FDA Feedback Clears Path to Registrational Phase III Trial for Ruxotemitide (LTX-315) in Patients with Resectable High-Risk Melanoma

Oslo, Norway, August 27, 2026 – Lytix Biopharma ASA ("Lytix" or the "Company"), a clinical-stage immuno-oncology company developing novel intratumoral cancer therapies, today announced feedback from its July meeting with the U.S. Food and Drug Administration (FDA) on the planned registrational trial of ruxotemitide (LTX-315) in combination with pembrolizumab in high-risk resectable melanoma.

The FDA raised no objection to Lytix's proposed randomized Phase III trial of neoadjuvant ruxotemitide plus pembrolizumab versus pembrolizumab alone, with event-free survival (EFS) as the primary endpoint. The FDA also confirmed that a single well-controlled trial may support a New Drug Application, depending on the totality of the data generated.

The FDA feedback follows previously reported interim data from NeoLIPA, an ongoing investigator-initiated Phase 2 study of neoadjuvant ruxotemitide in combination with pembrolizumab. Among the first 9 evaluable patients, 88% achieved an overall pathological response, including 55% with a major pathological response and 44% with a complete pathological response, with no relapses reported at the time of the analysis. Top-line results are expected in the second half of 2026.

"This constructive feedback from the FDA on our registrational study design removes a key source of uncertainty as we look toward a registrational trial. I want to thank our clinical, regulatory, and scientific teams for the work that went into this program over many years," Øystein Rekdal, Ph.D., CEO of Lytix, commented.

Lytix will continue preparations for the registrational study within its existing capital-efficient plan, and recently appointed Timothy F. Herpin, Ph.D., M.B.A., as Chief Business Officer on a fractional basis to lead partnership discussions. "With a defined regulatory pathway and a well-supported combination approach with pembrolizumab now in hand, we are well positioned to actively pursue partnerships to fund and execute the study and evaluate alternative options to advance the program," added Rekdal.

About Ruxotemitide (LTX-315)

Ruxotemitide (LTX-315) is a 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. This mechanism has the potential to convert immunologically "cold" tumors into "hot" tumors and enhance responses to checkpoint inhibitor therapies.

About Lytix Biopharma

Based in Oslo, Norway, Lytix Biopharma 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 maintaining durable anti-cancer immunity. Lytix Biopharma has a pipeline of molecules that work across multiple cancer indications and treatment settings, both as monotherapy and in combination therapy. Lytix is listed on Euronext Growth Oslo under the ticker LYTIX.

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