

해외 의약품 인허가 현황 (2020.12.21~2020.1.3)

한국바이오횰약품협회, 2021.1.5.

○ 미국 4건 (출처: FDA)

Approval date	Drug name	Active Ingredients	Submission Classification	Company	출처 URL	비고
12/23/2020	GEMTESA NDA #213006	VIBEGRON	신물질	UROVANT SCIENCES GMBH		

○ 유럽 1건 (출처: EMA)

Approval date	Name	Active Substance	Therapeutic area	Marketing-authorisation holder	출처 URL	비고
17/12/2020	Comirnaty	Single-stranded, 5'-capped messenger RNA produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2	COVID-19 virus infection	BioNTech Manufacturing GmbH		바이오횰약품