

## 해외 의약품 인허가 현황 (2020.9.28.~2020.10.4.)

한국바이오의약품협회, 2020.10.6.

### ○ 미국 3건 (출처: FDA)

Approval date	Drug name	Active Ingredients	Submission Classification	Company	비고
09/25/2020	XELJANZ NDA #213082	TOFACITINIB CITRATE	신용량	PFIZER INC	
09/29/2020	ALKINDI SPRINKLE NDA #213876	HYDROCORTISONE	신용량	DIURNAL LTD	
09/29/2020	ATROPINE SULFATE NDA #214652	ATROPINE SULFATE	신제형 또는 신제조원	ACCORD HLTHCARE	

### ○ 유럽 2건 (출처: EMA)

Approval date	Drug name	Active Ingredients	Therapeutic area	Marketing-authorisation holder	비고
24/09/2020	Fampridine Accord	Fampridine	Multiple Sclerosis	Accord Healthcare S.L.U.	
24/09/2020	Ayvakyt	Avapritinib	Gastrointestinal Stromal Tumors	Blueprint Medicines (Netherlands) B.V.	