Feb 2014	Waylivra - EU/1/19/1360 - 08 May 2019
EU/3/20/2278	Rilzabrutinib	Lečenje imunske trombocitopenije	Sanofi B.V.	04 Jun 2020	WAYRILZ - EU/1/25/1974 - 23 Dec 2025
EU/3/20/2369	Sotatercept	Lečenje plućne arterijske hipertenzije	Merck Sharp & Dohme B.V.	09 Dec 2020	Winrevair - EU/1/24/1850 - 27 Aug 2024
EU/3/01/056	Rekombinantni humani acid sphingomyelinase	Lečenje Niemann-Pickove bolesti	Sanofi B.V.	19 Sep 2001	Xenpozyme - EU/1/22/1659 - 27 Jun 2022
EU/3/09/661	(S)-ethyl 2-amino-3-(4-(2-amino-6-((R)-1-(4-chloro-2-(3-methyl-1H-pyrazol-1-yl)phenyl)-2,2,2-trifluoroethoxy)pyrimidin-4-yl)phenyl)propanoate	Lečenje karcinoidnog sindroma	Serb	08 Oct 2009	Xermelo - EU/1/17/1224 - 20 Sep 2017
EU/3/19/2183	Mavorixafor	Lečenje WHIM sindroma	Norgine B.V.	25 Jul 2019	Xolremdi - EU/1/26/2017 - 28 Apr 2026
EU/3/17/1961	Gilteritinib	Lečenje akutne mijeloidne leukemije	Astellas Pharma Europe B.V.	17 Jan 2018	Xospata - EU/1/19/1399 - 28 Oct 2019

EU/3/14/1393	Autologne T ćelije transdukovane pomoću retrovirusni vektor encoding an anti-CD19 CD28/CD3 zeta Himerno antigen receptor	Lečenje difuznog B-krupnoćelijskog limfoma	Kite Pharma EU B.V.	16 Dec 2014	Yescarta - EU/1/18/1299 - 27 Aug 2018
EU/3/15/1553	Autologne T ćelije transdukovane pomoću retrovirusni vektor encoding an anti-CD19 CD28/CD3-zeta Himerno antigen receptor	Lečenje primarnog medijastinalnog B-krupnoćelijskog limfoma	Kite Pharma EU B.V.	09 Oct 2015	Yescarta - EU/1/18/1299 - 27 Aug 2018
EU/3/15/1579	Autologne T ćelije transdukovane pomoću retrovirusni vektor encoding an anti-CD19 CD28/CD3-zeta Himerno antigen receptor	Lečenje folikularnog limfoma	Kite Pharma EU B.V.	11 Nov 2015	Yescarta - EU/1/18/1299 - 23 Jun 2022
EU/3/20/2350	Poly(oxy-1,2-ethanediyl), alfa-hydro-omega-methoxy, ether with N-[[[2-[[6-[[1-[3-[[3-(2,3-dihydroxypropoxy)propyl]amino]-3-oxopropyl]-2,5-dioxo-3-pyrrolidinyl]thio]hexyl]amino]ethyl]amino]carbonyl]-2-methylalanyl-teriparatide (2:1)	Lečenje hipoparatireoidizma	Ascendis Pharma Bone Diseases A/S	19 Oct 2020	Yorvipath - EU/1/23/1766 - 20 Nov 2023
EU/3/10/760	(3S)-3-{4-[7-(aminocarbonyl)-2H-indazol-2-yl] phenyl} piperidine tosylate monohydrate salt	Lečenje karcinoma jajnika	GlaxoSmithKline Trading Services Limited	04 Aug 2010	Zejula - EU/1/17/1235 - 20 Nov 2017

EU/3/20/2271	hematopoetske matične ćelije and blood progenitors umbilical cord-izveden expanded with (1R, 4R)-N1-(2-benzyl-7-(2-methyl-2H-tetrazol-5-yl)-9H-pyrimido[4,5-b]indol-4-yl)cyclohexane-1,4-diamine dihydrobromide dihydrate	lečenje pri transplantaciji hematopoetskih matičnih ćelija	Cordex Biologics International Limited	22 Apr 2020	Zemcelpro - EU/1/25/1960 - 26 Aug 2025
EU/3/21/2458	Zanidatamab	Lečenje karcinoma bilijarnog trakta	Jazz Pharmaceuticals Ireland Limited	19 Jul 2021	Ziihera - EU/1/25/1931 - 30 Jun 2025
EU/3/18/2118	Lonafarnib	Lečenje Hutchinson-Gilfordovog sindroma progerije	Integral Pharma Solutions EU Limited	14 Dec 2018	Zokinvy - EU/1/22/1660 - 19 Jul 2022
EU/3/15/1509	Adeno-associated virusni vektor serotype 9 koji sadrži the humani SMN gen	Lečenje spinalne mišićne atrofije	Novartis Europharm Limited	19 Jun 2015	Zolgensma - EU/1/20/1443 - 18 May 2020
EU/3/19/2224	Ganaxolone	Lečenje poremećaja usled nedostatka CDKL5	Immedica Pharma AB	13 Nov 2019	ZTALMY - EU/1/23/1743 - 28 Jul 2023
EU/3/20/2343	Retifanlimab	Lečenje analnog karcinoma	Incyte Biosciences Distribution B.V.	19 Oct 2020	ZYNYZ - EU/1/24/1800 - 06 Mar 2026
EU/3/22/2743	Retifanlimab	Lečenje karcinoma Merkelovih ćelija	Incyte Biosciences Distribution B.V.	13 Jan 2023	ZYNYZ - EU/1/24/1800 - 24 Apr 2024

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