



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

6 February 2019  
EMA/814052/2018  
Press office

## Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 28-31 January 2019

During its January 2019 meeting, the CHMP reviewed 7 recommendations for eligibility to PRIME: 1 was granted and 6 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
Anti-respiratory syncytial virus human IgG1κ monoclonal antibody (MEDI8897)	Biological	Infectious diseases	Prevention of lower respiratory tract infection caused by respiratory syncytial virus	Nonclinical+ Clinical exploratory	Other

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

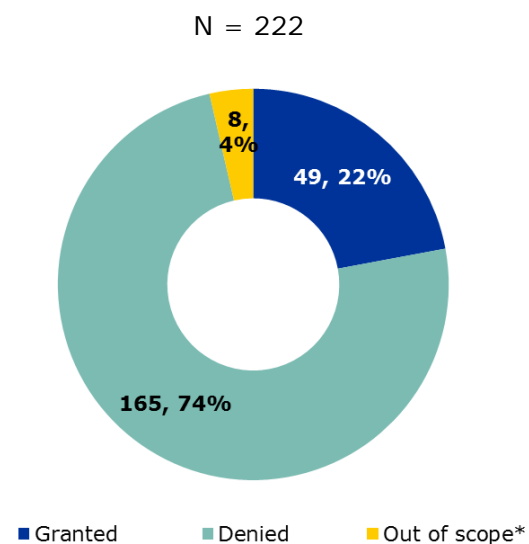
SME applicants are micro-, small-and medium-sized-enterprises registered with the Agency's SME office. Other types of applicants are those not qualifying or not registered as SME or not fulfilling the definition of academic sponsors.

## Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Biological	Neurology	Disease-modifying treatment for mild cognitive impairment due to Alzheimer's disease (AD) and mild AD dementia	Nonclinical+ Clinical exploratory	Other
Chemical	Neurology	Treatment of Parkinson's Disease Levodopa Induced Dyskinesia (PD-LID) and Parkinson's Disease Psychosis (PD-P)	Nonclinical+ Clinical exploratory	SME
Chemical	Neurology	Treatment of Parkinson's Disease dementia	Nonclinical+ Clinical exploratory	SME
Chemical	Pneumology-allergology	Treatment of Cystic Fibrosis	Nonclinical+ Clinical exploratory	SME
Chemical	Pneumology-allergology	Treatment of Cystic Fibrosis	Nonclinical+ Clinical exploratory	SME
Chemical	Pneumology-allergology	Treatment of Cystic Fibrosis	Nonclinical+ Clinical exploratory	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 or not fulfilling the definition of academic sponsors.

## Cumulative overview of recommendations on PRIME eligibility requests adopted by 31 January 2019

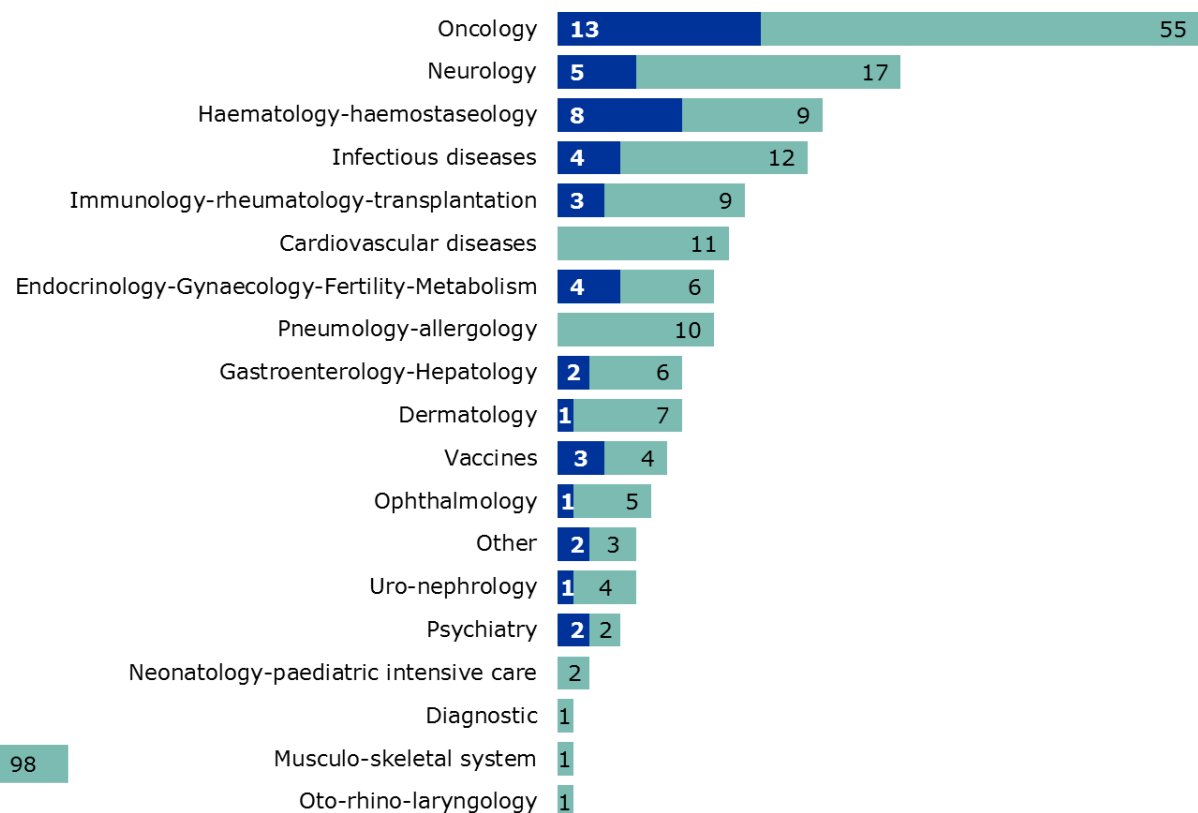


### By type of applicant



■ Granted ■ Denied

### By therapeutic area



\* 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.