

# 해외 의약품 인허가 현황 (2020.10.26.~2020.11.01.)

한국바이오횰약품협회, 2020.11.03.

## ○ 미국 2건 (출처: FDA)

Approval date	Drug name	Active Ingredients	Submission Classification	Company	비고
10/26/2020	EYSUVIS NDA #210933	LOTEPREDNOL ETABONATE	새로운 적응증으로 별개의 NDA 제출- 통합되지않음	KALA PHARMS INC	
10/30/2020	BRONCHITOL NDA #202049	MANNITOL	새로운 적응증으로 별개의 NDA 제출- 통합되지않음	CHIESI USA INC	

## ○ 유럽 2건 (출처: EMA)

Approval date	Drug name	Active Ingredients	Therapeutic area	Marketing-authorisation holder	비고
24/09/2020	Equidacent	Bevacizumab	<ul style="list-style-type: none"> <li>• Colorectal Neoplasms</li> <li>• Breast Neoplasms</li> <li>• Ovarian Neoplasms</li> <li>• Carcinoma, Non-Small-Cell Lung</li> <li>• Carcinoma, Renal Cell</li> </ul>	Centus Biotherapeutics Europe Limited	바이오횰약품
24/09/2020	Zynrelef	Bupivacaine Meloxicam	Pain, Postoperative	Heron Therapeutics, B.V.	