

# 해외 의약품 인허가 현황 (2020.7.6.~2020.7.12.)

한국바이오의약품협회, 2020.7.14.

## ○ 미국 4건 (출처: FDA)

Approval date	Drug name	Active Ingredients	Submission Classification	Company	비고
07/06/2020	QWO BLA #761146	COLLAGENASE CLOSTRIDIUM HISTOLYTICUM-AAES		ENDO GLOBAL AESTHETICS LTD	바이오의약품
07/06/2020	HULIO BLA #761154	ADALIMUMAB-FKJP		MYLAN PHARMS INC	바이오의약품
07/07/2020	INQOVI NDA #212576	DECITABINE;CEDAZURIDINE	신물질	ASTEX PHARMACEUTICALS INC	
07/08/2020	UPNEEQ NDA #212520	OXYMETAZOLINE HYDROCHLORIDE		RVL PHARMA INC	

## ○ 유럽 4건 (출처: EMA)

Approval date	Drug name	Active Ingredients	Therapeutic area	Marketing-authorisation holder	비고
26/06/2020	Daurismo	Glasdegib maleate	Leukemia, Myeloid, Acute	Pfizer Europe MA EEIG	
25/06/2020	Reblozyl	Luspatercept	<ul style="list-style-type: none"> <li>Anemia</li> <li>Myelodysplastic Syndromes</li> <li>beta-Thalassemia</li> </ul>	Celgene Europe B.V.	바이오의약품
25/06/2020	Insulin aspart Sanofi	Insulin aspart	Diabetes Mellitus	sanofi-aventis groupe	바이오의약품
18/06/2020	Paliperidone Janssen-Cilag International	Paliperidone palmitate	Schizophrenia	Janssen-Cilag International N.V.	