21 September
EMA/68000/2022
Press office

# Recommendations on eligibility to PRIME scheme

## Adopted at the CHMP meeting of 12-15 September 2022

During its September meeting, the CHMP reviewed 6 recommendations for eligibility to PRIME: 2 were granted and 4 were denied. The individual outcomes adopted this month are listed below.

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## Eligibility granted

| Name* | Substance type | Therapeutic area | Therapeutic indication | Type of data supporting request | Type of applicant |
|---|---|---|---|---|---|
| DTX401 | Advanced Therapy Medicinal Product | Endocrinology-Gynaecology-Fertility-Metabolism | Treatment of glycogen storage disease type Ia (GSDIa, von Gierke disease) | Nonclinical + Clinical exploratory | Other |
| GBS-NN/NN2 vaccine | Immunological Medicinal Product | Infectious Diseases | Prevention of Group B streptococcal invasive disease in infants by active immunization of pregnant women | Nonclinical + Clinical exploratory | SME |

* 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.

## Eligibility denied

| Substance type | Therapeutic area | Therapeutic indication | Type of data supporting request | Type of applicant |
|---|---|---|---|---|
| Chemical Medicinal Product | Cardiovascular Diseases | Treatment of Acute Ischemic Stroke (AIS) | Nonclinical + Tolerability first in man | SME |
| Chemical Medicinal Product | Neurology | Halting or slowing down the progression of ataxic dysphagia in patients 2 years of age and older with Niemann Pick disease type C | Nonclinical + Tolerability first in man | SME |
| Chemical Medicinal Product | Neurology | Slowing down the loss of ambulation and speech in symptomatic paediatric patients 2 years of age and older with late infantile or juvenile types of GM1 or GM2 gangliosidosis. | Nonclinical + Tolerability first in man | SME |
| Advanced Therapy Medicinal Product | Oncology | Treatment of metastatic melanoma | Nonclinical + Clinical exploratory | Academic sector |

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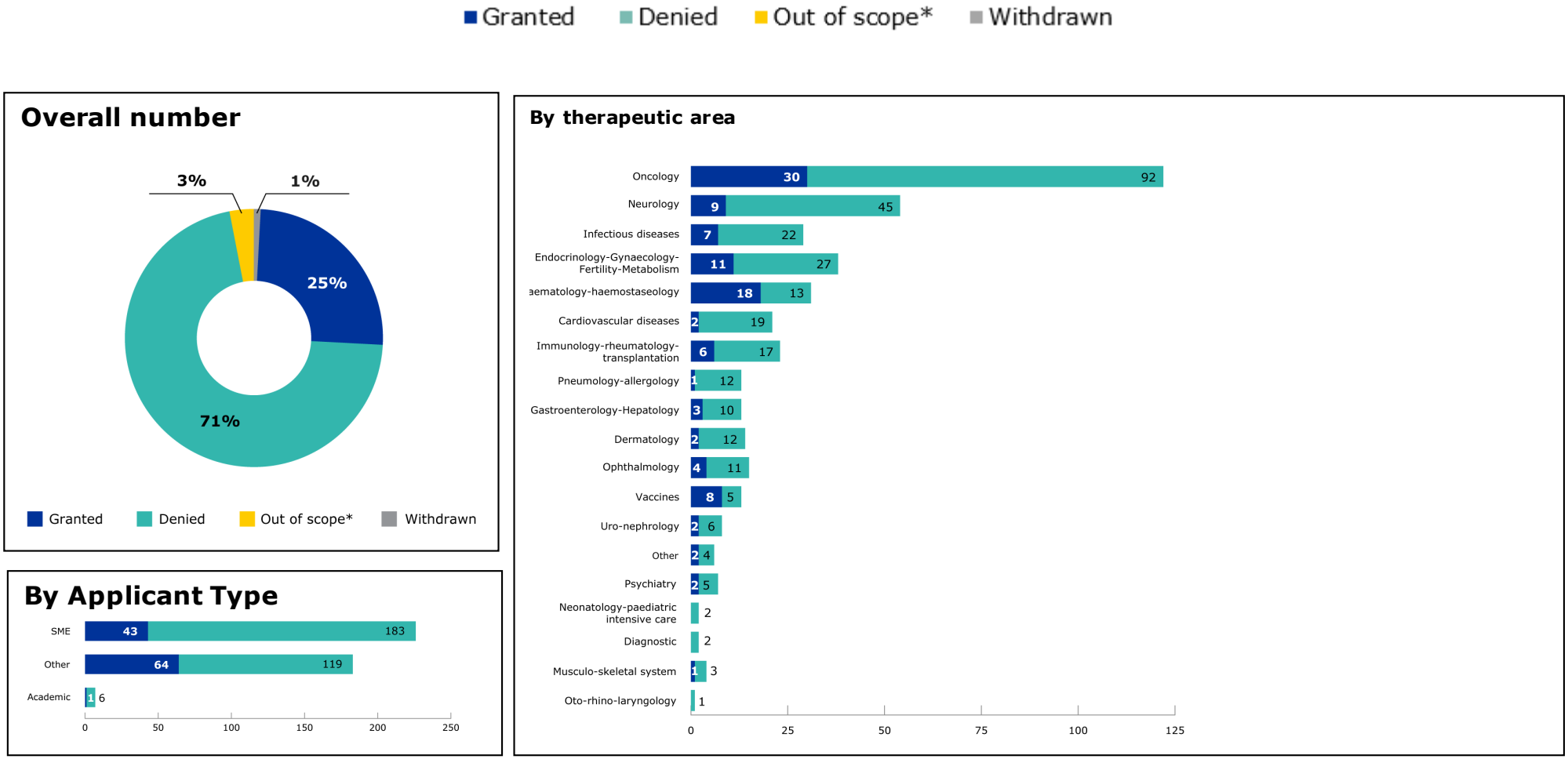
# Cumulative overview of PRIME eligibility recommendations adopted by 15 September 2022




* 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.