

# 해외 의약품 인허가 현황 (2020.4.27.~2020.5.3.)

한국바이오의약품협회, 2020.5.6

## ○ 미국 5건 (출처: FDA)

Approval date	Drug name	Active Ingredients	Submission Classification	Company	비고
04/28/2020	MONOMETHYL FUMARATE NDA #210296	MONOMETHYL FUMARATE		BANNER LIFE SCIENCES LLC	
04/29/2020	MILPROSA NDA #201110	PROGESTERONE	신용량	Ferring Pharmaceuticals, Inc.	
05/01/2020	FENSOLVI NDA #213150	LEUPROLIDE ACETATE	새로운 적응증으로 별개의 NDA 제출- 통합되지않음	TOLMAR	
05/01/2020	DARZALEX FASPRO BLA #761145	DARATUMUMAB;HYALURONIDASE-FIHJ		JANSSEN BIOTECH	바이오의약품
05/05/2020	ELYXYB NDA #212157	CELECOXIB	신용량	DR REDDYS LABS LTD	

## ○ 유럽 1건 (출처: EMA)

Approval date	Drug name	Active Ingredients	Therapeutic area	Marketing-authorisation holder	비고
23/04/2020	Fetcroja	Cefiderocol sulfate tosilate	Gram-Negative Bacterial Infections	Shionogi B.V.	