

## 해외 의약품 인허가 현황 (2021.1.18~2021.1.24)

한국바이오의약품협회, 2021.1.26.

### ○ 미국 4건 (출처: FDA)

Approval date	Drug name	Active Ingredients	Submission Classification	Company	상세 URL	비고
01/19/2021	VERQUVO NDA #214377	VERICIGUAT	신물질	MERCK SHARP DOHME	_____	
01/21/2021	VOCABRIA NDA #212887	CABOTEGRAVIR	신물질	VIIV HLTHCARE	_____	
01/21/2021	CABENUVA NDA #212888	CABOTEGRAVIR;RILPIVIRINE	신물질 및 신복합	VIIV HLTHCARE	_____	
01/22/2021	LUPKYNIS NDA #213716	VOCLOSPORIN	신물질	AURINIA PHARMACEUTICALS, INC.	_____	

### ○ 유럽 3건 (출처: EMA)

Approval date	Drug name	Active substance	Therapeutic area (MeSH)	Marketing-authorisation holder	상세 URL	비고
06/01/2021	COVID-19 Vaccine Moderna	CX-024414 (single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2)	COVID-19 virus infection	Moderna Biotech Spain, S.L.	_____	바이오의약품
07/01/2021	Xofluza	Baloxavir marboxil	Influenza, Human	Roche Registration GmbH	_____	
07/01/2021	Roclanda	• Latanoprost • Netarsudil mesilate	• Glaucoma, Open-Angle • Ocular Hypertension	Aerie Pharmaceuticals Ireland Limited	_____	

### ○ 일본 15건 (출처: PMDA)

판매명(販売名)	일반명/성분명(成分名)	분야(分野)	업체명(会社名)	승인연월(承認日)	상세 URL	비고
2021.1.22	SULPREP	• Anhydrous Sodium Sulfate • Potassium Sulfate • Magnesium Sulfate Hydrate	위장약, 피부과 의약품	NIHON PHARMACEUTICAL CO., LTD.	_____	
2021.1.22	MUSREDO tablets 5mg 同 tablets 12.5mg 同 tablets 25mg 同 tablets 50mg 同 tablets 75mg	Molidustat Sodium	위장약, 피부과 의약품	Bayer Yakuhin, Ltd	_____	
2021.1.22	Sogroya Subcutaneous Injection 5mg 同 Subcutaneous Injection 10mg	Somapacitan (Genetical Recombination)	호르몬 제제, 대사질환약(예. 항당뇨, 골다공증, 통풍, 선천성 대사질환의약품)	Novo Nordisk Pharma Ltd	_____	바이오의약품
2021.1.22	Hunterase Intracerebroventricular Injection 15 mg	Idursulfase Beta (Genetical Recombination)	호르몬 제제, 대사질환약(예. 항당뇨, 골다공증, 통풍, 선천성 대사질환의약품)	Clinigen K.K.	_____	바이오의약품
2021.1.22	Emgality® Subcutaneous Injection Autoinjectors 120mg 同 Subcutaneous Injection Syringe 120mg	Galcanezumab	심혈관약품, 파킨슨병 치료제, 알츠하이머병 치료제	Eli Lilly Japan K.K.	_____	바이오의약품
2021.1.22	①Xarelto dry syrup for pediatric 51.7mg ② 同 dry syrup for pediatric 103.4mg ③ 同 Tablet 15 mg ④ 同 Tablet 10 mg ⑤ 同 Fine-grained sub-package 15 mg ⑥ 同 Fine-grained sub-package 10 mg ⑦ 同 OD Tablet 15 mg ⑧ 同 OD Tablet 10 mg	Rivaroxaban	심혈관약품, 파킨슨병 치료제, 알츠하이머병 치료제	Bayer Yakuhin, Ltd	_____	
2021.1.22	Zymso Intravesical Solution 50%	Dimethyl Sulfoxide	비노생식 및 항문 치료제, 복합제	KYORIN Pharmaceutical Co.,Ltd.	_____	
2021.1.22	Nobelzin Granules 5%	Zinc acetate	위장약, 피부과 의약품	Nobelpharma Co., Ltd.	_____	
2021.1.22	ADLUMIZ Tablets 50mg	Anamorelin Hydrochloride	위장약, 피부과 의약품	Ono Pharmaceutical Co., Ltd.	_____	
2021.1.22	ORLADEYO Capsules 150mg	Berotrastat Hydrochloride	호흡기 의약품, 항알러지 의약품, 감각기관 의약품(염증질환의약품에 한함)	OrphanPacific, Inc.	_____	
2021.1.22	CALQUENCE capsules 100mg	Acalabrutinib	항종양제	AstraZeneca	_____	
2021.1.22	NUWIQ FOR I.V. INJECTION 250 同 FOR I.V. INJECTION 500 同 FOR I.V. INJECTION 1000 同 FOR I.V. INJECTION 2000 同 FOR I.V. INJECTION 2500 同 FOR I.V. INJECTION 3000 同 FOR I.V. INJECTION 4000	Simoctocog Alfa ( Genetical Recombination )	혈액제제	Fujimoto Pharmaceutical Corporation	_____	바이오의약품
2021.1.22	Lynspad for Intravenous Infusion 1000 mg	alpha-1 proteinase inhibitor	혈액제제	Grifols Therapeutics LLC	_____	
2021.1.22	ALUNBRIG Tablets 30mg 同 Tablets 90mg	Brigatinib	항종양제	Takeda Pharmaceutical Company Limited	_____	
2021.1.22	Adalimumab BS Subcutaneous Injection 20mg Syringe 0.4mL [ DAIICHI SANKYO ] 同 Subcutaneous Injection 40mg Syringe 0.8mL [ DAIICHI SANKYO ] 同 Subcutaneous Injection 40mg Pen 0.8mL [ DAIICHI SANKYO ]	Adalimumab	바이오 품질, 바이오시밀러	DAIICHI SANKYO COMPANY, LIMITED	_____	바이오의약품