

해외 의약품 인허가 현황 (2020.7.27.~2020.8.2.)

한국바이오의약품협회, 2020.8.4.

○ 미국 3건 (출처: FDA)

Approval date	Drug name	Active Ingredients	Submission Classification	Company	비고
07/30/2020	CYCLOPHOSPHAMIDE NDA #212501	CYCLOPHOSPHAMIDE	신제형 또는 신제조원	INGENUS PHARMS LLC	
07/30/2020	CARBON DIOXIDE, USP NDA #215007	CARBON DIOIDE		NEXAIR LLC	
07/31/2020	Monjuvi (tafasitamab-cxix) for injection BLA #761163	TAFASITAMAB-CXIX		MORPHOSYS US INC	바이오의약품

○ 유럽 2건 (출처: EMA)

Approval date	Drug name	Active Ingredients	Therapeutic area	Marketing-authorisation holder	비고
27/07/2020	Piqray	Alpelisib	Breast Neoplasms	Novartis Europharm Limited	
27/07/2020	Zercepac	Trastuzumab	<ul style="list-style-type: none"> Breast Neoplasms Stomach Neoplasms 	Accord Healthcare S.L.U.	바이오의약품

○ 일본 1건 (출처: PMDA)

승인연월(承認日)	판매명(販売名)	일반명/성분명(成分名)	분야(分野)	업체명(会社名)	비고
2020.7.21	SILGARD9 Aqueous Suspension for Intramuscular Injection Syringes	MSD K.K.	Recombinant precipitated 9-valent HPV-like particle vaccine (derived from yeast)	백신, 항독소	바이오의약품