

국내·외 바이오의약품 허가제품 현황 (2024년 1월)

한국바이오의약품협회, 2024.02.05.

※ 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: 2024.01.01. ~ 2024.01.31.

○ 국내 4건 (출처: 식품의약품안전처 의약품통합정보시스템)				
제품명	주성분	업체명	허가일	URL
하이투스주100단위(클로스트리디움 보툴리눔독소A형)	클로스트리디움보툴리눔독소A형	(주)한국비엠아이	2024-01-23	
에피스클리주(에콜리주맙)	에콜리주맙	한성바이오페스(주)	2024-01-19	
싸이쎬그프리필드시린지주 6mg/0.6mL(페그필그라스тім)	페그필그라스тім	싸이젠코리아(주)	2024-01-09	
테라텍트백신주(인플루엔자분할백신)(수출용)	정제불활화인플루엔자바이러스항원A형 [A/Victoria/2570/2019, IVR-215(H1N1)]/정제불활화인플루엔자바이러스항원A형 [A/Darwin/9/2021, SAN-010(H3N2)]/정제불활화인플루엔자바이러스항원B형 [B/California/12/2015, NYMC BX-59B]/정제불활화인플루엔자바이러스항원B형 [B/Austria/1359417/2021, BVR-26]	일양약품(주)	2024-01-04	

○ 미국 1건 (출처: Purple Book)				
Proprietary Name (BLA Number)	Proper Name	Applicant	Approval date	URL
Idacio (BLA761255)	adalimumab-aacf	Fresenius Kabi USA, LLC	2024-01-05	

○ 유럽 4건 (출처: EC)				
Product name	Active Substance	Marketing-authorisation holder	Date of authorisation	URL
Rimmyrah	ranibizumab	QILU PHARMA SPAIN S.L.	2024-01-05	
Rystiggo	rozanolixizumab	UCB Pharma SA	2024-01-05	
Uzpruvo	ustekinumab	STADA Arzneimittel AG	2024-01-05	
Loargys	pegzilarginase	Unmedica Pharma AB	2023-12-15	

○ 일본 6건 (출처: PMDA)				
Product name	Active Substance	Marketing-authorisation holder	Date of authorisation	URL
VYVDURA Combination Subcutaneous Injection	Efgartigimod Alfa(Genetical Recombination), Vorhyaluronidase Alfa(Genetical Recombination)	argenx Japan K.K.	2024-01-18	
EYLEA 8mg solution for IVT inj. 114.3mg/mL	Aflibercept(Genetical Recombination)	Bayer Yakuhin, Ltd	2024-01-18	

○ 일본 6건 (출처: PMDA)

Product name	Active Substance	Marketing-authorisation holder	Date of authorisation	URL
EVKEEZA® for Intravenous Infusion	Evinacumab(genetical recombination)	Ultragenyx Japan Co.	2024-01-18	Evinacumab (EVKEEZA®) for intravenous infusion
Ebglyss® Subcutaneous Injection Autoinjectors Ebglyss® Subcutaneous Injection Syringes	Lebrikizumab(Genetical Recombination)	Eli Lilly Japan K.K.	2024-01-18	Lebrikizumab (Ebglyss®) subcutaneous injection
ABRYVO intramuscular injection	RSV-A prefusion F protein RSV-B prefusion F protein	Pfizer Japan Inc.	2024-01-18	ABRYVO intramuscular injection
Reblozyl for S.C. injection	Luspatercept(Genetical Recombination)	Bristol-Myers Squibb K.K.	2024-01-18	Luspatercept (Reblozyl) subcutaneous injection