

해외 의약품 인허가 현황 (2020.12.14~2020.12.20)

한국바이오의약품협회, 2020.12.22.

○ 미국 4건 (출처: FDA)

Approval date	Drug name	Active Ingredients	Submission Classification	Company	비고
12/14/2020	KLISYRI NDA #213189	TIRBANIBULIN	신물질	ATHENEX INC	
12/16/2020	MARGENZA BLA #761150	MARGETUXIMAB-CMKB		MACROGENICS INC	바이오의약품
12/17/2020	RIABNI BLA #761140	RITUXIMAB-ARRX		AMGEN INC	바이오의약품
12/18/2020	ORGOVYX NDA #214621	RELUGOLIX	신물질	MYOVANT SCIENCES GMBH	

○ 유럽 1건 (출처: EMA)

Approval date	Name	Active Substance	Therapeutic area	Marketing-authorisation holder	비고
17/12/2020	Palforzia	Defatted powder of Arachis hypogaea L, semen (peanuts)	Peanut Hypersensitivity	Aimmune Therapeutics Ireland Limited	