

해외 의약품 인허가 현황 (2020.4.20.~2020.4.26.)

한국바이오의약품협회, 2020.4.28.

○ 미국 4건 (출처: FDA)

Approval date	Drug name	Active Ingredients	Submission Classification	Company	비고
04/17/2020	EMERPHED NDA #213407	EPHEDRINE SULFATE	신제형 또는 신제조원	NEXUS PHARMS	
04/17/2020	PEMAZYRE NDA #213736	PEMIGATINIB	신물질	INCYTE CORP	
04/22/2020	TRODELVY BLA #761115	SACITUZUMAB GOVITECAN-HZIY		IMMUNOMEDICS INC	바이오의약품
04/24/2020	ONGENTYS NDA #212489	OPICAPONE	신물질	NEUROCRINE	

○ 유럽 1건 (출처: EMA)

Approval date	Drug name	Active Ingredients	Therapeutic area	Marketing-authorisation holder	비고
17/04/2020	Tigecycline Accord	Tigecycline	<ul style="list-style-type: none"> • Soft Tissue Infections • Intraabdominal Infections • Bacterial Infections • Skin Diseases, Infectious 	Accord Healthcare S.L.U.	