



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 22-25 April 2024

During its April 2024 meeting, the CHMP reviewed 5 recommendations for eligibility to PRIME: 3 were granted and 2 were denied. In addition, 1 request was received but not started by EMA as it was 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
WU-CART-007	Advanced Therapy Medicinal Product	Blood and lymphatic system disorders	Treatment of Relapsed/Refractory T-cell acute lymphoblastic leukaemia (T-ALL) and T-cell lymphoblastic lymphoma (T-LBL)	Non-clinical + Clinical exploratory	SME
FLT201	Advanced Therapy Medicinal Product	Congenital, familial and genetic disorders	Treatment of Gaucher disease	Non-clinical + Clinical exploratory	Other
JNT-517	Chemical Medicinal Product	Congenital, familial and genetic disorders	Treatment of Hyperphenylalaninemia	Non-clinical + 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.

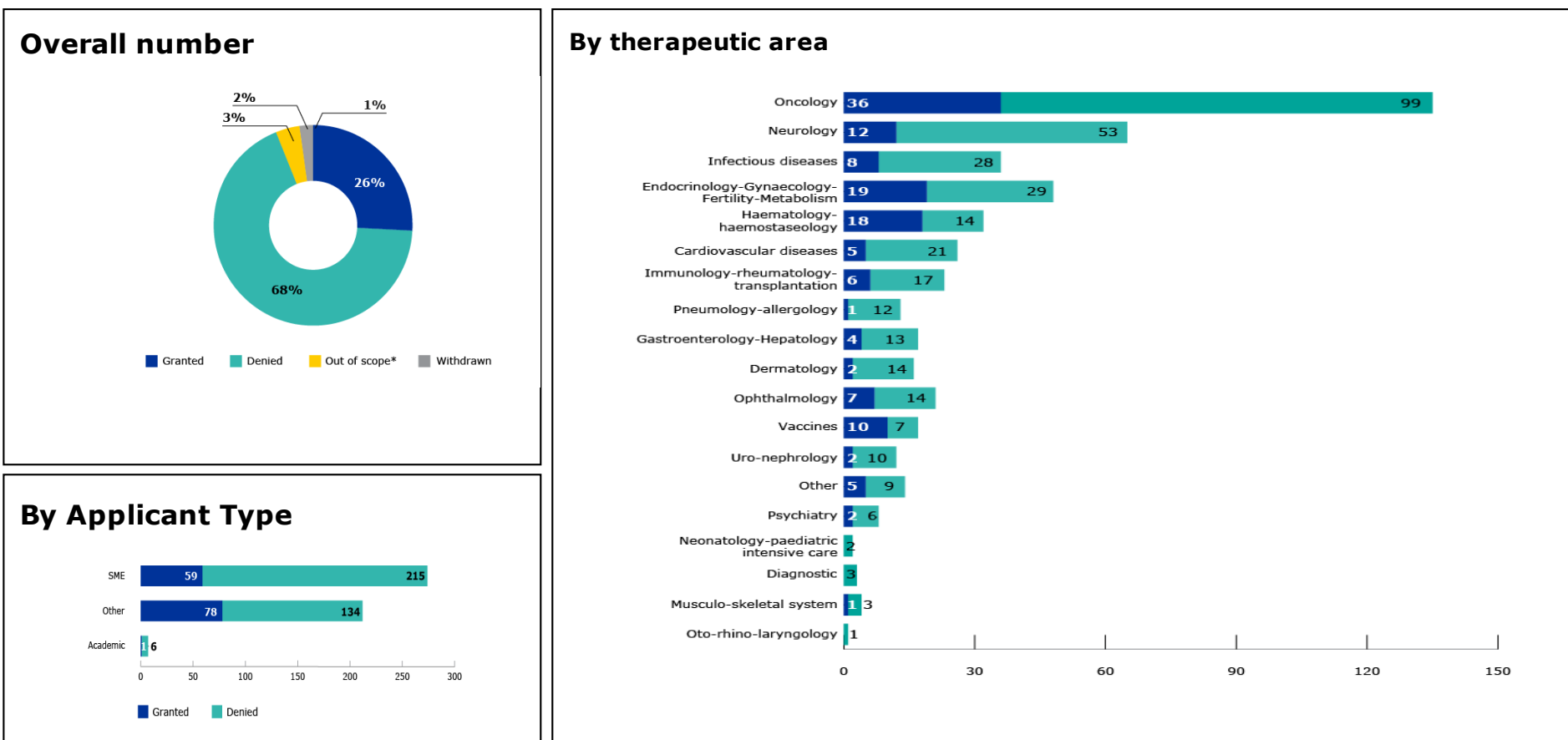
Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chemical Medicinal Product	Nervous system disorders	Treatment of Alzheimer disease	Non-clinical + Clinical exploratory	SME
Advanced Therapy Medicinal Product	Eye disorders	Treatment of Leber congenital amaurosis type 1 (LCA1)	Non-clinical + Clinical exploratory	Other

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 25 April 2024

■ Granted
 ■ Denied
 ■ Out of scope*
 ■ Withdrawn
 ■ Transition**



* 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.

** Application for transition from Early Entry to Full PRIME eligibility.