First patient treated in new phase II clinical trial at Radiumhospitalet in Oslo – promising use of Lytix cancer treatment in patients with early-stage melanoma

Oslo, Norway, November 6, 2024 - Lytix Biopharma, a Norwegian immuno-oncology company dedicated to being part of tomorrow's cancer treatment, announces that the first patient has been treated in a new Phase II trial (NeoLIPA). The study evaluates the effect of Lytix's lead drug candidate, LTX-315, in early-stage patients diagnosed with melanoma. Melanoma is the most severe type of skin cancer with a rising incidence globally and an estimated global market of USD 11 billion by 2030.

"By expanding our clinical trials to early-stage melanoma patients we are adding to our robust portfolio of clinical studies. Melanoma includes an extensive population of patients, implying a vast commercial potential for Lytix Biopharma. In addition, our treatment may provide several important advantages for this patient population," says Dr. Øystein Rekdal, CEO of Lytix Biopharma.

The investigator-led trial run by Oslo University Hospital (Radiumhospitalet) will enroll approximately 27 patients. The NeoLIPA trial will be led by Dr. Henrik Jespersen, Head of Melanoma at Oslo University Hospital and interim results from the study are expected in H2 2025.

Combination therapy
All patients will be treated with LTX-315 and standard immunotherapy (pembrolizumab) at an early stage of the disease (neoadjuvant setting). This setting allows for treating early-phase patients before undergoing surgical removal of their melanoma lesions.

"Leaning on the promising results from our ongoing study in late-stage melanoma patients, we have high expectations for LTX-315 also in early-stage patients with the same disease. These patients often have a more robust and responsive immune system, increasing the likelihood of a positive response to LTX-315. With its dual ability to kill cancer cells locally and activate the immune system to target cancer cells elsewhere, LTX-315 may represent an ideal combination agent with the current standard of care for early-stage melanoma. This combination could potentially prevent disease recurrence in many patients compared to the current treatment." he says.

Lytix Biopharma has today three ongoing phase II studies in the US and Europe, one (ATLAS IT-05) in patients with late-stage melanoma, another in patients with basal cell carcinoma in the US with partner Verrica Pharmaceuticals, and this third (NeoLIPA) that has been initiated at Radiumhospitalet, Oslo, Norway in early-stage melanoma patients.

Need for new therapies to improve patient outcomes
Melanoma patients often experience recurrence of their disease even after surgical

removal. New and more effective treatments are therefore needed to treat these patients with early-stage melanoma.

“There is still a need for new therapies that can improve melanoma patient outcomes. Currently, PD-1 inhibitors are used as standard of care for early-stage melanoma patients that are eligible for surgery. Since LTX-315 address some of the shortcomings of PD-1 inhibitors we are excited to investigate the effect of LTX-315 combined the PD-1 inhibitor, pembrolizumab, before surgery in this patient population. We are very delighted to have now started enrolling patients to the NeoLIPA study and look forward to investigating the clinical outcome and immunological responses with this new combination,” Dr. Henrik Jespersen says.

PD-1 inhibitors help the immune system to attack cancer cells.

Vast market
The market for melanoma treatment is expected to increase to USD 11.0 billion in 2030, according to market analyses done by Grand View Research[(1)]. This represents an annual growth of more than 10 percent from today. More than 300 thousand new patients get melanoma every year and this type of skin cancer disease often has severe consequences due to the risk of recurrence at other locations in the body.

About the study
In the NeoLIPA trial, LTX-315 and pembrolizumab will be given as a combination treatment before surgery. Pembrolizumab is currently the standard-of-care immune checkpoint inhibitor used to treat patients with early-stage and resectable melanoma. The primary endpoint of the trial is the pathologic complete response (pCR) rate, i.e. the complete absence of cancer cells in tissue samples removed during surgery. Key secondary endpoints are time to recurrence and overall survival.

The main study aim is to find out whether combined neo-adjuvant treatment of LTX-315 and pembrolizumab improves the pCR rate and prevents more patients from experiencing a recurrence of their melanoma disease.

For more information, please contact:
Dr. Øystein Rekdal, CEO
oystein.rekdal@lytixbiopharma.com
+47 975 73 358

Gjest Breistein, CFO
gjest.breistein@lytixbiopharma.com
+47 952 60 512

About Lytix Biopharma
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.

(1) https://www.grandviewresearch.com/industry-analysis/melanoma-therapeutics-market