



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 November 2021
EMA/498393/2021
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 08-11 November 2021

During its November 2021 meeting, the CHMP reviewed 3 recommendations for eligibility to PRIME: 1 was granted and 2 were denied. The individual outcomes adopted this month are listed below.

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



Eligibility granted

Name*	Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
CT041 (CAR-CLDN18.2 T cells)	Advanced Therapy Medicinal Product	Oncology	Treatment of patients with advanced gastric cancer who have failed at least 2 prior lines of systemic therapy	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.

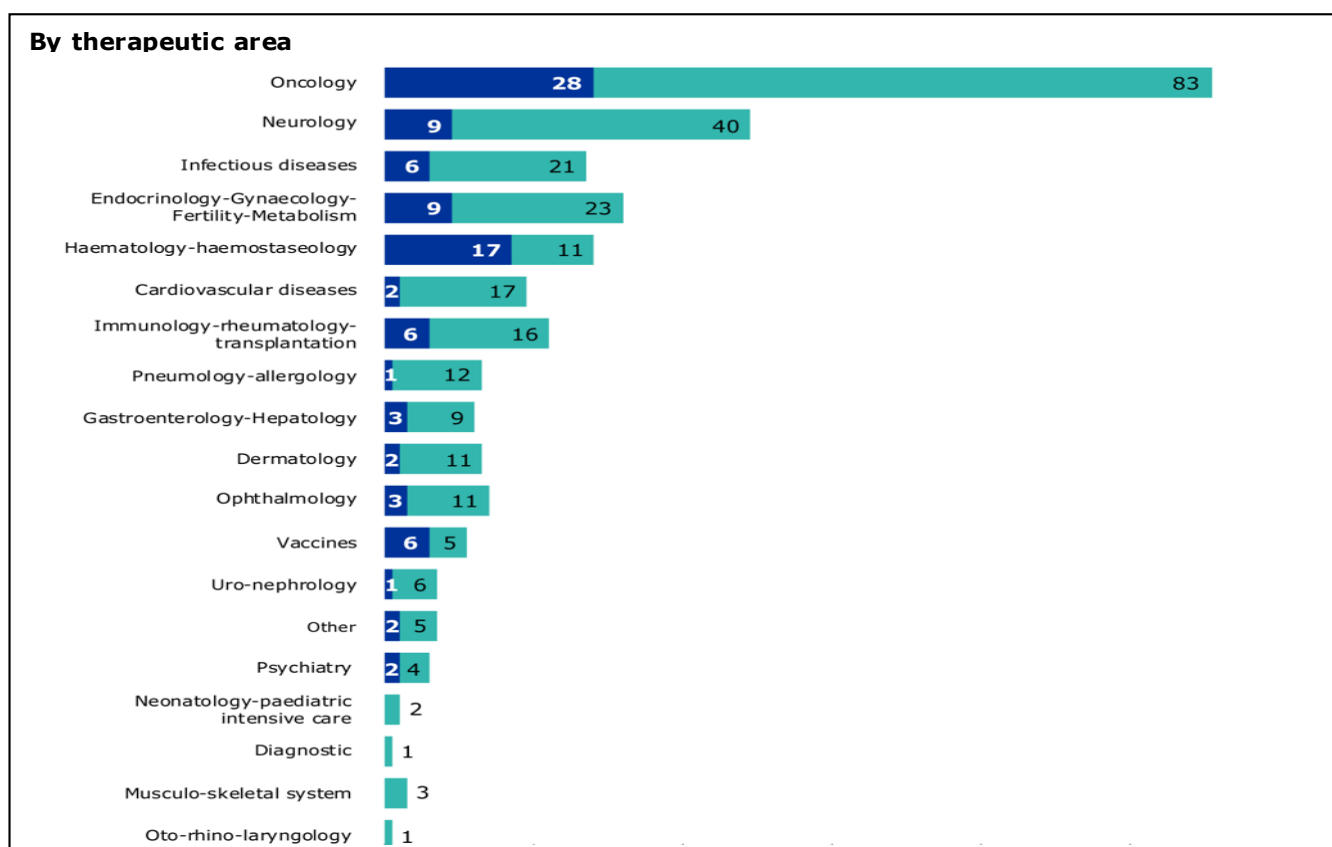
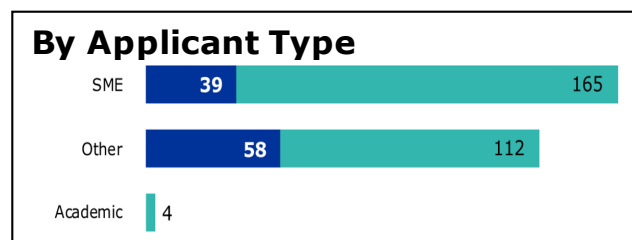
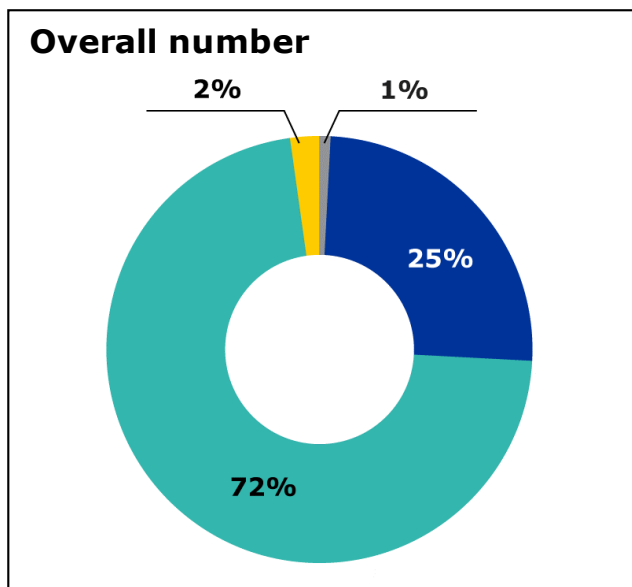
Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chemical Medicinal Product	Endocrinology-Gynaecology-Fertility-Metabolism	Treatment of congenital hyperinsulinism	Nonclinical + Clinical exploratory	SME
Chemical Medicinal Product	Neurology	Treatment of dementia with Lewy Bodies	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 PRIME eligibility recommendations adopted by 15 October 2020

■ Granted ■ Denied ■ Out of scope*



* 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.