23 October 2019
EMA/385345/2019
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 14-17 October 2019

During its October 2019 meeting, the CHMP reviewed 6 recommendations for eligibility to PRIME: 3 were granted and 3 were denied. In addition, 1 request was withdrawn at the request of the applicant after the start of the procedure.
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
Teplizumab	Biological	Endocrinology-Gynaecology-Fertility-Metabolism	Treatment to delay or prevent clinical Type 1 diabetes in “at-risk” individuals	Nonclinical+ Clinical exploratory	SME
Recombinant adeno-associated virus vector based on the AAV serotype hu37 containing a single stranded DNA genome encoding a form of human FVIII (BAY2599023)	Advanced Therapy	Haematology-haemostaseology	Treatment of haemophilia A	Nonclinical+ Clinical exploratory	Other
Autologous anti-CD19/CD20 CAR T transduced cells (MB-CART2019.1)	Advanced Therapy	Oncology	Treatment of patients with relapsed and refractory diffuse large B-cell lymphoma (DLBCL) after frontline therapy and who are ineligible for autologous stem cell transplantation	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	Oncology	Treatment of patients with previously-treated non-small cell lung cancer with a specific mutation	Nonclinical + Clinical exploratory	Other
Biological	Neurology	Disease modifying treatment for mild cognitive impairment (MCI) due to Alzheimer's disease (AD) and mild AD dementia	Nonclinical + Clinical exploratory	Other
Advanced Therapy	Immunology-Rheumatology-Transplantation	Prevention of graft versus host disease	Nonclinical + Clinical exploratory	SME

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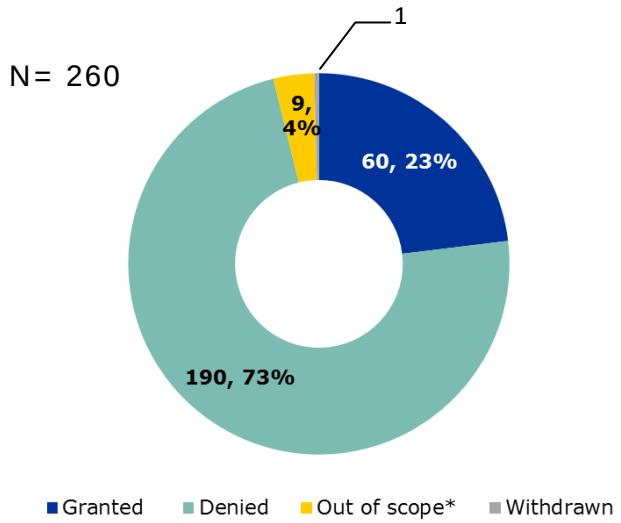
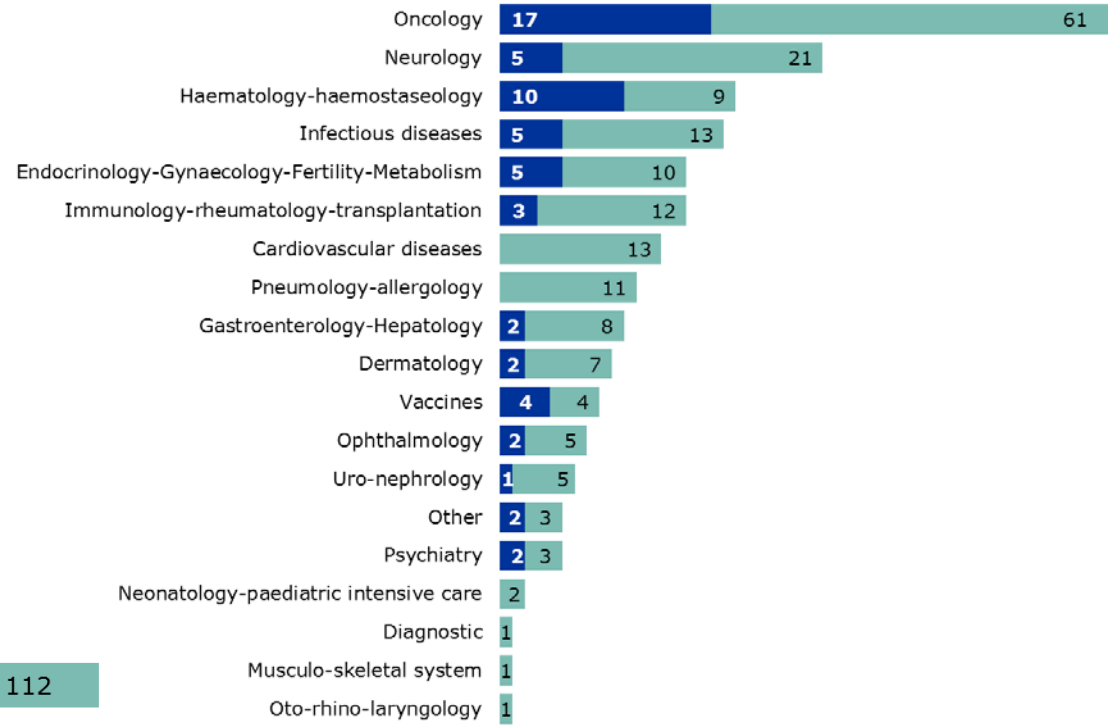
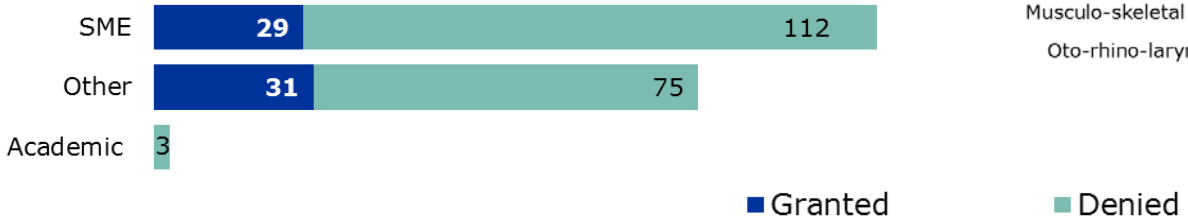
Cumulative overview of recommendations on PRIME eligibility requests adopted by 17 October 2019



By therapeutic area



By type of applicant



* 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.