

February 22, 2013 Newsletter from Lytix Biopharma AS

X Lytix Biopharma enrolls first patient in LTX-109 Phase II PoC infection study

Newsletter in Norwegian, click here.

The Norwegian pharma company Lytix Biopharma today announced the enrollment of the first patient in a Phase II clinical study aimed at developing a novel treatment for impetigo, overcoming bacterial resistance.

The study is Lytix Biopharma's fourth trial with the drug candidate LTX-109. Up to 210 patients above two years of age will be enrolled at two medical centers in the Dominican Republic. Patients suffering from impetigo will be treated with either 1% or 2% LTX-109 or placebo. They will be treated three times per day over a five day period.

Skin infections like impetigo are common among young children in several regions of the world. The infections are generally uncomplicated, but highly contagious, and are usually managed by topical agents. However, increased bacterial resistance to these drugs is becoming a problem. Resistance has been reported in as much as 50 per cent of the impetigo cases being treated at a single dermatology clinic.

"The study is an important milestone for Lytix Biopharma. A successful result will demonstrate that LTX-109 can become a new and effective treatment for children with impetigo, regardless of bacterial resistance," said Lytix Biopharma CEO Unni Hjelmaas.

"If this study proves positive, LTX-109 will have a potential for treating also other types of skin infections" said Chairman of the Board Knut Eidissen

Results from the Phase II study are expected in the first half of 2014.

For further information, please contact Unni Hjelmaas, CEO, telephone +47 9151 9651, e-mail unni.hjelmaas@lytixbiopharma.com.

Lytix Biopharma has a technology based on nature's own defence mechanisms. The membranes of harmful cells are destroyed, enabling the body's immune system to engage in a powerful way. The Company's technology has the potential to meet two immense medical needs: A new way to overcome bacterial resistance and a novel approach to cancer treatment. Lytix Biopharma's strategy is to develop drug candidates to Proof of Concept (PoC) level before seeking partnerships with industry majors. See www.lytixbiopharma.com.

About LTX-109

LTX-109 is a synthetic, bactericidal antimicrobial peptide, which rapidly degrades the membranes of harmful micro-organisms. Development focus has so far been on topical treatment of skin infections and nasal eradication of Staphylococcus aureus, regardless of resistance. The infection drug candidate has proven a broad spectrum of activity against bacteria, fungi and yeasts, including drugresistant strains.

The following clinical trials with LTX-109 have been completed:

- 1. A first in man Phase I study to investigate tolerability and safety of topical LTX-109 in healthy subjects (Study C08-109-01)
- 2. A Phase I/IIa study to evaluate the safety, tolerability and efficacy of topical LTX-109 in subjects nasally colonized with methicillin-resistant/-sensitive Staphylococcus aureus (MRSA/MSSA; Study C10-109-02)
- 3. A Phase IIa pilot study to evaluate the safety, tolerability and efficacy of LTX-109 in patients with uncomplicated, Gram-positive, skin infection (Study C10-109-03)

C Lytix Biopharma AS

Lytix Biopharma AS is a privately-owned pharmaceutical company focussed on anti-microbials and cancer therapeutics. Our mission is to improve human health. The Company develops novel drugs for the treatment of resistant bacterial and fungal infections, as well as first-in-class oncology treatments. This has resulted in an exciting pipeline - comprising both ultra-broad spectrum antimicrobials and an entirely new class of dual-action cancer therapeutics. For potential partners, we offer attractive co-development and licensing opportunities.

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