PRESS RELEASE

Urinary incontinence:
IXALTIS expands development of Litoxetine to the USA

Toulouse (31) / Archamps (74), October 16th, 2017 - Following the launch of the phase II clinical study of its leading compound Litoxetine IXA-001 in Europe and Canada, **Ixaltis** announces the acceptance by the Food and Drug Administration of their Investigational New Drug (IND) application.

The open IND will allow Ixaltis to conduct a clinical study in the US with the objective of assessing the safety, tolerability and efficacy of Litoxetine as treatment for men and women suffering from urinary incontinence.
While Ixaltis has already initiated a phase II clinical study in women affected by Mixed Urinary Incontinence disorders in Europe (25 centres in 6 countries: Canada, France, Georgia, Poland, Ukraine and United Kingdom), the start of clinical development in USA represents a major step in the program investigating the role of litoxetine to address unmet medical need in patients facing urinary incontinence.

Professor Roger Dmochowski (Vanderbilt University Medical Center, Nashville - USA), comments: "*Urinary incontinence represents an extremely common condition amongst individuals with urinary issues, and has significant quality of life impact. The possibility of an effective oral therapy to this condition would represent a great addition to care of those with urinary problems. New options would be warmly received by both patients and medical care givers*."

Ixaltis looks forward to working with clinical experts in the US in order to progress the study.

Overall, urinary incontinence affects about 400 million people worldwide and up to 50% of women over 50, with an estimated 21% increase in prevalence by 2018. No medical treatment is currently approved for mixed urinary incontinence.

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Ixaltis is a start-up pharmaceutical company specialized in genitourinary and renal diseases. It has acquired the rights to three molecules from Sanofi, and completed a round A of financing in 2016 to develop these compounds further. The company recently launched its first Phase II clinical study of its leading compound Litoxetine IXA-001.

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