



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 February 2020
EMA/634510/2019
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 27-30 January 2020

During its January 2020 meeting, the CHMP reviewed 7 recommendations for eligibility to PRIME: 2 were granted and 5 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
Allogeneic multi-virus specific T lymphocytes targeting BK Virus, cytomegalovirus, human herpes virus-6, Epstein Barr virus, and adenovirus (ALVR-105)	Advanced Therapy	Infectious Diseases	Treatment of serious infections with BK virus, cytomegalovirus, human herpes virus-6, Epstein Barr virus, and/or adenovirus in allogeneic HSCT recipients	Nonclinical+ Clinical exploratory	Other
PB2452	Biological	Cardiovascular Diseases	Reversal of antiplatelet effects of ticagrelor in patients with uncontrolled major or life-threatening bleeding or requiring urgent surgery or invasive procedure	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.

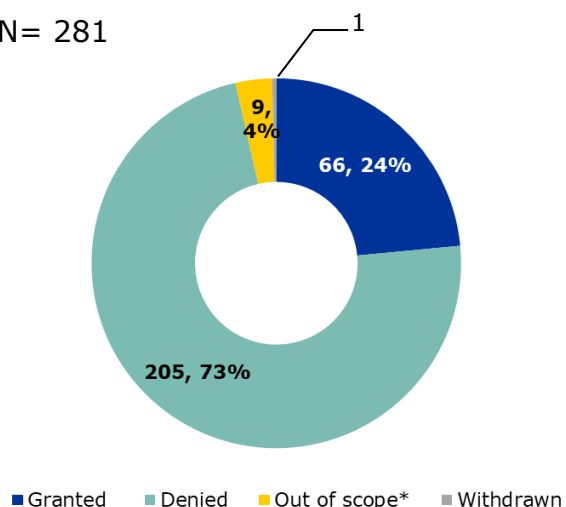
Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Advanced Therapy	Cardiovascular diseases	Treatment of no-option patients with critical limb ischemia	Nonclinical+ Clinical exploratory	SME
Chemical	Infectious diseases	Treatment of patients with septic shock induced by endotheliopathy (SHINE)	Nonclinical+ Clinical exploratory	SME
Chemical	Infectious Diseases	Treatment and prevention of complications associated with severe infections, in particular: organ failure associated with severe pneumonia	Nonclinical+ Clinical exploratory	SME
Chemical	Oncology	Treatment in combination with standard chemoradiotherapy of patients with histologically confirmed diagnosis of previously untreated and unresectable LA-SCCHN	Nonclinical+ Clinical exploratory	Other
Chemical	Other	Treatment of patients with Duchenne Muscular Dystrophy	Nonclinical+ Clinical exploratory	Other

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

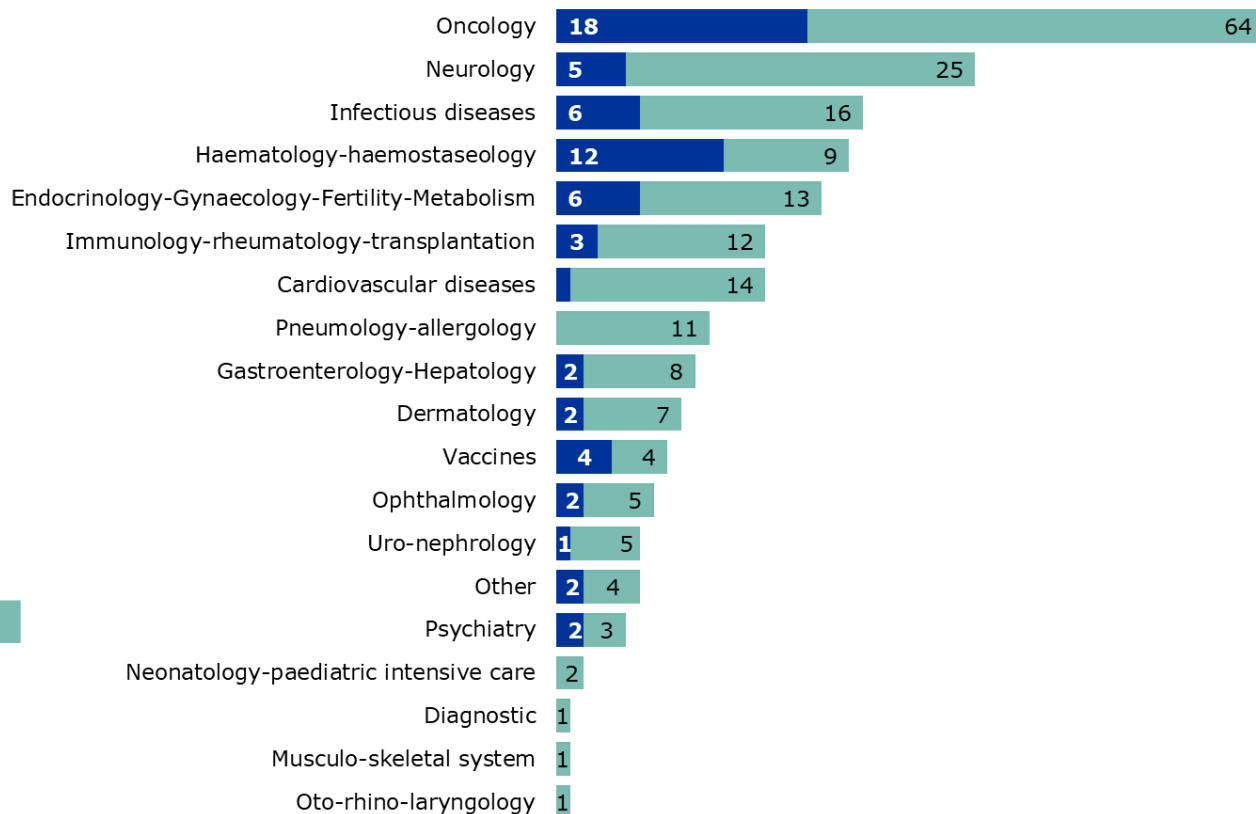
N= 281



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.