



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

21 December 2022  
EMA/68007/2022  
Press office

## 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.

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**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands  
**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)  
**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact) **Telephone** +31 (0)88 781 6000

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## Eligibility granted

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

\* 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).*

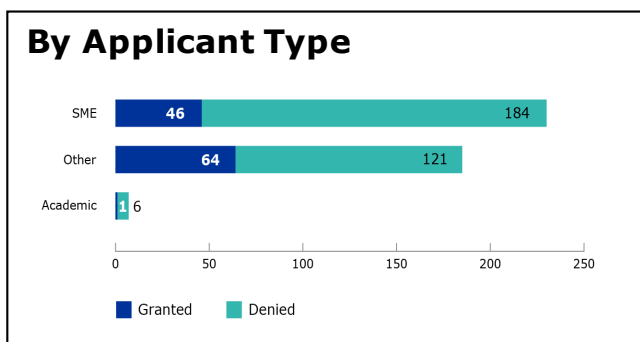
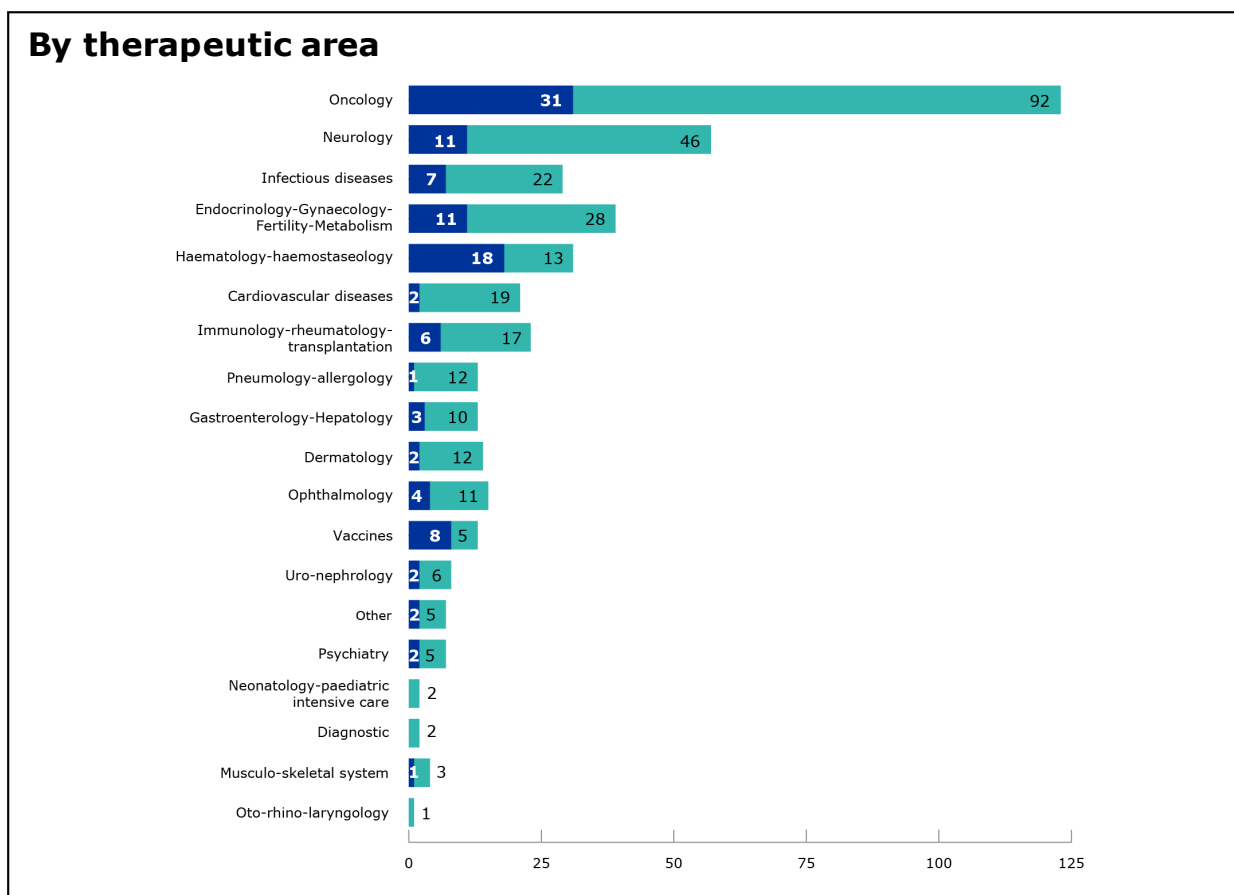
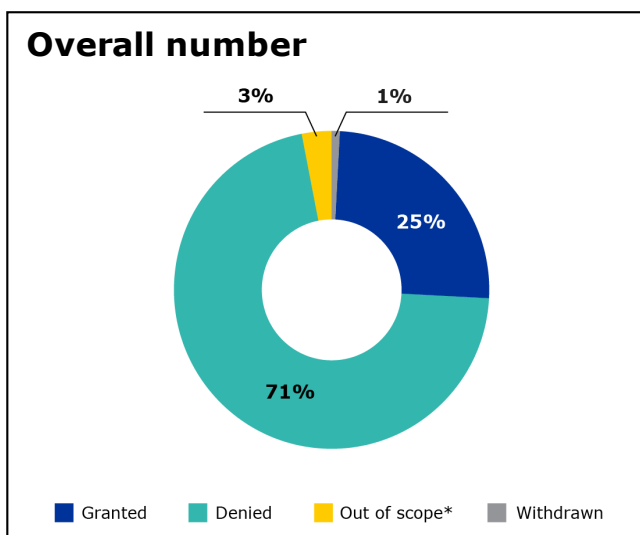
## Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Advanced Therapy Medicinal Product	Endocrinology- Gynaecology-Fertility- Metabolism	Treatment of propionic acidaemia	Nonclinical + Clinical exploratory	Other
Advanced Therapy Medicinal Product	Central and Peripheral Nervous systems	Treatment of Giant Axonal Neuropathy (GAN)	Nonclinical + Clinical exploratory	Other

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## Cumulative overview of PRIME eligibility recommendations adopted by 15 December 2022

■ Granted ■ Denied ■ Out of scope\* ■ Withdrawn



\* 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.