

Leads Biolabs's opamtistomig NDA accepted in China for neuroendocrine carcinoma

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The PD-L1/4-1BB bispecific antibody has entered NMPA review as a monotherapy for previously treated advanced extrapulmonary neuroendocrine carcinoma.



Nanjing Leads Biolabs has announced that China's Center for Drug Evaluation has accepted the New Drug Application for opamtistomig, or LBL-024, for previously treated advanced extrapulmonary neuroendocrine carcinoma.

Opamtistomig is a proprietary bispecific antibody targeting PD-L1 and 4-1BB.

The candidate is designed to combine blockade of PD-1/PD-L1-mediated immune suppression with conditional activation of the 4-1BB co-stimulatory pathway, with the aim of strengthening anti-tumour immune responses.

According to Leads Biolabs, opamtistomig is the first PD-L1/4-1BB bispecific antibody globally to enter regulatory review for marketing approval.

The candidate was granted Priority Review by China's Center for Drug Evaluation on 10 July 2026.

If approved, Leads Biolabs said opamtistomig could become the first approved antibody therapy directly targeting 4-1BB.

The NDA is supported by a registrational clinical study conducted across 34 sites and led by Professor Shen Lin of Peking University Cancer Hospital.

The study completed enrolment of 96 patients with extrapulmonary neuroendocrine carcinoma in August 2025.

Advanced extrapulmonary neuroendocrine carcinoma is an aggressive disease with limited treatment options after progression on first-line therapy.

Existing first-line treatment generally involves platinum-based chemotherapy, while treatment options and response rates become more limited after progression.

Leads Biolabs is also evaluating opamtistomig across other solid tumour settings.

The company said the candidate has been studied across 13 solid tumour indications in China and has received regulatory designations in China, the United States and Europe.

Acceptance of the NDA moves the programme into formal regulatory review and represents the most advanced development milestone to date for Leads Biolabs' 4-1BB-targeted immunotherapy platform.