

## 해외 의약품 인허가 현황 (2020.11.9~2020.11.15)

한국바이오횰약품협회, 2020.11.17.

### ○ 미국 2건 (출처: FDA)

Approval date	Drug name	Active Ingredients	Submission Classification	Company	비고
11/09/2020	LABETALOL HYDROCHLORIDE IN DEXTROSE NDA #213330	LABETALOL HYDROCHLORIDE	신제형 또는 신제조원	Hikma Pharmaceuticals International Limited	
11/10/2020	SUTAB NDA #213135	SODIUM SULFATE;MAGNESIUM SULFATE;POTASSIUM	신제형	BRAINTREE LABS	

### ○ 유럽 1건 (출처: EMA)

Approval date	Name	Active Substance	Therapeutic area	Marketing-authorisation holder	비고
05/11/2020	Calquence	Acalabrutinib	Leukemia, Lymphocytic, Chronic, B-Cell	AstraZeneca AB	