Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 12-15 December 2022

During its December 2022 meeting, the CHMP reviewed 4 recommendations for eligibility to PRIME: 2 were granted and 2 were denied. The individual outcomes adopted this month are listed below.
Eligibility granted

<table>
<thead>
<tr>
<th>Name*</th>
<th>Substance type</th>
<th>Therapeutic area</th>
<th>Therapeutic indication</th>
<th>Type of data supporting request</th>
<th>Type of applicant</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMB-05X</td>
<td>Biological Medicinal Product</td>
<td>Oncology</td>
<td>Tenosynovial giant cell tumour</td>
<td>Nonclinical + Clinical exploratory</td>
<td>SME</td>
</tr>
<tr>
<td>FBX-101</td>
<td>Advanced Therapy Medicinal Product</td>
<td>Neurology</td>
<td>Krabbe disease/Globoid Cell Leukodystrophy</td>
<td>Nonclinical + Tolerability first in man</td>
<td>SME</td>
</tr>
</tbody>
</table>

* Name of the active substance, INN, common name, chemical name or company code.

SME applicants are micro-, small- and medium-sized-enterprises registered with the Agency’s SME office. Other types of applicants are those not qualifying or not registered as SME or not fulfilling the definition of academic sponsors.

Product(s) in italic have been granted eligibility to the scheme at early stages of development (proof of principle/proof of mechanism).
### Eligibility denied

<table>
<thead>
<tr>
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<th>Therapeutic indication</th>
<th>Type of data supporting request</th>
<th>Type of applicant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advanced Therapy</td>
<td>Endocrinology-Gynaecology-Fertility-Metabolism</td>
<td>Treatment of propionic acidaemia</td>
<td>Nonclinical + Clinical exploratory</td>
<td>Other</td>
</tr>
<tr>
<td>Medicinal Product</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Advanced Therapy</td>
<td>Central and Peripheral Nervous systems</td>
<td>Treatment of Giant Axonal Neuropathy (GAN)</td>
<td>Nonclinical + Clinical exploratory</td>
<td>Other</td>
</tr>
<tr>
<td>Medicinal Product</td>
<td></td>
<td></td>
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</tr>
</tbody>
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Cumulative overview of PRIME eligibility recommendations adopted by 15 December 2022

Overall number

- 25% Granted
- 71% Denied
- 3% Out of scope*
- 1% Withdrawn

By therapeutic area

- Oncology: 31 Granted, 46 Out of scope*
- Neurology: 11 Granted, 22 Denied, 46 Out of scope*
- Infectious diseases: 7 Granted, 22 Denied
- Endocrinology-Gynaecology-Fertility-Metabolism: 11 Granted, 28 Denied
- Haematology-haemostasesiology: 10 Granted, 13 Denied
- Cardiovascular diseases: 2 Granted
- Immunology-rheumatology-transplantation: 6 Granted, 17 Denied
- Pneumology-allergology: 12 Granted
- Gastroenterology-Hepatology: 10 Granted
- Dermatology: 12 Granted
- Ophthalmology: 11 Granted
- Vaccines: 8 Granted
- Uro-nephrology: 6 Granted
- Other: 2 Granted
- Psychiatry: 2 Granted
- Neonatology-paediatric intensive care: 2
- Diagnostic: 2
- Musculo-skeletal system: 3
- Oto-rhino-laryngology: 1

By Applicant Type

- SME: 46 Granted, 184 Denied
- Other: 64 Granted, 121 Denied
- Academic: 6 Granted

* This indicates eligibility requests received but not started by EMA as they were deemed outside the scope of the scheme or with a format and content inadequate to support their review. These are not included in the breakdown by type of applicant or by therapeutic area.