

## 해외 의약품 인허가 현황 (2021.2.15~2021.2.21)

한국바이오횰약품협회, 2021.2.23.

### ○ 미국 3건 (출처: FDA)

Approval date	Drug name	Active Ingredients	Submission Classification	Company	상세 URL	비고
02/11/2021	EVKEEZA BLA #761181	EVINACUMAB-DGNB		REGENERON PHARMACEUTICALS		바이오횰약품
02/12/2021	COSELA NDA #214200	TRILACICLIB DIHYDROCHLORIDE	신물질	G1 THERAPEUTICS INC		
02/18/2021	ACETAMINOPHEN NDA #204957	ACETAMINOPHEN	신제형 또는 신제조원	B BRAUN MEDICAL INC		

### ○ 유럽 5건 (출처: EMA)

Approval date	Drug name	Active substance	Therapeutic area (MeSH)	Marketing-authorisation holder	상세 URL	비고
29/01/2021	COVID-19 Vaccine AstraZeneca	Chimpanzee Adenovirus encoding the SARS CoV 2 Spike glycoprotein (ChAdOx1-S)	COVID-19 virus infection	AstraZeneca AB		바이오횰약품
11/02/2021	Tukysa	Tucatinib	<ul style="list-style-type: none"> <li>Breast Neoplasms</li> <li>Neoplasm Metastasis</li> </ul>	Seagen B.V.		
11/02/2021	Lenalidomide Krka	Lenalidomide hydrochloride monohydrate	<ul style="list-style-type: none"> <li>Multiple Myeloma</li> <li>Lymphoma, Follicular</li> </ul>	Krka, d.d., Novo mesto		
11/02/2021	Lenalidomide Krka d.d. Novo mesto	Lenalidomide hydrochloride monohydrate	<ul style="list-style-type: none"> <li>Multiple Myeloma</li> <li>Myelodysplastic Syndromes</li> <li>Lymphoma, Follicular</li> <li>Lymphoma, Mantle-Cell</li> </ul>	Krka, d.d., Novo mesto		
11/02/2021	Lenalidomide Krka d.d.	Lenalidomide hydrochloride hydrate	<ul style="list-style-type: none"> <li>Multiple Myeloma</li> <li>Lymphoma, Follicular</li> <li>Myelodysplastic Syndromes</li> </ul>	Krka, d.d., Novo mesto		