



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 September 2016
EMA/605563/2016
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 12-15 September 2016

During its September 2016 meeting, the CHMP reviewed 9 recommendations for eligibility to PRIME: 2 were granted and 7 were denied. In addition, 2 requests were received but not started by EMA as they were deemed outside the scope of the scheme.

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
Autologous CD3+ T Cells Expressing CD19 Chimeric Antigen Receptor (JCAR015)	Advanced Therapy	Oncology	Treatment of relapsed/refractory adult B-cell Acute Lymphoblastic Leukaemia (ALL)	Nonclinical + Clinical exploratory	Other
Autologous CD34+ haematopoietic stem cells transduced with lentiviral vector encoding the human β A-T87Q-globin gene (Lentiglobin)	Advanced Therapy	Haematology - Hemostaseology	Treatment of transfusion-dependent beta-thalassaemia (also referred to as beta-thalassaemia major)	Nonclinical + Clinical exploratory	SME

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

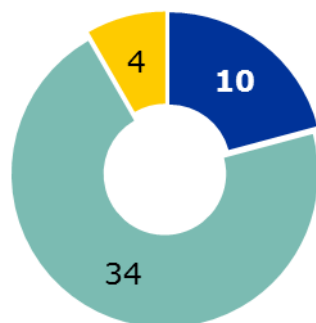
SME applicants are micro-, small-and medium-sized-enterprises registered with the Agency's SME office. Other types of applicants are those not qualifying or not registered as SME or not fulfilling the definition of academic sponsors.

Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chemical	Neurology	Treatment of hereditary TTR-mediated amyloidosis	Nonclinical + Clinical exploratory	Other
Chemical	Diagnostic	Diagnostic magnetic resonance imaging for detection and localisation of focal liver lesion	Nonclinical + Clinical exploratory	SME
Advanced Therapy	Oncology	Treatment of glioblastoma multiforme	Nonclinical + Clinical exploratory	Other
Advanced Therapy	Immunology- Rheumatology- Transplantation	Treatment of patients diagnosed with severe combined immunodeficiency	Nonclinical + Clinical exploratory	Other
Immunological	Oncology	Treatment of acute myeloid leukaemia	Clinical exploratory	Other
Advanced Therapy	Ophthalmology	Treatment of Leber's Hereditary Optic Neuropathy	Nonclinical + Clinical exploratory	SME
Advanced Therapy	Ophthalmology	Improvement of visual acuity in patients with vision loss from geographic atrophy secondary to age-related macular degeneration	Nonclinical + Clinical exploratory	Other

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.

Cumulative overview of recommendations on PRIME eligibility requests received as of 29 June 2016



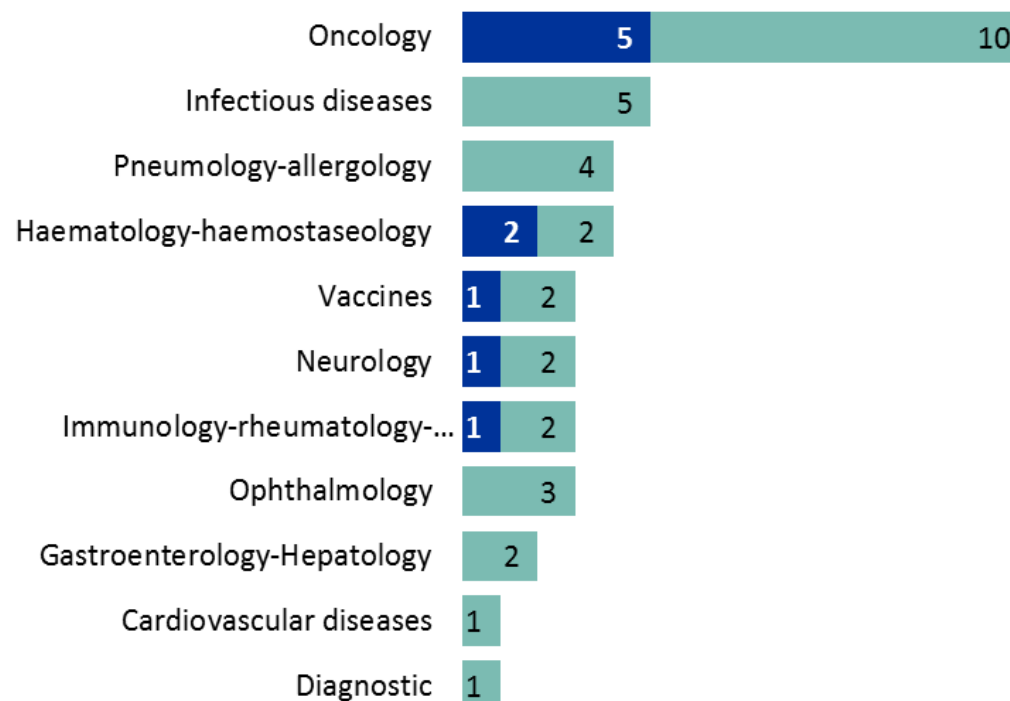
■ Granted ■ Denied ■ Out of scope*

By type of applicant



■ Granted ■ Denied

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.