04 February 2021
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Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 25-29 January 2021

During its January 2021 meeting, the CHMP reviewed 13 recommendations for eligibility to PRIME: 3 were granted and 10 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
ARU-1801	Advanced Therapy Medicinal Product	Haematology - Hemostaseology	Treatment of Sickle Cell Disease	Nonclinical + Clinical exploratory	Other
Talquetamab	Biological Medicinal Product	Oncology	Treatment of adult patients with relapsed or refractory multiple myeloma, who previously received ≥3 prior lines of therapy	Nonclinical + Clinical exploratory	Other
Teclistamab	Biological Medicinal Product	Oncology	Treatment of adult patients with relapsed or refractory multiple myeloma, who previously received ≥3 prior lines of therapy	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.

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	Infectious Diseases	Treatment of sepsis	Nonclinical + Clinical exploratory	SME
Biological Medicinal Product	Infectious Diseases	HIV vaccination	Nonclinical + Clinical exploratory	Other
Chemical Medicinal Product	Infectious Diseases	Prevention of abdominal surgery infection	Nonclinical + Clinical exploratory	SME
Chemical Medicinal Product	Neurology	Treatment of amyotrophic lateral sclerosis	Nonclinical + Clinical exploratory	SME
Biological Medicinal Product	Oncology	Treatment of previously untreated, unresectable or metastatic melanoma regardless of BRAF mutation status in combination with an anti-PD-1 antibody	Nonclinical + Clinical exploratory	SME
Biological Medicinal Product	Immunology-Rheumatology-Transplantation	Treatment of acute graft versus host disease (aGVHD)	Nonclinical + Clinical exploratory	Other
Advanced Therapy Medicinal Product	Ophthalmology	Treatment of retinitis pigmentosa	Nonclinical + Clinical exploratory	Other
Chemical Medicinal Product	Oncology	Treatment of relapsed/refractory myelofibrosis	Nonclinical + Clinical exploratory	SME
Advanced Therapy Medicinal Product	Neurology	Treatment of amyotrophic lateral sclerosis[1]	Nonclinical+ Clinical exploratory	SME
Chemical Medicinal Product	Musculoskeletal system	Treatment of primary mitochondrial myopathy	Nonclinical + Clinical exploratory	SME

[1] Final outcome after consideration from October 2020.

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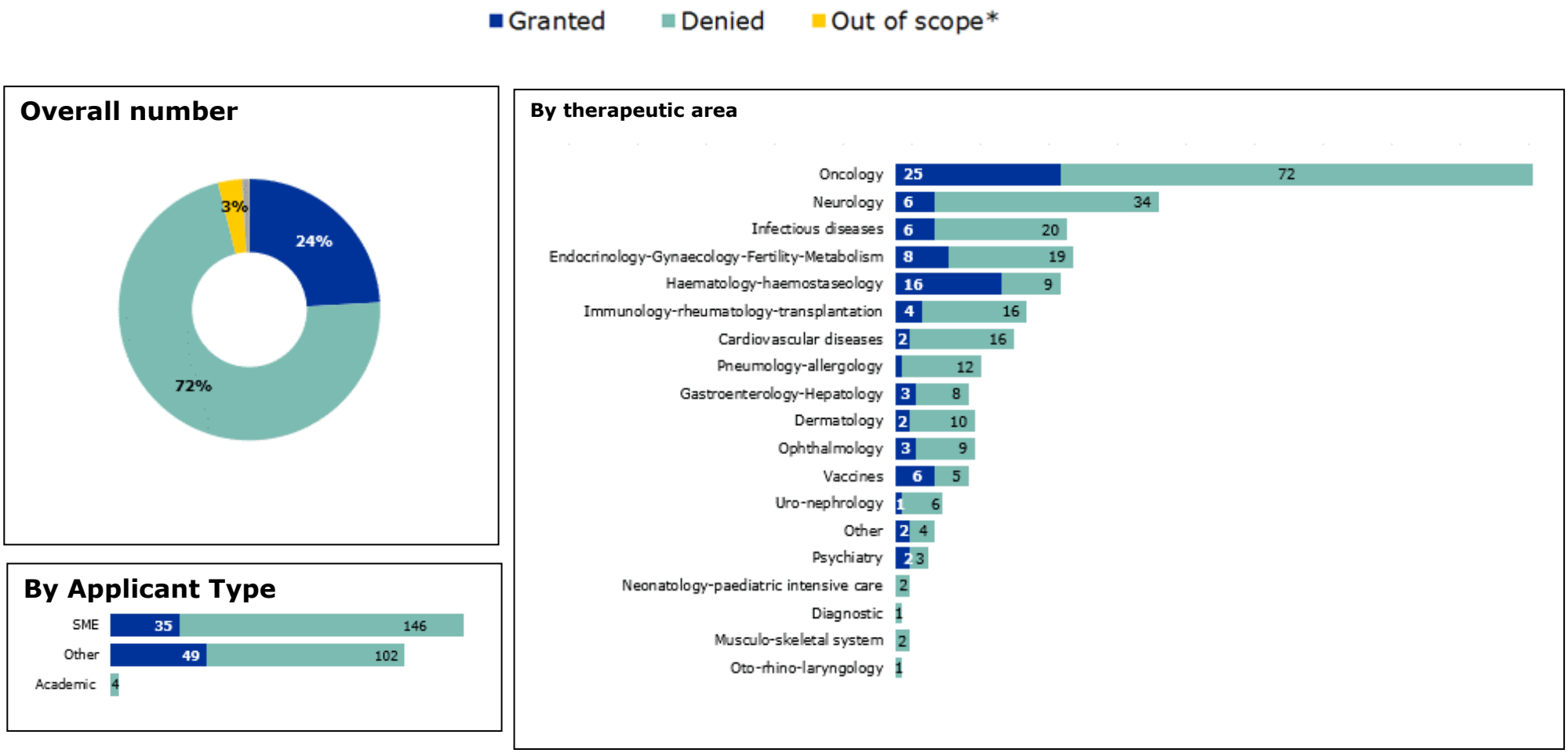
Cumulative overview of PRIME eligibility recommendations adopted by 29 January 2021



* 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.