

## 해외 의약품 인허가 현황 (2020.1.21~2020.1.26)

한국바이오의약품협회, 2020.1.28.

### ○ 미국 2건 (출처: FDA)

| Approval date | Drug name           | Active Ingredients | Submission Classification | Company                      | 비고     |
|---------------|---------------------|--------------------|---------------------------|------------------------------|--------|
| 01/21/2020    | TEPEZZABLA #761143  | TEPROTUMUMAB-TRBW  |                           | HORIZON THERAPEUTICS IRELAND | 바이오의약품 |
| 01/23/2020    | TAZVERIKNDA #211723 | TAZEMETOSTAT       | 신물질                       | EPIZYME INC                  |        |

### ○ 유럽 3건 (출처: EMA)

| Approval date | Drug name                                   | Active Ingredients   | Therapeutic area   | Marketing-authorisation holder | 비고     |
|---------------|---|--|--|--------------------------------|--------|
| 09/01/2020    | Clopidogrel / Acetylsalicylic acid<br>Mylan | <ul style="list-style-type: none"> <li>Acetylsalicylic acid</li> <li>Clopidogrel hydrogen sulfate</li> </ul> | <ul style="list-style-type: none"> <li>Acute Coronary Syndrome</li> <li>Myocardial Infarction</li> </ul> | Mylan S.A.S.                   |        |
| 13/01/2020    | Mayzent                                     | Siponimod fumaric acid   | Multiple Sclerosis, Relapsing-Remitting  | Novartis Europharm Limited     |        |
| 16/01/2020    | Polivy                                      | Polatuzumab vedotin  | Lymphoma, B-Cell   | Roche Registration GmbH        | 바이오의약품 |