



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

28 September 2018  
EMA/674542/2018 - corr  
Information Management Division

## Applications for new human medicines under evaluation by the Committee for Medicinal Products for Human Use October 2018

This document lists information on applications for centralised marketing authorisation for human medicines that the European Medicines Agency has received for evaluation. It includes the international non-proprietary names (INN) and therapeutic areas for all new innovative medicines under evaluation by the Committee for Medicinal Products for Human Use (CHMP). For generic and biosimilar medicines, it includes the INN (active moiety only, with no information on salt, ester or derivative) and therapeutic area.

This list only includes information for medicines whose applications have been validated at the time the report was compiled. The information in this report was compiled on 28 September 2018.

Information on designated orphan medicines that are being assessed for marketing authorisation is also available in the monthly reports of the Committee for Orphan Medicinal Products (COMP).

Information in bold corresponds to new entries in the monthly list.

Entries are removed from this list once the medicine has received a positive or negative opinion from the CHMP or when the applicant has withdrawn the application. The Agency publishes information on these opinions and withdrawn applications on its website.

Information on CHMP opinions is also published in the monthly CHMP highlights.



## Non-orphan medicinal products

| International non-proprietary name<br>(salt, ester, derivative, etc.) / Common<br>Name | Therapeutic area <sup>i</sup>                    |
|--|--|
| Andexanet alfa   | Other therapeutic medicines                      |
| Angiotensin II (acetate)   | Medicines acting on the renin-angiotensin system |
| Apalutamide  | Endocrine therapy                                |
| Avatrombopag (maleate)   | Antihemorrhagics                                 |
| Botulinum toxin type A   | Muscle relaxants                                 |
| Buprenorphine (hydrochloride)  | Other nervous system medicines                   |
| Canakinumab*   | Immunosuppressants                               |
| Cemiplimab   | Antineoplastic medicines                         |
| Ciprofloxacin  | Antibacterials for systemic use                  |
| Crisaborole  | Other dermatological medicines                   |
| Dacomitinib (monohydrate)  | Antineoplastic medicines                         |
| Dapagliflozin<br>(propanediol)/saxagliptin/metformin<br>(hydrochloride)                | Medicines used in diabetes                       |
| Delafloxacin (meglumine)   | Antibacterials for systemic use                  |
| Dengue tetravalent vaccine (live,<br>attenuated)                                       | Vaccines   |
| Fremanezumab   | Analgesics                                       |
| Glucagon   | Pancreatic hormones                              |
| Glycopyrronium / formoterol (fumarate<br>dihydrate)                                    | Medicines for obstructive airway diseases        |
| Ibalizumab <sup>ii</sup>   | Antivirals for systemic use                      |
| Influenza vaccine surface antigen inactivated<br>prepared in cell cultures             | Vaccines   |
| Levodopa   | Anti-parkinson medicines                         |
| L-lysine (hydrochloride) / L-arginine<br>(hydrochloride)                               | Urologicals                                      |
| Lorlatinib   | Antineoplastic medicines                         |
| Lusutrombopag  | Antihemorrhagics                                 |
| Macimorelin (acetate)  | Diagnostic medicines                             |
| Naldemedine (tosilate)   | Medicines for constipation                       |
| Risankizumab   | Immunosuppressants                               |
| Romosozumab  | Medicines for bone diseases                      |

| International non-proprietary name<br>(salt, ester, derivative, etc.) / Common<br>Name | Therapeutic area <sup>i</sup>  |
|--|--------------------------------|
| Sodium oxybate <sup>ii</sup>   | Other nervous system medicines |
| Sotagliflozin  | Medicines used in diabetes     |
| Talazoparib  | Antineoplastic medicines       |
| Zanamivir  | Antivirals for systemic use    |

<sup>i</sup> Based on the ATC therapeutic sub-group.

<sup>ii</sup> Application being reviewed under EMA's accelerated assessment programme.

\* Canakinumab was reported before, but omitted in the Aug and Sep reports. Now the evaluation has resumed.

## Non-orphan generic and biosimilar medicinal products

| International non-proprietary name /<br>Common Name | Therapeutic area <sup>i</sup>                     | Total number of<br>applications |
|---|---|---------------------------------|
| Adalimumab  | Immunosuppressants                                | 2                               |
| Ambrisentan   | Antihypertensives                                 | 2                               |
| Atazanavir  | Antivirals for systemic use                       | 1                               |
| Bevacizumab   | Antineoplastic medicines                          | 1                               |
| Cabazitaxel   | Antineoplastic medicines                          | 1                               |
| Deferasirox   | Other therapeutic<br>medicines                    | 1                               |
| Doxorubicin   | Antineoplastic medicines                          | 1                               |
| Erlotinib   | Antineoplastic medicines                          | 1                               |
| Etanercept  | Immunosuppressants                                | 1                               |
| Febuxostat  | Antigout medicines                                | 1                               |
| Hydroxycarbamide                                    | Antineoplastic medicines                          | 1                               |
| Ioflupane (123I)                                    | Diagnostic<br>radiopharmaceuticals                | 1                               |
| Miglustat   | Other alimentary tract and<br>metabolism products | 1                               |
| Paclitaxel  | Antineoplastic medicines                          | 1                               |
| Pegfilgrastim                                       | Immunostimulants                                  | 3                               |
| Posaconazole  | Antimycotics for systemic<br>use                  | 1                               |
| Rituximab   | Antineoplastic medicines                          | 2                               |
| Silodosin   | Urologicals                                       | 1                               |
| Tigecycline   | Antibacterials for systemic<br>use                | 1                               |

| International non-proprietary name / Common Name | Therapeutic area <sup>i</sup>   | Total number of applications |
|--|---------------------------------|------------------------------|
| Tobramycin                                       | Antibacterials for systemic use | 1                            |
| Trastuzumab                                      | Antineoplastic medicines        | 1                            |

<sup>i</sup> Based on the ATC therapeutic sub-group.

## Orphan medicinal products

| International non-proprietary name (salt, ester, derivative, etc.) / Common Name | Therapeutic area <sup>i</sup>                                |
|--|--|
| Avacopan   | Immunosuppressants   |
| Cannabidiol  | Antiepileptics   |
| Edaravone  | Other nervous system medicines                               |
| Emapalumab <sup>**</sup>   | Immunosuppressants   |
| Enasidenib (mesylate)  | Antineoplastic medicines                                     |
| Entolimod  | Immunostimulants   |
| Glutamine  | Other alimentary tract and metabolism products               |
| Lanadelumab <sup>ii</sup>  | Other hematological medicines                                |
| Larotrectinib (sulfate) <sup>ii</sup>  | Antineoplastic medicines                                     |
| Mexiletine (hcl)   | Other medicines for disorders of the musculo-skeletal system |
| Pacritinib (citrate)   | Antineoplastic medicines                                     |
| Pegvaliase   | Other alimentary tract and metabolism products               |
| Ravulizumab  | Immunosuppressants   |
| Ropeginterferon alfa-2b  | Immunostimulants   |
| Treosulfan   | Antineoplastic medicines                                     |
| Trientine (dihydrochloride)  | Other alimentary tract and metabolism products               |
| Turoctocog alfa pegol  | Antihemorrhagics   |
| Viable T-cells   | Antineoplastic and immunomodulating agents                   |
| Volanesorsen (sodium)  | Lipid modifying medicines                                    |

<sup>i</sup> Based on the ATC therapeutic sub-group.

<sup>ii</sup> Application being reviewed under EMA's accelerated assessment programme.

<sup>\*\*</sup> Emapalumab was by mistake reported as being reviewed under EMA's accelerated assessment programme in the first version of this October report.