

해외 의약품 인허가 현황 (2020.5.25.~2020.5.31.)

한국바이오의약품협회, 2020.6.2.

○ 미국 4건 (출처: FDA)

Approval date	Drug name	Active Ingredients	Submission Classification	Company	비고
05/26/2020	VESICARE LS NDA #209529	SOLIFENACIN SUCCINATE	신용량	ASTELLAS	
05/26/2020	ARTESUNATE NDA #213036	ARTESUNATE	신물질	AMIVAS	
05/28/2020	TAUVID NDA #212123	FLORTAUCIPIR F18	신물질	AVID RADIOPHARMS INC	
05/28/2020	ZILXI NDA #213690	MINOCYCLINE	신제형 또는 신제조원	FOAMIX	

○ 유럽 2건 (출처: EMA)

Approval date	Name	Active Substance	Therapeutic area	Marketing-authorisation holder	비고
18/05/2020	Zolgensma	onasemnogene abeparvovec	Muscular Atrophy, Spinal	AveXis EU Limited	바이오의약품
20/05/2020	Zeposia	Ozanimod hydrochloride	Multiple Sclerosis, Relapsing-Remitting	Celgene Europe BV	