

해외 의약품 인허가 현황 (2020.11.23~2020.11.29)

한국바이오횰약품협회, 2020.12.1.

○ 미국 6건 (출처: FDA)

Approval date	Drug name	Active Ingredients	Submission Classification	Company	비고
11/20/2020	ZOKINVY NDA #213969	IONAFARNIB	신물질	EIGER BIOPHARMACEUTICALS INC	
11/23/2020	OXLUMO NDA #214103	LUMASIRAN	신물질	ALNYLAM PHARMS INC	
11/23/2020	XOFLUZA NDA #214410	BALOXAVIR MARBOXIL	신용량	GENENTECH INC	
11/25/2020	MICAFUNGIN SODIUM NDA #212125	MICAFUNGIN SODIUM	신제형 또는 신제조원	TEVA PHARMS USA	
11/25/2020	IMCIVREE NDA #213793	SETMELANOTIDE	신물질	RHYTHM PHARMACEUTICALS INC	
11/25/2020	DANYELZA BLA #761171	NAXITAMAB-GQGK		Y-MABS THERAPEUTICS INC	바이오횰약품

○ 유럽 3건 (출처: EMA)

Approval date	Name	Active Substance	Therapeutic area	Marketing-authorisation holder	비고
19/11/2020	Oxlumo	Lumasiran sodium	Hyperoxaluria, Primary	Alnylam Netherlands B.V.	
18/11/2020	Obiltoxaximab SFL	Obiltoxaximab	Anthrax	SFL Pharmaceuticals Deutschland GmbH	바이오횰약품
18/11/2020	MenQuadfi	<ul style="list-style-type: none"> Neisseria meningitidis group C polysaccharide conjugated to tetanus toxoid Neisseria meningitidis group A polysaccharide conjugated to tetanus toxoid Neisseria meningitidis group Y polysaccharide conjugated to tetanus toxoid Neisseria meningitidis group W-135 polysaccharide conjugated to tetanus toxoid 	Meningitis, Meningococcal	Sanofi Pasteur	바이오횰약품

○ 일본 2건 (출처: PMDA)

승인연월(承認日)	판매명(販売名)	일반명/성분명(成分名)	분야(分野)	업체명(会社名)	비고
2020.11.27	Lasvic Intravenous Drip Infusion Kit 150mg	Lascufloxacin Hydrochloride	항균제, 항바이러스제(항HIV/AIDS 치료제 제외)	KYORIN Pharmaceutical Co., Ltd.	
2020.11.27	Trelegy 200 Ellipta 30 doses 同 200 Ellipta 14 doses	<ul style="list-style-type: none"> Fluticasone Furoate Umeclidinium Bromide Vilanterol Trifenatate 	호흡기 의약품, 항알러지 의약품, 감각기 관 의약품(염증질환의약품에 한함)	GlaxoSmithKline KK	