

# 국내·외 바이오의약품 허가제품 현황 (2023년 9월)

한국바이오의약품협회, 2023.10.04.

※ 국가별 규제기관(출처)에서 허가된 바이오의약품 목록을 한국바이오의약품협회에서 월간 업데이트하여 제공합니다.

세부 허가사항은 제품별 상세 URL을 참고하시기 바랍니다.

- 출처: 국가별 의약품 규제기관 웹사이트
- 모니터링 기간: 2023.09.01. ~ 2023.09.30.

## ○ 국내 2건 (출처: 식품의약품안전처 의약품통합정보시스템)

제품명	주성분	업체명	허가일	URL
<a href="#">스파이크박스듀오2주(엘라소메란, 다베소메란)(사스코로나바이러스-2 mRNA 백신)</a>	사스코로나바이러스-2 스파이크 단백질 발현 메신저 리보핵산(엘라소메란)(숙주: DIG315, 벡터: PL-022856)/사스코로나바이러스-2 스파이크 단백질 발현 메신저 리보핵산(다베소메란)(숙주: DIG315, 벡터: PL-030872)	모더나코리아(주)	2023-09-27	
<a href="#">하이투스주200단위(클로스트리디움 보툴리눔독소A형)(수출용)</a>	클로스트리디움보툴리눔독소A형	(주)한국비엠아이	2023-09-21	

## ○ 유럽 6건 (출처: EMA)

Product name	Active Substance	Marketing-authorisation holder	Date of authorisation	URL
<a href="#">Tyruko</a>	natalizumab	Sandoz GmbH	2023-09-22	
<a href="#">Yesafili</a>	aflibercept	Viartis Limited	2023-09-15	
<a href="#">Tevimbra</a>	Tislelizumab	Novartis Europharm Limited	2023-09-15	
<a href="#">Tyenne</a>	tocilizumab	Fresenius Kabi Deutschland GmbH	2023-09-15	
<a href="#">Abrysvo</a>	Respiratory syncytial virus, subgroup A, stabilized prefusion F protein / Respiratory syncytial virus, subgroup B, stabilized prefusion F protein	Pfizer Europe MA EEIG	2023-08-23	
<a href="#">Talvey</a>	talquetamab	Janssen-Cilag International N.V.	2023-08-21	

## ○ 일본 12건 (출처: PMDA)

Product name	Active Substance	Marketing-authorisation holder	Date of authorisation	URL
<a href="#">Quintovac Aqueous Suspension Injection</a>	Adsorbed Diphtheria-purified Pertussis-Tetanus-inactivated polio (Sabin strain)-Hib Combined vaccine	KM Biologics Co., Ltd.	2023-09-25	
<a href="#">Rystiggo for S.C. Injection</a>	Rozanolixizumab(Genetical Recombination)	UCB Japan Co. Ltd.	2023-09-25	
<a href="#">Arexvy Intramuscular Injection</a>	Respiratory Syncytial Virus Vaccine Recombinant, Adjuvanted	GSK plc.	2023-09-25	
<a href="#">Ustekinumab BS 45mg Syringe for S.C. injection 「F」</a>	Ustekinumab(Genetical Recombination) [Ustekinumab Biosimilar 1]	FujiPharma	2023-09-25	

○ 일본 12건 (출처: PMDA)				
Product name	Active Substance	Marketing-authorisation holder	Date of authorisation	URL
<a href="#">PHESGO Combination for Subcutaneous Injection</a>	Pertuzumab(Genetical Recombination)	Chugai Pharmaceutical Co., Ltd.	2023-09-25	_____
<a href="#">Alhemo Subcutaneous Injection 15mg</a> <a href="#">Alhemo Subcutaneous Injection 60mg</a> <a href="#">Alhemo Subcutaneous Injection 150mg</a> <a href="#">Alhemo Subcutaneous Injection 300mg</a>	Concizumab(Genetical Recombination)	Novo Nordisk Pharma Ltd.	2023-09-25	_____
<a href="#">LEQEMBI for Intravenous Infusion</a>	Lecanemab(Genetical Recombination)	Eisai Co., Ltd.	2023-09-25	_____
<a href="#">ALTUVIIIO Intravenous 250</a> <a href="#">ALTUVIIIO Intravenous 500</a> <a href="#">ALTUVIIIO Intravenous 1000</a> <a href="#">ALTUVIIIO Intravenous 2000</a> <a href="#">ALTUVIIIO Intravenous 3000</a> <a href="#">ALTUVIIIO Intravenous 4000</a>	Efanesoctocog Alfa(Genetical Recombination)	Sanofi K.K.	2023-09-25	_____
<a href="#">Cuvitru 20% S.C. Injection 2g/10mL</a> <a href="#">Cuvitru 20% S.C. Injection 4g/20mL</a> <a href="#">Cuvitru 20% S.C. Injection 8g/40mL</a>	pH4-Treated Acidic Normal Human Immunoglobulin(Subcutaneous injection)	Takeda Pharmaceutical Co. Ltd.	2023-09-25	_____
<a href="#">EPKINLY Subcutaneous Injection</a>	Epcoritamab(Genetical Recombination)	Genmab K.K.	2023-09-25	_____
<a href="#">①Pegfilgrastim BS Subcutaneous Injection 3.6mg MOCHIDA</a> <a href="#">②Pegfilgrastim BS Subcutaneous Injection 3.6mg NIPRO</a>	Pegfilgrastim(Genetical Recombination)	Nipro Corporation	2023-09-25	_____ _____
<a href="#">Adalimumab BS Subcutaneous Injection 20mg Syringe 0.2mL 「CTNK」</a> <a href="#">Adalimumab BS Subcutaneous Injection 40mg Syringe 0.4mL 「CTNK」</a> <a href="#">Adalimumab BS Subcutaneous Injection 80mg Syringe 0.8mL 「CTNK」</a> <a href="#">Adalimumab BS Subcutaneous Injection 80mg Syringe 0.8mL 「CTNK」</a> <a href="#">Adalimumab BS Subcutaneous Injection 80mg Pen 0.8mL 「CTNK」</a>	Adalimumab(Genetical Recombination)	Nippon Kayaku Co.,Ltd.	2023-09-25	_____