Lytix Biopharma Q2 and H1 2024 results: Significant clinical advancements take Lytix Biopharma closer to commercialization

Oslo, 29 August 2024. Lytix Biopharma ("Lytix") (Euronext Growth Oslo: LYTIX), a Norwegian immuno-oncology company dedicated to being part of tomorrow's cancer treatment, today releases its second quarter and first half 2024 results. Lytix Biopharma is experiencing a pivotal shift for its lead drug candidates, marked by significant clinical progress.

Results from the Phase II study in patients with the skin cancer disease basal cell carcinoma (BCC) demonstrate that Lytix's lead drug candidate, LTX-315, achieved an 86% reduction in tumor size and complete elimination in over half of the cases. BCC is the most common type of cancer globally with an estimated 3.6 million new cases in the US alone, each year. This success, in collaboration with licensing partner Verrica Pharmaceuticals, significantly increases the likelihood of LTX-315 being commercialized as a cancer treatment.

"This is a breakthrough for both our company and the many cancer patients who suffer from this skin cancer disease, as LTX-315 has the potential to become a first-line treatment. We look forward to the End of Phase II meeting with FDA during the first half of 2025, where the path forward will be discussed. In addition, Lytix has an exciting program in melanoma and we are preparing our second promising lead candidate for clinical development in deep-seated cancer", says CEO of Lytix Biopharma Dr. Øystein Rekdal.

Robust clinical portfolio

Lytix's ongoing ATLAS-IT-05 study, combining LTX-315 with pembrolizumab in late-stage melanoma patients, continues to yield promising results, with partial responses and durable disease control observed in heavily pre-treated patients. These are patients who have previously failed other lines of therapy.

Lytix is expanding its clinical portfolio by launching a third study with LTX-315 for early-stage melanoma patients. Enrollment will begin this quarter at Oslo University Hospital, Radium Hospital. In this study, LTX-315 will be given before surgery alongside pembrolizumab, the current standard of care. Based on the positive results from the Verrica study and the observed tumor-specific immune responses in later-stage patients, we believe LTX-315 holds significant potential for early-stage cancer patients with a stronger immune system.

Expanding into deep-seated cancer

In collaboration with the University of Tromsø, Lytix has developed a promising new drug candidate, LTX-401 with promising anticancer activity in preclinical models, especially in liver cancer. A new formulation of LTX-401 has demonstrated significantly enhanced anti-cancer activity. This improved formulation not only boosts the drug's efficacy but also has the potential to significantly extend its patent protection. LTX-401 represents a major commercial opportunity by expanding Lytix's focus to include the treatment of deeper-seated cancers.

Lytix has progressed significantly the last period which take the company closer to commercialization. These advancements underscore Lytix's strategic foundation and commitment to late-stage development and commercialization through partnerships. The company looks forward to continued success and the achievement of new milestones in the near future.

Highlights from Q2 2024 and post-period events:

- **Verrica Pharmaceuticals' Phase II study in basal cell carcinoma (BCC) – positive early results**
  - 86 percent overall reduction of tumor size and complete clearance in 51 percent of the patients.
  - Showcase the potential of LTX-315 to be utilized as a first-line therapy in BCC.
- **A new developed LTX-401 formulation provides an opportunity for improved efficacy in addition to prolonged IP protection.**
  - Superior efficacy of LTX-401 in a new developed formulation demonstrated in two "hard to treat" preclinical cancer models.
  - A PCT patent application aiming to protect the new formulation of LTX-401 was published in June 2024.
- **ATLAS-IT-05 study still ongoing – encouraging new interim data from 20 late stage melanoma patients**
  - Disease control in 40% of patients and with stabilization of the disease of up to 17 months
  - Two patients achieving a durable partial response
- **NeoLIPA- expanding to earlier stage melanoma patients with a stronger immune system**
  - The clinical trial application approved in April 2024
  - Enrollment of patients starting Q3 2024
- **Publications/events**
  - CEO Øystein Rekdal gave a presentation with the title "Oncolytic Molecules Adress the Major Challenge in Current Cancer Therapy" at the Immuno UK 2024 conference in May.
- **Business and Financial:**
  - In H1 2024, Lytix generated a revenue of NOK 10.5 million for the sale of LTX-315 to Verrica for use in their clinical trial.
  - Lytix raised NOK 50 million in a share offering primarily directed towards existing shareholders, extending the cash runway into 2025.

In April, Lytix Biopharma successfully raised NOK 50 million, backed by strong support from existing shareholders and interest from new investors. This funding will enable the company to progress through key upcoming milestones.

The results will be presented in a webcast with CEO Øystein Rekdal and CFO Gjest Breistein today at 10.00 CEST.

The presentation and subsequent Q&A session will be held in English and may be viewed live by registering here: https://forms.office.com/e/iBe6HkGYmW

A recording of the presentation will be made available on https://www.lytixbiopharma.com/investors/financial-reports.html (after the presentation).

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About Lytix:
Based in Oslo, Norway, Lytix Biopharma is a clinical-stage biotech company with a highly novel technology based on world leading research in host-defense peptide-derived molecules. Lytix Biopharma's lead product, LTX-315, is a first-in-class oncolytic molecule representing a new principle to boost anti-cancer immunity. Lytix Biopharma has a pipeline of molecules that can work in many different cancer indications and treatment settings, both as mono- and combination therapy.