

## 해외 의약품 인허가 현황 (2020.6.1.~2020.6.7.)

한국바이오의약품협회, 2020.6.9.

### ○ 미국 2건 (출처: FDA)

Approval date	Drug name	Active Ingredients	Submission Classification	Company	비고
05/29/2020	ARTESUNATE NDA #213170	ARTESUNATE	신물질	LA JOLLA PHARMA	
05/29/2020	ORIAHNN (COPACKAGED) NDA #213388	ELAGOLIX SODIUM, ESTRADIOL, NORETHINDRONE ACETATE; ELAGOLIX SODIUM	신복합	ABBVIE INC	

### ○ 유럽 2건 (출처: EMA)

Approval date	Name	Active Substance	Therapeutic area	Marketing-authorisation holder	비고
20/05/2020	Fluad Tetra	Influenza virus surface antigens (haemagglutinin and neuraminidase), inactivated, of the following strains: A/(H1N1)-like virus antigen / A/(H3N2)-like virus antigen / B (victoria lineage)-like virus antigen B (yamagata lineage)-like virus antigen	Influenza, Human	Seqirus Netherlands B.V.	바이오의약품
20/05/2020	Nepexto	Etanercept	<ul style="list-style-type: none"> <li>• Arthritis, Rheumatoid</li> <li>• Arthritis, Juvenile Rheumatoid</li> <li>• Arthritis, Psoriatic</li> <li>• Spondylarthropathies</li> <li>• Spondylitis, Ankylosing</li> <li>• Psoriasis</li> </ul>	Mylan IRE Healthcare Limited	바이오의약품