

NeoLIPA

Bringing Ruxotemitide Into the Window Before Surgery

Lytix Biopharma

NeoLIPA: Phase II Study in Resectable Melanoma

NeoLIPA is an investigator-initiated Phase II study of neoadjuvant ruxotemitide plus pembrolizumab (KEYTRUDA®) in patients with resectable stage III-IV melanoma.

Study	NeoLIPA (NCT06651151)
Phase	II, open-label, single-arm
Population	Clinically detectable, resectable stage III-IV melanoma
Treatment	Intratumoral ruxotemitide plus pembrolizumab, given before surgery
Planned enrollment	27 patients
Sites	Oslo University Hospital (Radiumhospitalet) and Haukeland University Hospital
Sponsor	Investigator-initiated, Oslo University Hospital
Status	Enrolling.



Why the Neoadjuvant Setting

Treating before surgery gives ruxotemitide something it cannot have later: a tumor that is still in place. Ruxotemitide is injected directly into the tumor, where it disrupts cancer cells and releases tumor antigens and danger signals. These can help the immune system recognize the tumor and respond to pembrolizumab. In the neoadjuvant window, the surgical specimen then shows us how well that response worked.

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Study Design

Single-arm, open-label Phase II

1. **Screening**
   Patients with resectable stage III-IV melanoma and an injectable tumor lesion.

2. **Neoadjuvant Treatment**
   Intratumoral ruxotemitide with pembrolizumab.

3. **Surgery**
   Resection of the tumor, with pathology review of the specimen.

4. **Follow-up**
   Long-term monitoring for recurrence.

Endpoints

Primary: Pathological complete response (pCR), meaning no viable tumor cells remain in the surgical specimen.

Key objectives: Safety and feasibility, and pathologic response at surgery, including major pathological response (MPR).

Exploratory: Immunologic readouts from tumor and blood.

Interim Data, November 2025

44%

pathological complete response

55%

major pathological response

88%

showed a pathological response.

Informing the Registrational Phase III Study

NeoLIPA is generating clinical evidence on pathological response, safety and feasibility with neoadjuvant ruxotemitide plus pembrolizumab. Interim findings from a small cohort support continued evaluation; the full dataset will provide a more complete assessment.

NeoLIPA's Role in Our Clinical Strategy

NeoLIPA evaluates ruxotemitide with pembrolizumab, while ALETTA, led independently by the Netherlands Cancer Institute, evaluates ruxotemitide with ipilimumab and nivolumab in biomarker-selected resectable stage III melanoma. Together, these studies explore both leading checkpoint inhibitor backbones and inform our planned registrational Phase III study in high-risk resectable melanoma. Its primary endpoint is event-free survival, with a design aligned with the FDA.

Milestones

Nov 2024	Study start
Nov 2025	Interim data (n=9)
H1 2026	Haukeland site activated
Aug 2026	23 of 27 patients enrolled
H2 2026	Topline results expected

Ruxotemitide is an investigational product and has not been approved by any regulatory authority. NeoLIPA is an investigator-initiated study. KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC.