Lytix Biopharma announces ruxotemitide plus pembrolizumab meets primary endpoint in Phase II NeoLIPA study in resectable melanoma

- NeoLIPA met its primary endpoint of pathological complete response
- No new safety signals identified
- Full data will be presented at an upcoming international oncology conference

Oslo, Norway, November 3, 2026 – Lytix Biopharma ASA ("Lytix" or the "Company"), a clinical-stage immuno-oncology company developing novel intratumoral cancer therapies, today announced that NeoLIPA, an investigator-initiated, single-arm Phase II study evaluating ruxotemitide in combination with pembrolizumab before surgery in patients with resectable melanoma, has met its primary endpoint of pathological complete response (pCR).

Based on the evaluable population to date, the pCR rate met the prespecified success criterion defined in the study protocol of at least 40% pCR. A pCR means that no viable cancer cells are detected in the tumor tissue removed at surgery. No new safety signals have been identified in the data available to date.

Full data, including the exact pCR rate for the complete evaluable population, will be presented at an upcoming international oncology conference, and will be published simultaneously by way of a stock exchange announcement.

"We are encouraged that NeoLIPA has met its primary endpoint. We thank the patients and the clinical teams who have contributed to the study and look forward to sharing the detailed findings with the oncology community," said Henrik Jespersen, Principal Investigator of NeoLIPA at Oslo University Hospital.

"Meeting the primary endpoint confirms NeoLIPA as a successful study and a meaningful step in the development of ruxotemitide in resectable melanoma. This result strengthens our rationale for advancing ruxotemitide in combination with pembrolizumab into a randomized Phase III study. We look forward to sharing further information when the detailed results can be presented," said Øystein Rekdal, PhD, Chief Executive Officer of Lytix Biopharma.

NeoLIPA is a single-arm, non-randomized Phase II study assessed against a prespecified historical benchmark. The planned randomized Phase III study will compare ruxotemitide plus pembrolizumab with pembrolizumab alone, with event-free survival as the primary endpoint.

About NeoLIPA
NeoLIPA is an investigator-initiated, single-arm, open-label Phase II study led by Oslo University Hospital. It evaluates ruxotemitide, administered directly into tumors, in combination with pembrolizumab before surgery in patients with resectable melanoma (ClinicalTrials.gov: NCT06651151, EU CT 2023-508649-42-00). The primary endpoint is pCR. The protocol prespecified a threshold of at least 40% pCR, with the lower bound of the 95% confidence interval above the historical pCR of 20% for pembrolizumab alone.

For more information about NeoLIPA and the treatment approach, visit https://www.lytixbiopharma.com/clinical-trials.

About ruxotemitide
Ruxotemitide (LTX-315) is an investigational, first-in-class oncolytic peptide designed for intratumoral administration. The molecule disrupts tumor cells locally, leading to the release of tumor antigens and danger signals that may activate systemic antitumor immune responses, with the aim of preventing cancer recurrence. Its mode of action provides a rationale for combination with immune checkpoint inhibitors such as pembrolizumab.

About Lytix Biopharma ASA
Based in Oslo, Norway, Lytix Biopharma ASA is a clinical-stage biotech company with a highly differentiated oncolytic molecule platform based on world-leading research in host-defense peptide-derived molecules. Lytix Biopharma's lead product, ruxotemitide (formerly LTX-315), is a first-in-class oncolytic molecule representing a new approach to achieve durable anti-cancer immunity. Lytix Biopharma has a pipeline of molecules with potential across multiple cancer indications and treatment settings, both as monotherapy and in combination therapy. Lytix Biopharma is listed on Euronext Growth Oslo under the ticker symbol LYTIX.

For more information, visit www.lytixbiopharma.com.

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