Lytix Biopharma AS: Phase II preliminary results from skin cancer (BCC) clinical trial show an 86 percent overall reduction of tumor size, complete clearance in half of the patients and the potential to be utilized as a first-line therapy

Oslo, 14 August 2024. Lytix Biopharma ("Lytix") announces that its Nasdaq-listed licensing partner Verrica Pharmaceuticals reports positive top-line Phase II results from its study in patients with basal cell carcinoma (BCC) - the largest skin cancer disease globally with a projected global market size of USD 11.5 bn in 2028 (CAGR 7.9%) and 3.6 million new cases in the US annually [1].

The study investigates Lytix's lead drug candidate LTX-315 in BCC patients and shows impressively an:

- 86 percent overall reduction of tumor size
- 51 percent complete clearance rate of basal cell carcinomas (total removal)
- 71 percent average reduction in tumor size of patients with residual carcinomas

Based on the phase II data and primary market research, Verrica states that Lytix's leading drug candidate "has the potential to be utilized as a first-line therapy". The preliminary efficacy results were retrieved from 93 patients and included a highly favorable safety profile with no severe adverse events.

"Together with our partner Verrica, we're immensely proud of these results, showing that our lead drug candidate LTX-315 has a powerful anticancer effect in basal cell carcinoma. It has the potential to be used either alone or in combination with surgery in early lines of treatment in this vast cancer population. This is a major leap for our unique treatment technology and an instrumental milestone in progressing LTX-315 towards commercialization", says Dr. Øystein Rekdal, CEO of Lytix Biopharma.

Verrica will host a conference call today, August 14, at 14:30 CEST which can be accessed through this link:
https://viavid.webcasts.com/starthere.jsp?ei=1678543&tp_key=8db298d3d3

Lytix will host a webcast tomorrow, 15 August, at 11:00 CEST which can be accessed through this link:
https://channel.royalcast.com/hegnarmedia/#!/hegnarmedia/20240815_12

Licensing partners for skin cancer diseases
In 2020 Lytix entered a worldwide license agreement with Verrica Pharmaceuticals to develop and commercialize LTX-315 for dermatologic oncology conditions (skin cancer) except metastatic melanoma and Merkel cell carcinoma. Verrica Pharmaceuticals is a US-based dermatology therapeutics company developing medications for skin diseases requiring medical interventions.

[1] www.skincancer.org/skin-cancer-information/skin-cancer-facts /

Basal cell carcinomas are typically found in areas of the body more exposed to the sun, with ~80% of BCCs located on the face and head[2], and the disease has a high unmet need for new treatment options.

"The encouraging Phase II data with our lead drug candidate demonstrate our commitment to developing innovative immunotherapies for cancer patients. And we are excited to follow Verrica's further development of LTX-315 to commercialization. The findings from Verrica confirm Lytix's advanced role in drug development for the global cancer segment", said Rekdal.

Verrica expects to finalize the phase II study in H1 2025 and plans to request an End-of-phase 2 meeting with the Food and Drug Administration (FDA) to determine next steps for the development of VP-315 for the treatment of BCC in the first half of 2025.

Financial implications and next steps
Under the license agreement with Verrica Pharmaceuticals, Lytix may receive aggregate payments of up to USD 110 million upon achieving certain clinical, regulatory, and sales milestones and tiered royalties based on worldwide annual net sales ranging in the low double digits to the mid-teens.

"This is a result of dedication and hard work for more than 20 years. LTX-315 effectiveness is now proven in one of the largest cancer indications globally. Verrica has already succeeded in commercializing a medical drug for skin disease and we are convinced that Verrica will move forward in the most optimal way to explore the possibilities and paths forward to commercialize the LTX-315 (VP-315)", adds Rekdal.

Expanding to early-stage patients in new Phase II study
Lytix currently has ongoing phase II studies in patients with various types of skin cancer, both in the USA and Europe. The positive results in patients with basal cell carcinoma are encouraging for Lytix's new Phase II study at the Radium Hospital, Norway.

LTX-315 will be tested in patients in early-stage melanoma of the illness before surgical intervention, the so-called neoadjuvant setting. The study is set to initiate during the current quarter, led by Dr. Henrik Jespersen, Head of Melanoma Oncology at Radium Hospital.

"Interim data from this study is expected next year and represents the next major milestone for Lytix. In addition, the positive news from Verrica makes us even more motivated to bring our next lead candidate LTX-401 to the clinic. We foresee a large commercial potential for this compound in deep-seated cancer types such as liver cancer". continues Rekdal.

[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7192293/

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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.

About Verrica
Verrica is a dermatology therapeutics company developing medications for skin diseases requiring medical interventions. On July 21, 2023, YCANTH® (cantharidin), became the first treatment approved by the FDA to treat adult and pediatric patients two years of age and older with molluscum contagiosum, a highly contagious viral skin infection affecting approximately 6 million people in the United States, primarily children. YCANTH (VP-102) is also in development to treat common warts and external genital warts, two of the largest remaining unmet needs in medical dermatology. Verrica is also developing VP-103, its second cantharidin-based product candidate, for the treatment of plantar warts. Verrica has also entered a worldwide license agreement with Lytix Biopharma AS to develop and commercialize VP-315 (formerly LTX-315 and VP-LTX-315) for non-melanoma skin cancers including basal cell carcinoma and squamous cell carcinoma. For more information, visit www.verrica.com.