Lytix Biopharma Q4 and H2 2023 results: Promising interim results from multiple phase II studies, expanding clinical roadmap to early-stage cancer patients

Oslo, 29 February 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 fourth quarter and second half 2023 results.

During the fourth quarter, the company reached important clinical progress through positive interim results from both its phase II studies on different types of skin cancer with its lead product candidate LTX-315. Early results from the partnership study on basal cell carcinoma (regular skin cancer) with Nasdaq-listed Verrica Pharmaceuticals were positive, with complete clearance of cancer cells in four out of six patients treated with the highest dose of Lytix' LTX-315. The entire study is set to be completed in H1 2024.

"Lytix is maturing with two highly promising clinical studies approaching conclusion, providing a solid foundation for our further clinical development. Our unique cancer drug is injected directly into the tumor and combined with other treatments activating the body's immune system, we are well positioned to solve the shortcomings of today's cancer treatment. In addition, we are looking forward to initiating a Phase II study in earlier-stage cancer patients with a more robust immune system and a larger commercial potential", says Dr. Øystein Rekdal, CEO of Lytix Biopharma.

Highlights from Q4 and H2 2023 and post-period events:

Partnership:

- **Verrica Pharmaceuticals' Phase II study in basal cell carcinoma – Positive early results.**
    - Verrica reported positive early results from Part 1 of its ongoing Phase II trial in August 2023.
        - Complete clearance of basal cell carcinoma cells in four out of six patients treated with the highest LTX-315 dose.
    - In January 2024, Verrica reported that all patients have been dosed in their Phase II trial and that they will complete the entire study in H1 2024.

R&D:

- **ATLAS-IT-05 study ongoing – Encouraging interim data from 20 melanoma patients.**
    - In August, Lytix announced complete enrollment of 20 patients.
    - Clinical interim data obtained from all patients.
        - Disease control in approximately half of the patients with durable responses up to one year and one patient with partial response.
    - LTX-315 in combination with pembrolizumab was well tolerated.
- **Expanding to earlier-stage melanoma patients with a stronger immune system**
    - Investigator-led neoadjuvant Phase II study at Oslo University Hospital, Radiumhospitalet planned to start in H1 2024.

- The study protocol was presented at the 15th Nordic Melanoma Meeting in October 2023.
- In December 2023, the clinical trial application for the NeoLIPA trial was submitted to the regulatory authorities for approval.

- **Clinical results generating attention in highly profiled journals**
  - Results from the ATLAS-IT-04 study were published in a paper entitled "LTX-315 and adoptive cell therapy using tumor-infiltrating lymphocytes generate tumor-specific T cells in patients with metastatic soft tissue sarcoma". The paper was published in OncoImmunology, a high-profile, open-access journal.
  - A paper describing LTX-315 unique way of activating immune cells that are critical for T cell priming has been accepted for publication in the high profiled journal Frontiers of Cancer.
- **Strengthening intellectual property**
  - Two Patent Corporation Treaty (PCT) applications were filed in December 2023 to secure additional IP protection.

Business and Financial:

- In October the Research Council of Norway approved Lytix's application for up to NOK 14.3m (US$1.3m) of non-dilutive financial support from the 'SkatteFUNN' R&D tax incentive scheme for a project in respect of its lead program: 'Intratumoral LTX-315 in advanced melanoma'.

The full report and a presentation are linked to this press release (and available at https://www.lytixbiopharma.com/investors/financial-reports.html).

The results will be presented in a webcast with CEO Øystein Rekdal, CDO Graeme Currie and CFO Gjest Breistein today at 15.00 CET. As part of the webcast, the KOL Dr. Robert Andtbacka will share his perspective on our clinical development program and strategy.

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/veVZgFKk2C

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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Lytix in brief:
Based in Oslo, Norway, Lytix Biopharma is a clinical stage immuno-oncology company developing novel cancer immunotherapies, an area within cancer therapy that is aimed at activating the patient's immune system to fight cancer. The Company's technology is based

on pioneering research in “host defense peptides” – nature’s first line of defense towards foreign pathogens. Lytix Biopharma’s lead product, LTX-315, is a first-in-class oncolytic molecule representing a new and superior *in situ* therapeutic vaccination principle to boost anti-cancer immunity, with the potential to be the ideal combination partner with other types of immunotherapy. LTX-315 target cancer cells and disintegrate their cell membranes, causing immunogenic cell death and release of a patient’s tumor specific antigens. This mode of action allows cytotoxic T cells to recognize, infiltrate, and attack cancer cells. The Company was listed on Euronext Growth in Oslo in June 2021, following a private placement covered by investors such as PBM Capital, a US based, healthcare-focused investment firm.