



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 24-26 April 2023

During its April 2023 meeting, the CHMP reviewed 2 recommendations for eligibility to PRIME: 1 was granted and 1 was 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
AGTC-501 (laruparetigene zovaparvovec)	Advanced Therapy Medicinal Product	Ophthalmology	Treatment of XLRP	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.

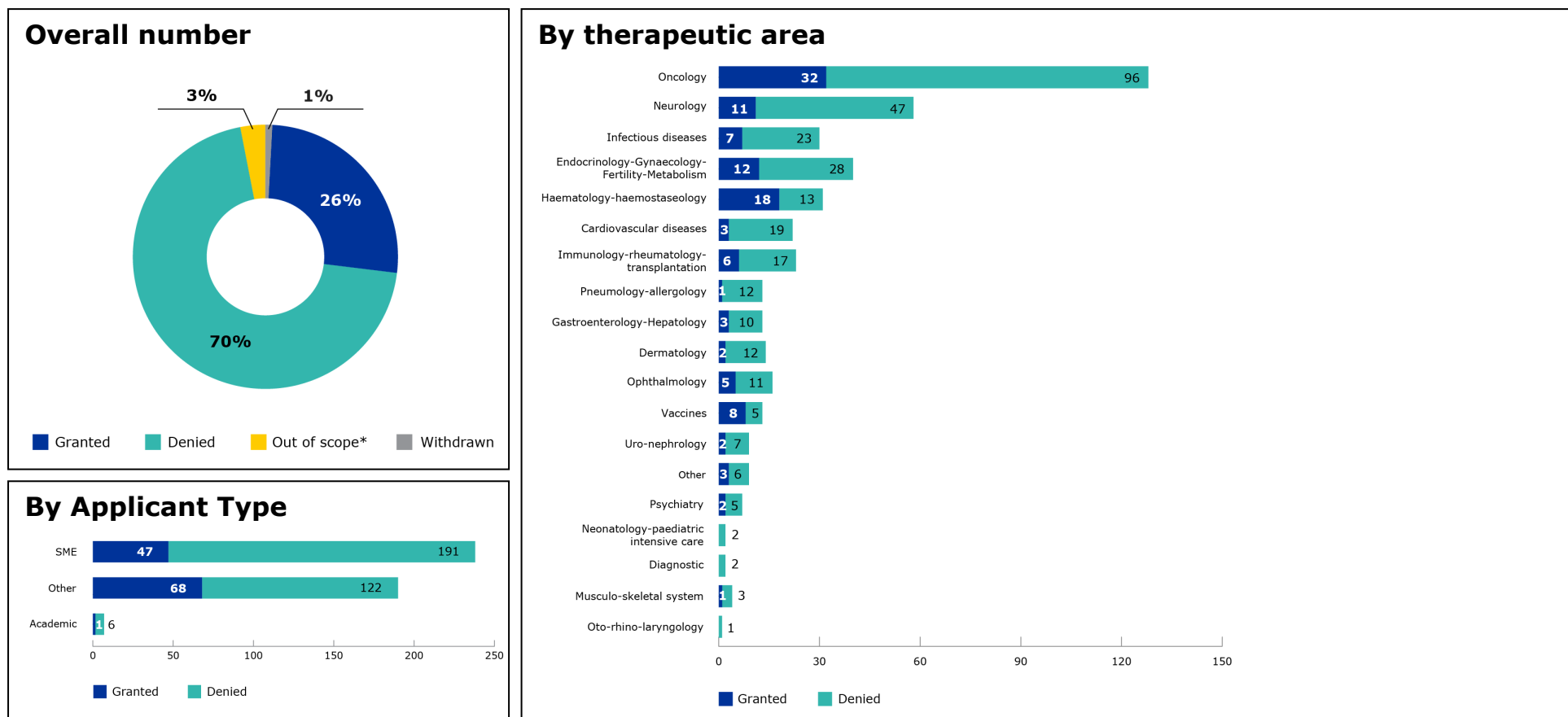
Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chemical Medicinal Product	Uro-nephrology	Visual enhancement of the anatomic location of the ureters using near-infrared (NIR) fluorescent light	Nonclinical + Clinical exploratory	SME

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Cumulative overview of PRIME eligibility recommendations adopted by 26 April 2023

■ Granted ■ Denied ■ Out of scope* ■ Withdrawn



* 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.