



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

1 June 2016  
EMA/345382/2016  
Press office

## Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 23-26 May 2016

During its May 2016 meeting, the CHMP reviewed 18 recommendations for eligibility to PRIME: 4 were granted and 14 were denied. The individual outcomes adopted this month are listed below.

---

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom

**Telephone** +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5550

**Send a question via our website** [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact)

An agency of the European Union



## Eligibility granted

Name*	Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Aducanumab	Biological	Neurology	Treatment of Alzheimer's disease	Nonclinical + Clinical exploratory	Other
CCX168	Chemical	Immunology- Rheumatology- Transplantation	Treatment of patients with active ANCA-associated vasculitis (including granulomatosis with polyangiitis and microscopic polyangiitis)	Nonclinical + Clinical exploratory	SME
KTE-C19	Advanced Therapy	Oncology	Treatment of adult patients with diffuse large B-cell lymphoma (DLBCL) who have not responded to their prior therapy, or have had disease progression after autologous stem cell transplant (ASCT)	Nonclinical + Clinical exploratory	SME
NI-0501	Biological	Haematology- Hemostaseology	Treatment of primary haemophagocytic lymphohistiocytosis (HLH)	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.

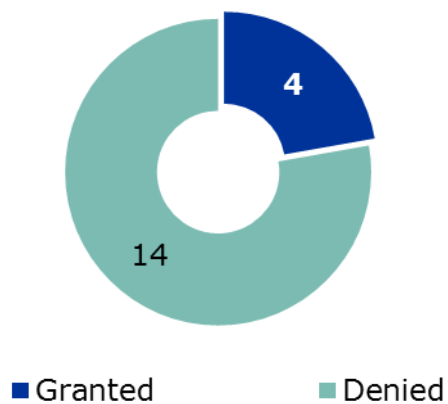
## Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Advanced Therapy	Oncology	Treatment of adult patients with primary mediastinal B-cell lymphoma (PMBCL)	Non clinical + Clinical exploratory	SME
Advanced Therapy	Oncology	Treatment of adult patients with transformed follicular lymphoma (TFL)	Non clinical + tolerability first in man	SME
Chemical	Infectious Diseases	Treatment of serious bacterial infections	Nonclinical + Clinical exploratory + Clinical confirmatory	Other
Chemical	Infectious Diseases	Prevention of poliomyelitis	Nonclinical + Clinical exploratory	SME
Biological	Infectious Diseases	Treatment of adult patients with active recurrent Clostridium difficile infection	Nonclinical + Clinical exploratory	SME
Biological	Vaccines	Prevention of respiratory syncytial virus (RSV) disease in adults 60 years of age and older	Nonclinical + Clinical exploratory	Other
Biological	Vaccines	Prevention of lower respiratory tract infection due to RSV in infants ≤6 months of age	Nonclinical + Clinical exploratory	Other
Biological	Pneumology-Allergology	Treatment of peanut allergy	Nonclinical + Clinical exploratory	SME
Herbal	Pneumology-Allergology	Treatment of peanut allergy	Clinical exploratory	Other
Biological	Pneumology-Allergology	Prevention of acute attacks of hereditary angioedema	Nonclinical + Clinical exploratory	Other
Biological	Immunology-Rheumatology-Transplantation	Treatment of steroid-resistant acute graft-versus-host disease	Nonclinical + Clinical exploratory	SME
Chemical	Neurology	Adjunctive treatment of super-refractory status epilepticus	Nonclinical + Clinical exploratory	Other

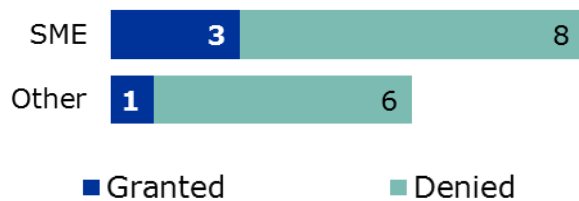
Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Advanced Therapy	Cardiovascular Diseases	Adjunct therapy for adult heart failure patients undergoing coronary arterial bypass graft (CABG)	Nonclinical + Clinical exploratory	SME
Chemical	Ophthalmology	Treatment of neurotrophic keratitis	Nonclinical + other	SME

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

## Cumulative overview of recommendations on PRIME eligibility requests received as of 6 April 2016



### By type of applicant



### By therapeutic area

