

21 October 2020 EMA/363072/2020 Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 15 October 2020

During its October 2020 meeting, the CHMP reviewed eight recommendations for eligibility to PRIME: four were granted, three were denied, and one is currently under consideration.

The individual outcomes adopted this month are listed below.



Eligibility granted

Name*	Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
VLA1553	Immunological Medicinal Product	Vaccines	Prophylaxis against Chikungunya disease	Nonclinical+ Clinical exploratory	Other
PF-06823859	Biological Medicinal Product	Immunology- Rheumatology- Transplantation	Treatment of Dermatomyositis	Nonclinical+ Clinical exploratory	Other
Efruxifermin	Biological Medicinal Product	Gastroenterology- Hepatology	Nonalcoholic steatohepatitis	Nonclinical+ Clinical exploratory	SME
Magrolimab	Biological Medicinal Product	Oncology	Myelodysplastic Syndromes	Nonclinical+ Clinical exploratory	Other

^{*} 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.

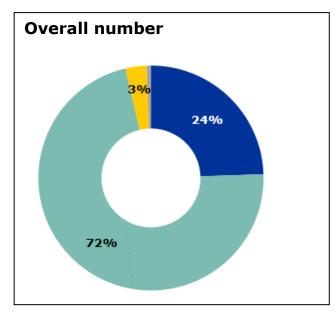
Eligibility denied

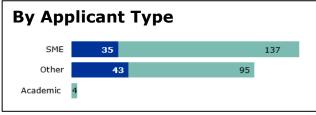
Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chemical Medicinal Product	Neurology	Treatment of Adrenoleukodystrophy	Nonclinical+ Clinical exploratory	SME
Chemical Medicinal Product	Neurology	Treatment of idiopathic intracranial hypertension	Nonclinical+ Clinical exploratory	SME
Advanced Therapy Medicinal Product	Metabolic	Treatment of Pearson Syndrome	Nonclinical+ Clinical exploratory	SME

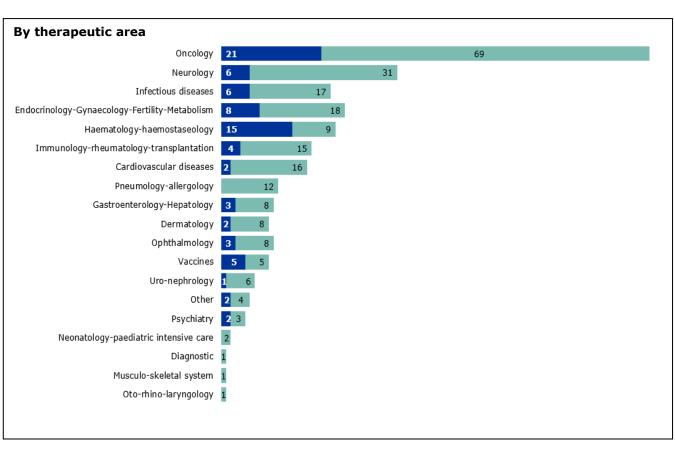
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Cumulative overview of PRIME eligibility recommendations adopted by 15 October 2020









^{*} 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.