

해외 의약품 인허가 현황 (2021.2.1~2021.2.7)

한국바이오의약품협회, 2021.2.9.

○ 미국 3건 (출처: FDA)

Approval date	Drug name	Active Ingredients	Submission Classification	Company	상세 URL	비고
02/01/2021	POSIMIR NDA #204803	BUPIVACAINE	신용량	DURECT CORP		
02/03/2021	TEPMETKO NDA #214096	TEPOTINIB HYDROCHLORIDE	신물질	EMD SERONO INC		
02/05/2021	UKONIQ NDA #213176	UMBRALISIB	신물질	TG THERAPEUTICS INC		

○ 유럽 1건 (출처: EMA)

Approval date	Drug name	Active substance	Therapeutic area (MeSH)	Marketing-authorisation holder	상세 URL	비고
18/01/2021	Enhertu	Trastuzumab deruxtecan	Breast Neoplasms	Daiichi Sankyo Europe GmbH		바이오의약품