

해외 의약품 인허가 현황 (2021.1.11~2021.1.17)

한국바이오횰약품협회, 2021.1.19.

○ 미국 1건 (출처: FDA)

Approval date	Drug name	Active Ingredients	Submission Classification	Company	출처 URL	비고
01/15/2021	NOREPINEPHRINE BITARTRATE;DEXTROSE NDA #214313	NOREPINEPHRINE BITARTRATE;DEXTROSE	신제형 또는 신제조원	BAXTER HLTHCARE CORP		

○ 유럽 8건 (출처: EMA)

Approval date	Drug name	Active substance	Therapeutic area (MeSH)	Marketing-authorisation holder	출처 URL	비고
21/12/2020	Phesgo	<ul style="list-style-type: none"> • Pertuzumab • Trastuzumab 	Breast Neoplasms	Roche Registration GmbH		바이오횰약품
18/12/2020	Lenalidomide Mylan	Lenalidomide	Multiple Myeloma	Mylan Ireland Limited		
18/12/2020	Fintepla	Fenfluramine hydrochloride	Epilepsies, Myoclonic	Zogenix ROI Limited		
17/12/2020	Libmeldy	Autologous CD34+ cell enriched population that contains hematopoietic stem and progenitor cells transduced ex vivo using a lentiviral vector encoding the human arylsulfatase A gene	Leukodystrophy, Metachromatic	Orchard Therapeutics (Netherlands) BV		바이오횰약품
17/12/2020	Rekamby	Rilpivirine	HIV Infections	Janssen-Cilag International N.V.		
17/12/2020	Vocabria	<ul style="list-style-type: none"> • Cabotegavir sodium • Cabotegravir 	HIV Infections	ViiV Healthcare B.V.		
09/12/2020	Trixeo Aerosphere	<ul style="list-style-type: none"> • Formoterol fumarate dihydrate • Glycopyrronium bromide • Budesonide 	Pulmonary Disease, Chronic Obstructive	AstraZeneca AB		
09/12/2020	Leqvio	Inclisiran	<ul style="list-style-type: none"> • Hypercholesterolemia • Dyslipidemias 	Novartis Europharm Limited		