

해외 의약품 인허가 현황 (2020.8.3.~2020.8.9.)

한국바이오회약품협회, 2020.8.11.

○ 미국 6건 (출처: FDA)

Approval date	Drug name	Active Ingredients	Submission Classification	Company	비고
08/03/2020	VASOPRESSIN NDA #212593	VASOPRESSIN	이미 시판되고 있는 의약품이나 기존에 NDA로 허가받지 않은 의약품	American Regent, Inc.	
08/04/2020	XTANDI NDA #213674	ENZALUTAMIDE	신제형	ASTELLAS	
08/05/2020	BLINREP BLA #761158	BELANTAMAB MAFODOTIN-BLMF		GLAXOSMITHKLINE	바이오회약품
08/06/2020	LAMPIT NDA #213464	NIFURTIMOX	신물질	BAYER HEALTHCARE PHARMS	
08/07/2020	OLINVYK NDA #210730	OLICERIDINE	신물질	TREVENA INC	
08/07/2020	EVRYSDI NDA #213535	RISDIPLAM	신물질	GENENTECH INC	

○ 유럽 2건 (출처: EMA)

Approval date	Drug name	Active Ingredients	Therapeutic area	Marketing-authorisation holder	비고
27/07/2020	Xenleta	Lefamulin acetate	<ul style="list-style-type: none"> Pneumonia, Bacterial Community-Acquired Infections 	Nabriva Therapeutics Ireland DAC	
23/07/2020	Apixaban Accord	Apixaban	<ul style="list-style-type: none"> Venous Thromboembolism Stroke Arthroplasty 	Accord Healthcare S.L.U.	