

## IXALTIS presents positive results from phase 2 studies for its lead compound Litoxetine, a potential “first in class” treatment for urinary incontinence.

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Toulouse (31) / Archamps (74), October 1st, 2019 – Ixaltis is pleased to announce that the results from both phase 2 studies for its main compound Litoxetine (LTX) have been presented at major urology conferences during 2019. Litoxetine is an SSRI (Selective Serotonin Reuptake Inhibitor) and serotonin agonist-antagonist with specific activities on some receptor subtypes. This profile makes it a candidate for treatment of urinary incontinence, a disease that affects millions of patients worldwide and impacts significantly quality of life while inducing significant costs. The clinical program with litoxetine in urinary incontinence conducted to date comprised two studies conducted in Europe, Canada and USA in a total of about 300 patients and has demonstrated a clinically meaningful treatment effect to reduce involuntary urinary leaks.

The effect seems to be more pronounced in patients with more severe urinary incontinence. The improvement in incontinence frequency (reduction in number of leaks) is accompanied by an improvement in patient perception of their bladder condition and its impact on their quality of life. Few subjects discontinued treatment due to side effects, which suggests that LTX is well tolerated. Side effects that appear after treatment start are generally mild or moderate in severity, transient and resolve spontaneously. Dr Dudley Robinson MD FRCOG, Consultant Urogynecologist at Kings College Hospital, London, UK who participated in the study says: “Mixed urinary incontinence, the complaint of both stress and urgency incontinence, is the commonest type of urinary incontinence to affect women. It significantly impairs Quality of Life. The Phase II studies with litoxetine in Europe and North America have suggested that Litoxetine is a safe and effective treatment for mixed urinary incontinence, and possibly offers an important first in class emerging medical treatment for women with mixed urinary symptoms.” On the basis of these encouraging results, Ixaltis is preparing for meeting with Regulatory Authorities and finalize plans for phase 3, while in parallel looking for partnerships for pursuing this development.

\* \* \*

Start-up biopharmaceutical company specialized in genitourinary diseases, Ixaltis was born out of the combined expertise of scientists specialized in urology, pharmaceutical experts and experienced managers: Dr. Philippe Lluet, Christian Chavy, Stefano Palea, Dr. Roberto Gradnik and Prof Pascal Rischmann and Xavier Gamé. Its vision is to develop treatments for genito-urinary tract diseases by identifying drugs having already reached clinical stage and re-explore these for use in genitourinary tract disorders. Ixaltis has established a proprietary position covering Litoxetine for use in urogenital and other disorders based on its specific mechanism of action. Overall, urinary incontinence affects about 400 million people worldwide and up to 50% of women over 50, with an estimated trend to increase in prevalence. No medical treatment is currently approved for mixed urinary incontinence.

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