

# 해외 의약품 인허가 현황 (2020.8.17.~2020.8.23.)

한국바이오의약품협회, 2020.8.25.

## ○ 미국 2건 (출처: FDA)

Approval date	Drug name	Active Ingredients	Submission Classification	Company	비고
08/19/2020	CYSTADROPS NDA #211302	CYSTEAMINE OPHTHALMIC SOLUTION	신제형 또는 신제조원	RECORDATI RARE	
08/21/2020	PEMETREXED NDA #208419	PEMETREXED		ACTAVIS LLC AN INDIRECT WHOLLY OWNED SUB OF TEVA P	

## ○ 유럽 1건 (출처: EMA)

Approval date	Drug name	Active Ingredients	Therapeutic area	Marketing-authorisation holder	비고
21/08/2020	Kaftrio	lvacaftor / tezacaftor / elexacaftor	Cystic Fibrosis	Vertex Pharmaceuticals (Ireland) Limited	