



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

19 December 2018  
EMA/758070/2018  
Press office

## Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 10-13 December 2018

During its December 2018 meeting, the CHMP reviewed 4 recommendations for eligibility to PRIME: 2 were granted and 2 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
Lonafarnib	Chemical	Infectious Diseases	Treatment of hepatitis D virus infection	Nonclinical+ Clinical exploratory	SME
Risdiplam	Chemical	Neurology	Treatment of 5q spinal muscular atrophy	Nonclinical+ Clinical exploratory	Other

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

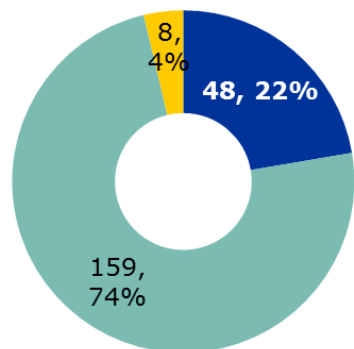
SME applicants are micro-, small-and medium-sized-enterprises registered with the Agency's SME office. Other types of applicants are those not qualifying or not registered as SME or not fulfilling the definition of academic sponsors.

## Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chemical	Oncology	Treatment of triple negative breast cancer	Nonclinical+ Clinical exploratory	SME
Chemical	Endocrinology-Gynaecology- Fertility-Metabolism	Treatment of Niemann-Pick disease, type C (NPC)	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 13 December 2018



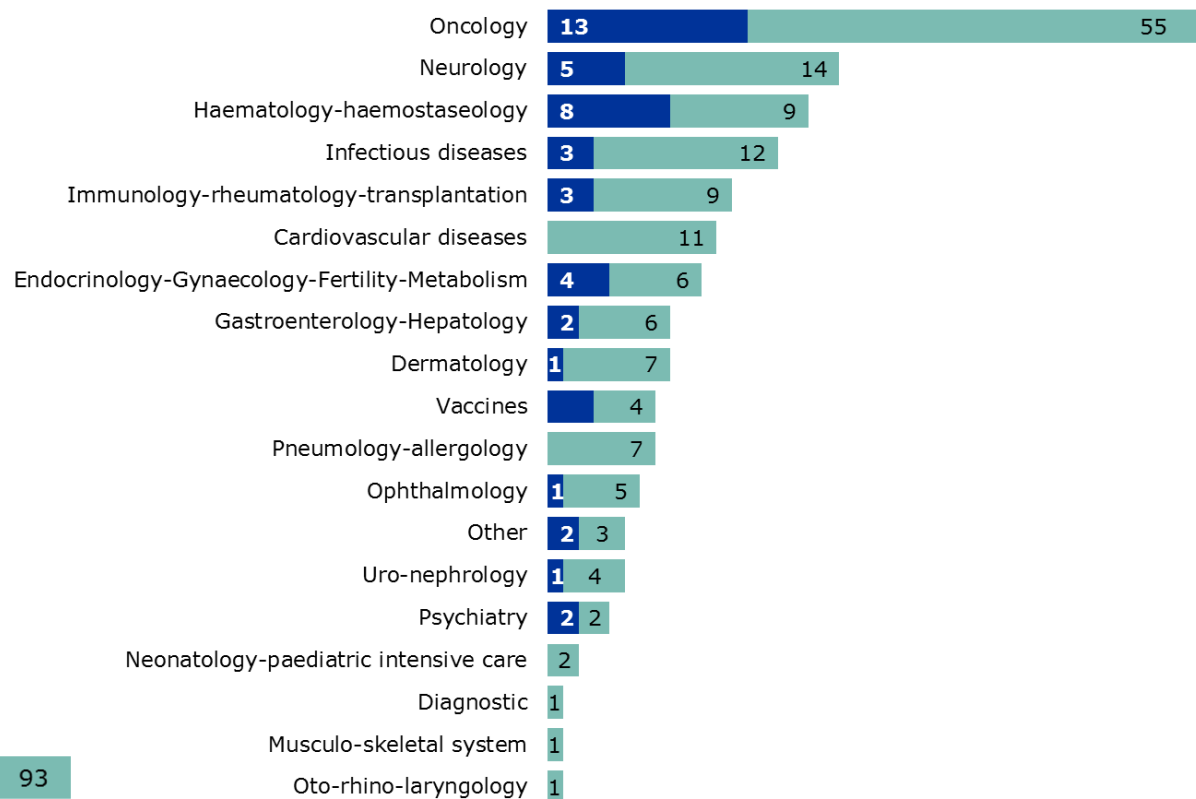
■ Granted ■ Denied ■ Out of scope\*

### 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.