

해외 의약품 인허가 현황 (2021.3.8~2021.3.14)

한국바이오의약품협회, 2021.3.16.

○ 미국 1건 (출처: FDA)

Approval date	Drug name	Active Ingredients	Submission Classification	Company	상세 URL	비고
03/10/2021	FOTIVDA NDA #212904	TIVOZANIB	신물질	AVEO PHARMACEUTICALS INC		

○ 유럽 5건 (출처: EMA)

Approval date	Drug name	Active Ingredients	Submission Classification	Company	상세 URL	비고
08/02/2021	Lumoxiti	Moxetumomab pasudotox	Leukemia, Hairy Cell	AstraZeneca AB		바이오의약품
08/02/2021	Inrebic	Fedratinib dihydrochloride monohydrate	<ul style="list-style-type: none"> Myeloproliferative Disorders Primary Myelofibrosis 	Celgene Europe BV		
11/02/2021	Yuflyma	Adalimumab	<ul style="list-style-type: none"> Arthritis, Rheumatoid Spondylitis, Ankylosing Psoriasis Arthritis, Psoriatic Colitis, Ulcerative Crohn Disease Arthritis, Juvenile Rheumatoid Hidradenitis Suppurativa Uveitis 	Celltrion Healthcare Hungary Kft.		바이오의약품
11/02/2021	Ogluo	Glucagon	Diabetes Mellitus	Xeris Pharmaceuticals Ireland Limited		
11/03/2021	COVID-19 Vaccine Janssen	Adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein (Ad26.COV2-S)	COVID-19 virus infection	Janssen-Cilag International NV		바이오의약품