Urinary incontinence: IXALTIS' Litoxetine, a potential "first in class" treatment for mixed urinary incontinence, progresses in its development and hits new milestones

Thursday 20 February, 2020

Toulouse (31) / Archamps (74), Feb 20th 2020 – **Ixaltis** is pleased to announce completion of Scientific Advice and End-of-Phase 2 interactions with EMA and FDA respectively. The interactions enable **Ixaltis** to finalize the design of the registrational development program in urinary incontinence for its lead compound Litoxetine with the aim to complete a Marketing Authorization Application /New Drug Application. Litoxetine is an SSRI (Serotonin Selective Reuptake Inhibitor) and serotonin agonist-antagonist with specific activities on some receptor subtypes and would address an unmet medical need in patients suffering from moderate to severe mixed urinary incontinence. Mixed urinary incontinence represents about a third of all incontinence cases and no specific treatment is currently available to patients.

The positive results from the phase 2 program have been accepted for presentation at the upcoming European Association of Urology (EAU) congress in March 2020. These data paved the way for the constructive and collaborative discussions with EMA and FDA to finalize the design of further development.

Ixaltis is currently exploring options on how to best conduct this development program.

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Start-up pharmaceutical 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 Lluel, Christian Chavy, Stefano Palea, Dr. Roberto Gradnik and Professors 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 with high medical need. **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. It is affecting significantly quality of life and is linked with substantial costs to the healthcare system. No medical treatment is currently approved for mixed urinary incontinence.

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