



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 March 2021
EMA/25115/2021
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 22-25 March 2021

During its March 2021 meeting, the CHMP reviewed 8 recommendations for eligibility to PRIME: 4 were granted and 4 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
Apitegromab	Biological Medicinal Product	Neurology	Treatment of spinal muscular atrophy	Nonclinical + Clinical exploratory	SME
Obecabtagene autoleucel/ AUTO1	Advanced Therapy Medicinal Product	Oncology	Treatment of relapsed or refractory B cell acute lymphoblastic leukaemia in adults	Nonclinical + Clinical exploratory	Other
PF-06863135	Biological Medicinal Product	Oncology	Treatment of multiple myeloma	Nonclinical + Clinical exploratory	Other
RP-L201	Advanced Therapy Medicinal Product	Immunology- Rheumatology- Transplantation	Treatment of Leukocyte Adhesion Deficiency-I	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.

Product(s) in italic have been granted eligibility to the scheme at early stages of development (proof of principle/proof of mechanism).

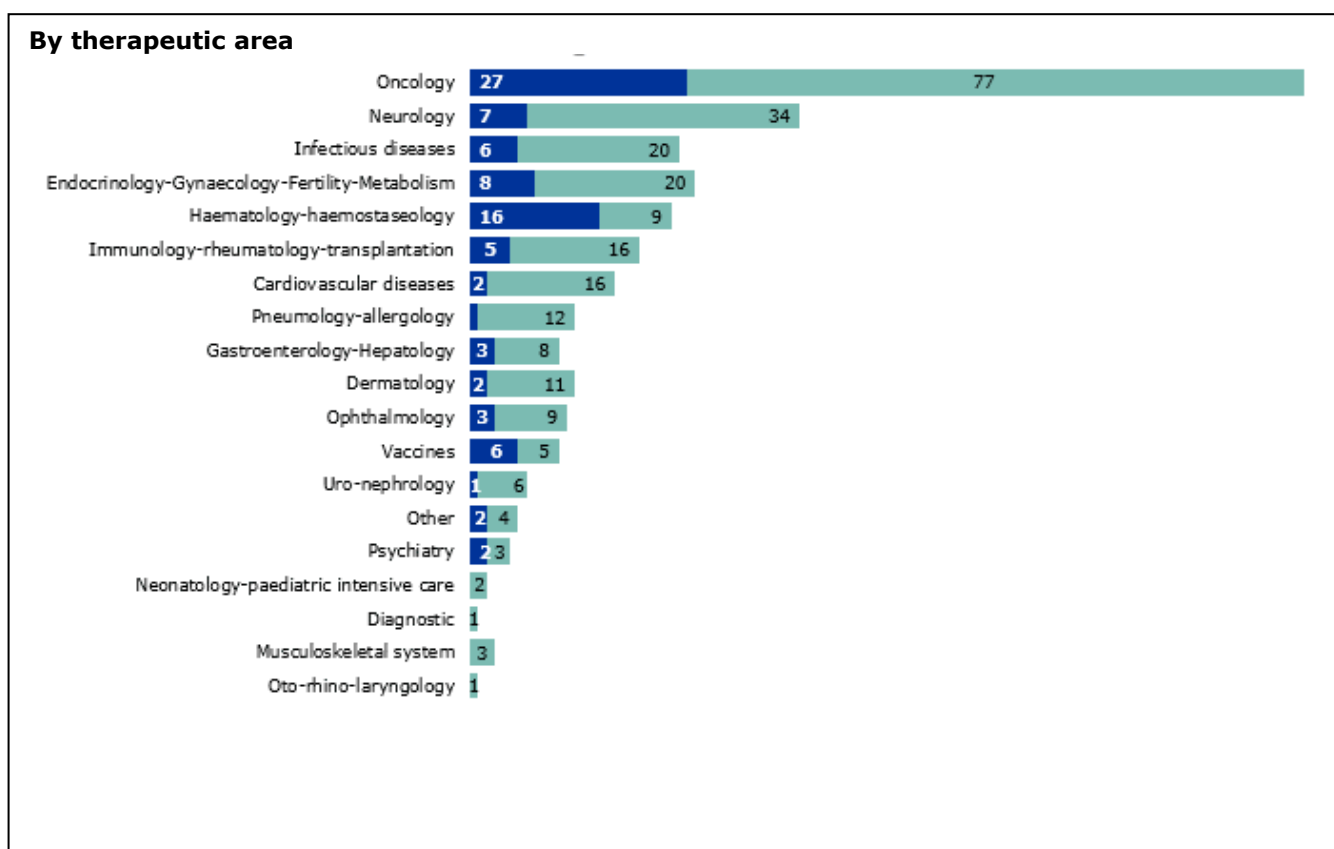
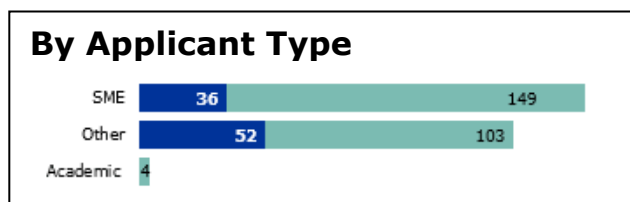
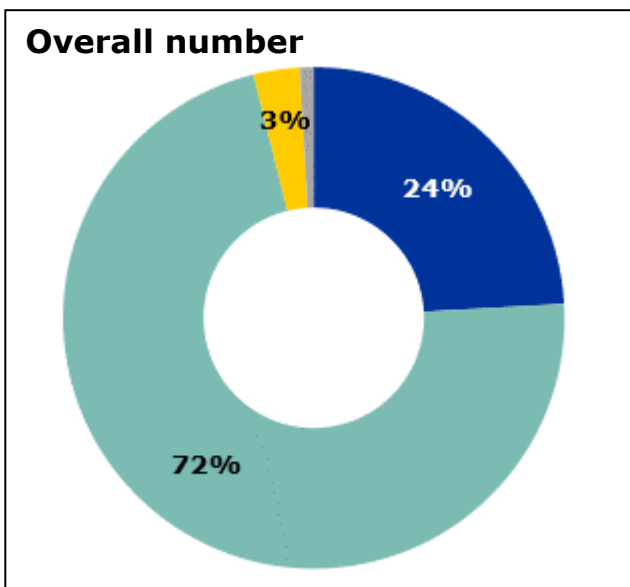
Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Herbal Medicinal Product	Oncology	Treatment of Pseudomyxoma peritonei - peritoneal mucinous tumours	Nonclinical + Clinical exploratory	SME
Chemical Medicinal Product	Dermatology	Treatment of patients with Olmsted syndrome	Nonclinical + Clinical exploratory	SME
Biological Medicinal Product	Oncology	Treatment of Blastic Plasmacytoid Dendritic Neoplasm (BPDCN)	Nonclinical + Clinical exploratory	Other
Chemical Medicinal Product	Oncology	Treatment of biochemical relapsed prostate cancer without metastatic disease after radical prostatectomy or definitive radiation therapy	Nonclinical + Clinical exploratory	SME

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Cumulative overview of PRIME eligibility recommendations adopted by 25 March 2021

■ 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.