



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 May 2020
EMA/65740/2020
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 28-30 April 2020

During its April 2020 meeting, the CHMP reviewed 9 recommendations for eligibility to PRIME: 1 was granted and 8 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
Sotatercept	Biological	Cardiovascular diseases	Treatment of pulmonary arterial hypertension (PAH)	Nonclinical+ Clinical exploratory	SME

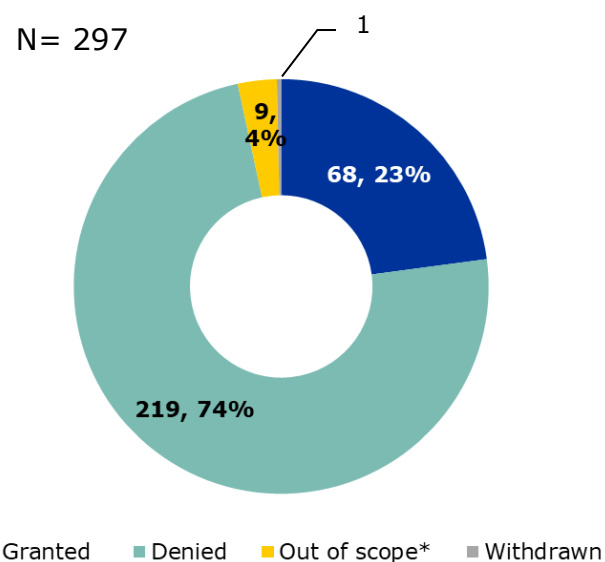
SME applicants are micro-, small-and medium-sized-enterprises registered with the Agency's SME office. Other type of applicants are those not qualifying or not registered as SME or not fulfilling the definition of academic sponsors.

Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Advanced Therapy	Dermatology	Treatment of autosomal recessive congenital ichthyosis	Nonclinical+ Clinical exploratory	SME
Advanced Therapy	Endocrinology-Gynaecology-Fertility-Metabolism	Treatment of mucopolysaccharidosis type II (Hunter's syndrome)	Nonclinical+ Clinical exploratory	SME
Advanced Therapy	Endocrinology-Gynaecology-Fertility-Metabolism	Treatment of mucopolysaccharidosis type IIIB (Sanfilippo B syndrome)	Nonclinical+ Clinical exploratory	SME
Advanced Therapy	Ophthalmology	Treatment of retinal dystrophy associated with defects in RPE65 (LCA2)	Nonclinical+ Clinical exploratory	Other
Chemical	Immunology-Rheumatology-Transplantation	Treatment of patients with WHIM syndrome	Nonclinical+ Clinical exploratory	SME
Chemical	Neurology	Treatment of Amyotrophic Lateral Sclerosis	Nonclinical+ Clinical exploratory	SME
Chemical	Oncology	Treatment of patients with intermediate-2 or high-risk myelofibrosis including primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis	Nonclinical+ Clinical exploratory	SME
Chemical	Oncology	Treatment of patients with advanced or metastatic (Stage IIIB/IV) non-small cell lung cancer (NSCLC) harbouring MET exon 14 skipping alterations	Nonclinical+ Clinical exploratory	Other

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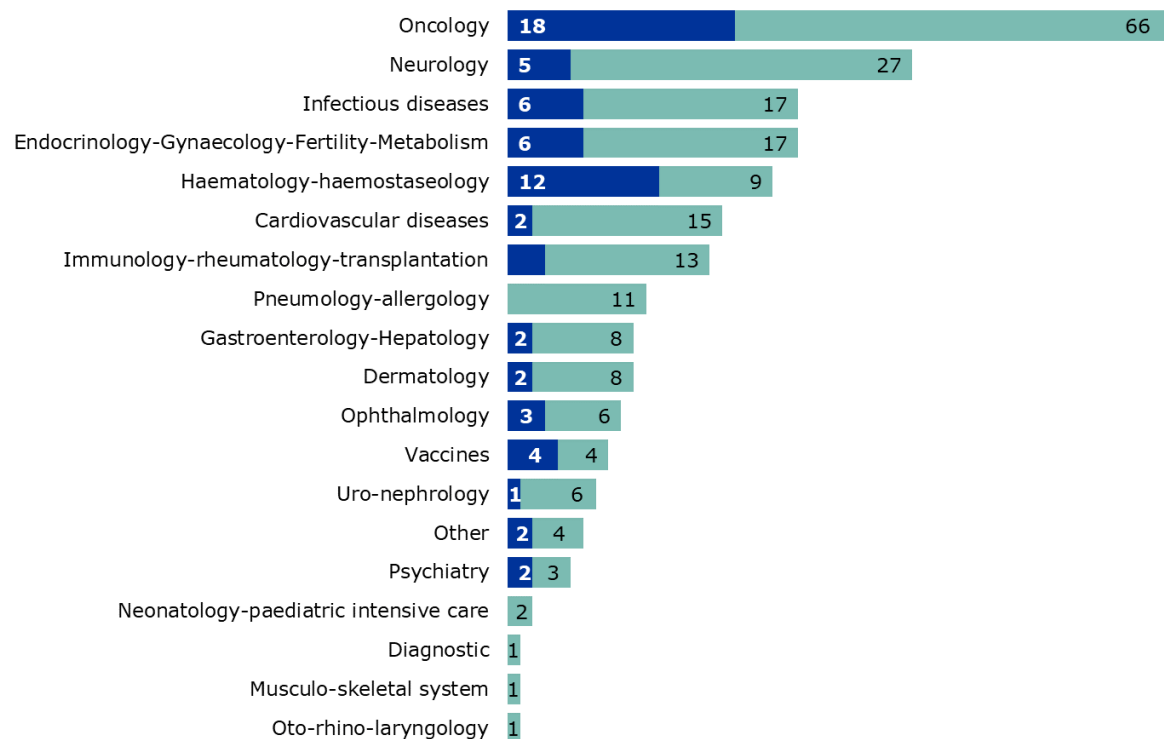
Cumulative overview of recommendations on PRIME eligibility requests adopted by 30 April 2020



By type of applicant



By therapeutic area



■ Granted ■ Denied

* 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.