



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Press office

## Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 16-19 September 2019

During its September 2019 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
Fully human anti-BCMA autologous CAR T Cell (CT053)	Advanced Therapy	Oncology	Treatment of patients with relapsed and/or refractory multiple myeloma (MM) whose prior regimens included a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody	Nonclinical+ Clinical exploratory	SME
Chikungunya virus virus-like particle vaccine (PXVX0317)	Biological	Infectious Diseases	Active immunisation to prevent disease caused by chikungunya virus infection	Nonclinical+ Clinical exploratory	Other

\* Name of the active substance, INN, common name, chemical name or company code.

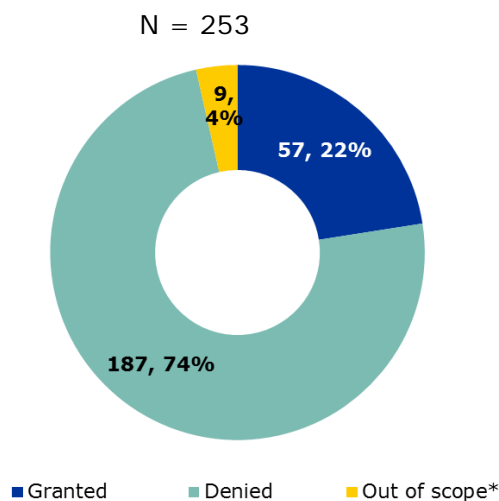
SME applicants are micro-, small-and medium-sized-enterprises registered with the Agency's SME office. Other types of applicants are those not qualifying or not registered as SME or not fulfilling the definition of academic sponsors.

## Eligibility denied

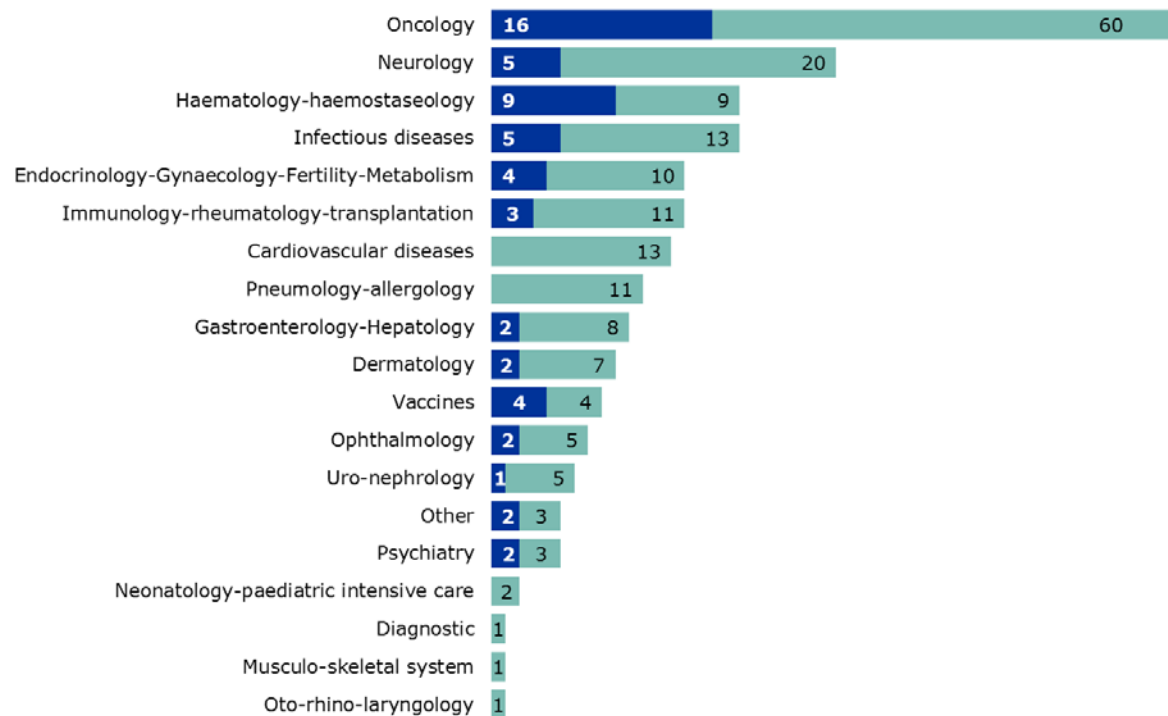
Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Biological	Oncology	Treatment, in combination with carboplatin and paclitaxel, of patients with stage III or IV epithelial ovarian, or primary peritoneal cancer following optimally debulked initial surgical resection	Nonclinical+ Clinical exploratory	Other
Advanced Therapy	Oncology	Treatment of patients with recurrent, metastatic, or persistent cervical cancer with disease progression during or after chemotherapy	Nonclinical+ Clinical exploratory	SME
Advanced Therapy	Cardiovascular diseases	Treatment of no-option patients with peripheral arterial disease and critical limb ischemia	Nonclinical+ Clinical exploratory	SME
Chemical	Neurology	Treatment of multiple system atrophy	Nonclinical+ Clinical exploratory	SME
Chemical	Psychiatry	Treatment of schizophrenia	Nonclinical+ Clinical exploratory	Other

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## Cumulative overview of recommendations on PRIME eligibility requests adopted by 19 September 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.