

# 바이오시밀러 허가 및 개발 현황

- 미국, 유럽, 일본, 한국 -

■ 2020년 3월

■ KoBIA 산업정보팀

## < 개 요 >

### 【 바이오시밀러 허가현황 】

오리지널 의약품별 바이오시밀러 허가품목명/개발사/  
미국, 유럽, 일본, 한국 허가연도 현황

### 【 바이오시밀러 개발현황 】

오리지널 주 성분별 적응증 등 제품의 개요, 전세계  
개발 현황 GaBI의 발표 웹페이지 모음

※ GaBI(제네릭 및 바이오시밀러 전문지): Generics and Biosimilars Initiative

# 주요국(미, 유, 일) 및 한국의 바이오시밀러 허가제품 현황 ('20.3 기준)

2020.3., (사)한국바이오의약품협회

자료 : FDA(2020.3), EMA(2020.3), National Institute of Health Sciences Japan(2019.10), 한국바이오의약품협회 추가 조사

주1) 미국 허가연도(\*) 표시(3건) : FD&C Act 505(b)(2) 합성의약품(개량신약)으로 허가 받은 의약품, 주2) 허가연도 괄호 표시 : '20.3 기준 허가상태 '취소/취하'인 제품

오리지널 의약품		바이오시밀러					
성분명	제품명	제품명	개발사	허가연도			
				미국	유럽	일본	한국
somatropin	Genotropin	(유럽) Omnitrope (일본) Somatropin BS S.C. Injection 5 mg [Sandoz] (ソマトロピンBS皮下注「サンド」)	Sandoz	2006*	2006	2009	-
		Valtropin	BioPartners GmbH	-	-	(2006)	-
		싸이트로핀에이카트리지주 (Scitropin A®)	SciGen (한국 수입사 : 싸이젠코리아)	-	-	-	2014
insulin glargine	Lantus	(유럽) Abasaglar (previously Abasria) (일본) Insulin Glargine BS Injection "Lily" (インスリングルガリンBS注「リリー」)	Eli Lilly	-	2014	2014	-
		Lusduna	MSD	-	(2017)	-	-
		Semglee	Mylan	-	2018	-	-
		(미국) Basaglar (한국) 베이사글라카트리지	Eli Lilly (한국 수입사 : 한국릴리)	2016*	-	-	2015
		글라지아프리필드펜(Glargia)	Biocon (한국 수입사 : 녹십자)	-	-	-	2018
insulin lispro	Humalog	(미국) Admelog (유럽) Insulin lispro Sanofi	sanofi-aventis	2017*	2017	-	-
		Insulin Glargine BS Injection "FFP" (インスリングルガリンBS注「FFP」)	Fujifilm Pharma Co., Ltd.	-	-	2016	-
teriparatide	Forsteo	Movymia	Stada Arzneimittel	-	2017	-	-
		(유럽) Terrosa (한국) 테로사카트리지주	Gedeon Richter Plc (한국 수입사 : 대원제약)	-	2017	-	2019
		Teriparatide BS subcutaneous injection "Mochida" (テリバラチドBS皮下注「モチダ」)	Mochida Pharmaceutical Co., Ltd.	-	-	2019	-
epoetin alfa/zeta	Epogen/ Eprex/ Erypo	Binocrit	Sandoz	-	2007	-	-
		Epoetin alfa Hexal	Hexal Biotech	-	2007	-	-
		Abseamed	Medicine Arzneimittel	-	2007	-	-
		Epoetin Alfa BS Injection [JCR] (エポエチン アルファBS注「JCR」)	JCR Pharmaceuticals Co., Ltd.	-	-	2010	-
		(미국, 유럽) Retacrit	Pfizer	2018	2007	-	-
		팬포틴프리필드시린지주	팬젠	-	-	-	2019
darbepoetin alfa	Nesp	Silapo	Stada Arzneimittel	-	2007	-	-
		Darbepoetin Alfa BS Injection "JCR" (ダルベポエチン アルファBS注「JCR」)	JCR Pharmaceuticals Co., Ltd.	-	-	2019	-
		Darbepoetin Alfa BS Injection "Sanwa" (ダルベポエチン アルファBS注「三和」)	Sanwa Kagaku Kenkyusho Co., Ltd.	-	-	2019	-
follitropin alfa	Gonal-f	(한국) 네스벨 (일본) Darbepoetin Alfa BS Injection "MYL" (ダルベポエチン アルファBS注射液「MYL」)	종근당	-	-	2019	2018
		Ovaleap	Theramex Ireland Limited	-	2013	-	-
		Bemfol	Gedeon Richter Plc.	-	2014	-	-

오리지널 의약품		바이오시밀러					
성분명	제품명	제품명	개발사	허가연도			
				미국	유럽	일본	한국
agalsidase beta	Fabrazyme	Agalsidase Beta BS I.V. Infusion "JCR" (アガシダーゼ ベータBS点滴静注「JCR」)	JCR Pharmaceuticals Co., Ltd.	-	-	2018	-
filgrastim	Neupogen	Tevagrastim	Teva Generics	-	2008	-	-
		Biograstim	CT Arzneimittel	-	(2008)	-	-
		Ratiograstim	Ratiopharm	-	2008	-	-
		(미국) Zarxio (유럽) Zarzio (일본) Filgrastim BS Inj. "Sandoz" (フィルグラスチムBS注「サンド」)	Sandoz	2015	2009	2014	-
		Filgrastim Hexal	Hexal Biotech	-	2009	-	-
		Nivestim	Pfizer	-	2010	-	-
		Grastofil	Apotex Europe	-	2013	-	-
		Accofil	Accord	-	2014	-	-
		Nivestym	Pfizer	2018	-	-	-
		Filgrastim ratiopharm	Ratiopharm GmbH		(2008)		
		Filgrastim BS injection "Mochida", "F" (フィルグラスチムBS注「モチダ」, 「F」)	Mochida Pharmaceutical Co., Ltd., Fuji Pharma Co., Ltd.	-	-	2012	-
pegfilgrastim	Neulasta	(미국, 유럽) Fulphila	Mylan	2018	2018	-	-
		Pelmeg	Mundipharma Biologics S.L.	-	2018	-	-
		(미국, 유럽) Ziextenzo	Sandoz	2019	2018	-	-
		Udenyca	Coherus BioSciences	2018	2018	-	-
		Pelgraz	Accord Healthcare	-	2018	-	-
		Grasustek	Juta Pharma	-	2019	-	-
		Cegfila (previously Pegfilgrastim Mundipharma)	Mundipharma Biologics S.L.	-	2019	-	-
infiximab	Remicade	(한국) 램시마주 (미국, 유럽) Inflectra (유럽) Remsima (일본) Infiximab BS for I.V. Infusion "NK", "CTH" (インフリキシマブBS点滴静注「NK」, 「CTH」)	셀트리온	2016	2013	2014	2013
		(한국) 레마로체주 (미국) Renflexis (유럽) Flixabi	삼성바이오에피스	2017	2016	-	2015
		Zessly	Sandoz	-	2018	-	-
		(미국) Ixifi (일본) Infiximab BS for I.V. Infusion (インフリキシマブBS点滴静注「ファイザー」)	Pfizer	2017	-	2018	-
		Infiximab BS for I.V. Infusion "Nichiiko", "AYUMI" (インフリキシマブBS点滴静注「あゆみ」, 「日医工」)	Nichi-Iko Pharmaceutical Co., Ltd., Yakuhan Pharmaceutical Co., Ltd.	-	-	2017	-
		Avsola	Amgen	2019	-	-	-

오리지널 의약품		바이오시밀러					
성분명	제품명	제품명	개발사	허가연도			
				미국	유럽	일본	한국
adalimumab	Humira	(미국) Amjevita (유럽) Amgevita	Amgen	2016	2017	-	-
		Cyltezo	Boehringer Ingelheim	2017	(2017)	-	-
		(한국) 아달로체프리필드시린지주 (미국) Hadlima (유럽) Imraldi	삼성바이오에피스	2019	2017	-	2017
		(미국) Hyrimoz (유럽) Hefiya, Halimatoz, Hyrimoz	Sandoz	2018	2018	-	-
		Hulio	Mylan	-	2018	-	-
		Idacio, Kromeya	Fresenius Kabi	-	2019	-	-
		(미국) Abrilada (유럽) Amsparity	Pfizer	2019	2020	-	-
rituximab	Rituxan/ MabThera	(한국) 트룩시마주 (미국) Truxima (유럽) Truxima, Blitzima, Ritemvia	셀트리온	2018	2017	-	2015 (2016 내수용 전환)
		(유럽) Riximyo, Rixathon (일본) Rituximab BS Intravenous Infusion "KHK" (リツキシマBS点滴静注「KHK」)	Sandoz	-	2017	2017	-
		(미국) Ruxience (일본) Rituximab BS Intravenous Infusion "Pfizer" (リツキシマBS点滴静注「ファイザー」)	Pfizer	2019	-	2019	-
trastuzumab	Herceptin	(한국) 삼페넛주 (미국, 유럽) Ontruzant	삼성바이오에피스	2019	2017	-	2017
		(한국) 허쥬마주 (미국, 유럽) Herzuma (일본) Trastuzumab BS for I.V. Infusion "NK", "CTH" (トラストズマブBS点滴静注用「NK」, 「CTH」),	셀트리온	2018	2018	2018	2014
		(미국, 유럽) Kanjinti (일본) Trastuzumab BS for Intravenous Drip Infusions "Daiichi Sankyo" (トラストズマブBS点滴静注用「第一三共」)	Amgen	2019	2018	2018	-
		(미국, 유럽) Trazimera (일본) Trastuzumab BS for Intravenous Infusion "Pfizer" (トラストズマブBS点滴静注用「ファイザー」)	Pfizer	2019	2018	2018	-
		(미국, 유럽) Ogivri	Mylan	2017	2018	-	-
bevacizumab	Avastin	(미국, 유럽) Mvasi (일본) Bevacizumab BS Intravenous Drip Infusions "Daiichi Sankyo" (ベバシズマブBS点滴静注「第一三共」)	Amgen	2017	2018	2019	-
		(미국, 유럽) Zirabev (일본) Bevacizumab BS Intravenous Infusion "Pfizer" (ベバシズマブBS点滴静注「ファイザー」)	Pfizer	2019	2019	2019	-
etanercept	Enbrel	(한국) 에톨로체프리필드시린지 (미국) Eticovo (유럽) Benepali	삼성바이오에피스	2019	2016	-	2015
		Erelzi	Sandoz	2016	2017	-	-
		(한국) 유셉트 (일본) Etanercept BS S.C. injection, "MA" for subcutaneous injection (エタネルセプトBS皮下注, 皮下注用「MA」)	엘지화학	-	-	2018	2018
		Etanercept BS S.C. injection "TY", "Nichiko" (エタネルセプトBS皮下注「TY」, 「日医工」)	YL Biologics, Kyowa Pharmaceutical Industry	-	-	2019	-
		다빅트렐주사25밀리그램	한화케미칼	-	-	-	(2014)

# 주 성분별 바이오시밀러 개발 정보

2020.3. (사)한국바이오의약품협회

※ 주소를 클릭하면 각 성분별 바이오시밀러 개발 정보를 확인하실 수 있습니다.

자료: GaBI (Generics and Biosimilars Initiative)

연번	성분명	주소	업데이트연월
1	ranibizumab	<a href="http://gabionline.net/Biosimilars/General/Biosimilars-of-ranibizumab">http://gabionline.net/Biosimilars/General/Biosimilars-of-ranibizumab</a>	2019.12.
2	etanercept	<a href="http://gabionline.net/Biosimilars/General/Biosimilars-of-etanercept">http://gabionline.net/Biosimilars/General/Biosimilars-of-etanercept</a>	2019.12.
3	adalimumab	<a href="http://gabionline.net/Biosimilars/General/Biosimilars-of-adalimumab">http://gabionline.net/Biosimilars/General/Biosimilars-of-adalimumab</a>	2019.11.
4	bevacizumab	<a href="http://gabionline.net/Biosimilars/General/Biosimilars-of-bevacizumab">http://gabionline.net/Biosimilars/General/Biosimilars-of-bevacizumab</a>	2019.11.
5	infliximab	<a href="http://gabionline.net/Biosimilars/General/Biosimilars-of-infliximab">http://gabionline.net/Biosimilars/General/Biosimilars-of-infliximab</a>	2019.11.
6	pegfilgrastim	<a href="http://gabionline.net/Biosimilars/General/Biosimilars-of-pegfilgrastim">http://gabionline.net/Biosimilars/General/Biosimilars-of-pegfilgrastim</a>	2019.11.
7	epoetin alfa	<a href="http://gabionline.net/Biosimilars/General/Biosimilars-of-epoetin-alfa">http://gabionline.net/Biosimilars/General/Biosimilars-of-epoetin-alfa</a>	2019.11.
8	somatropin	<a href="http://gabionline.net/Biosimilars/General/Biosimilars-of-somatropin">http://gabionline.net/Biosimilars/General/Biosimilars-of-somatropin</a>	2019.4.
9	pertuzumab	<a href="http://gabionline.net/Biosimilars/General/Biosimilars-of-pertuzumab">http://gabionline.net/Biosimilars/General/Biosimilars-of-pertuzumab</a>	2019.4.
10	darbepoetin alfa	<a href="http://gabionline.net/Biosimilars/General/Biosimilars-of-darbepoetin-alfa">http://gabionline.net/Biosimilars/General/Biosimilars-of-darbepoetin-alfa</a>	2019.2.
11	filgrastim	<a href="http://gabionline.net/Biosimilars/General/Biosimilars-of-filgrastim">http://gabionline.net/Biosimilars/General/Biosimilars-of-filgrastim</a>	2019.1.
12	trastuzumab	<a href="http://gabionline.net/Biosimilars/General/Biosimilars-of-trastuzumab">http://gabionline.net/Biosimilars/General/Biosimilars-of-trastuzumab</a>	2018.7.
13	rituximab	<a href="http://gabionline.net/Biosimilars/General/Biosimilars-of-rituximab">http://gabionline.net/Biosimilars/General/Biosimilars-of-rituximab</a>	2018.7.
14	cetuximab	<a href="http://gabionline.net/Biosimilars/General/Biosimilars-of-cetuximab">http://gabionline.net/Biosimilars/General/Biosimilars-of-cetuximab</a>	2018.4.
15	insulin glargine	<a href="http://gabionline.net/Biosimilars/General/Biosimilars-of-insulin-glargine">http://gabionline.net/Biosimilars/General/Biosimilars-of-insulin-glargine</a>	2018.3.
16	denosumab	<a href="http://gabionline.net/Biosimilars/General/Biosimilars-of-denosumab">http://gabionline.net/Biosimilars/General/Biosimilars-of-denosumab</a>	2018.2.
17	insulin lispro	<a href="http://gabionline.net/Biosimilars/General/Biosimilars-of-insulin-lispro">http://gabionline.net/Biosimilars/General/Biosimilars-of-insulin-lispro</a>	2018.1.
18	teriparatide	<a href="http://gabionline.net/Biosimilars/General/Biosimilars-of-teriparatide">http://gabionline.net/Biosimilars/General/Biosimilars-of-teriparatide</a>	2018.1.
19	palivizumab	<a href="http://gabionline.net/Biosimilars/General/Biosimilars-of-palivizumab">http://gabionline.net/Biosimilars/General/Biosimilars-of-palivizumab</a>	2017.12.
20	abatacept	<a href="http://gabionline.net/Biosimilars/General/Biosimilars-of-abatacept">http://gabionline.net/Biosimilars/General/Biosimilars-of-abatacept</a>	2017.12.
21	omalizumab	<a href="http://gabionline.net/Biosimilars/General/Biosimilars-of-omalizumab">http://gabionline.net/Biosimilars/General/Biosimilars-of-omalizumab</a>	2017.11.
22	eculizumab	<a href="http://gabionline.net/Biosimilars/General/Biosimilars-of-eculizumab">http://gabionline.net/Biosimilars/General/Biosimilars-of-eculizumab</a>	2017.10.
23	pegaspargase	<a href="http://gabionline.net/Biosimilars/General/Biosimilars-of-pegaspargase">http://gabionline.net/Biosimilars/General/Biosimilars-of-pegaspargase</a>	2017.6.
24	abatacept	<a href="http://gabionline.net/Biosimilars/General/Biosimilars-of-abatacept">http://gabionline.net/Biosimilars/General/Biosimilars-of-abatacept</a>	2017.4.
25	certolizumab pegol	<a href="http://gabionline.net/Biosimilars/General/Biosimilars-of-certolizumab-pegol">http://gabionline.net/Biosimilars/General/Biosimilars-of-certolizumab-pegol</a>	2017.4.
26	natalizumab	<a href="http://gabionline.net/Biosimilars/General/Biosimilars-of-natalizumab">http://gabionline.net/Biosimilars/General/Biosimilars-of-natalizumab</a>	2016.11.
27	basiliximab	<a href="http://gabionline.net/Biosimilars/General/Biosimilars-of-basiliximab">http://gabionline.net/Biosimilars/General/Biosimilars-of-basiliximab</a>	2016.8.
28	tocilizumab	<a href="http://gabionline.net/Biosimilars/General/Biosimilars-of-tocilizumab">http://gabionline.net/Biosimilars/General/Biosimilars-of-tocilizumab</a>	2016.7.