IXALTIS announces successful completion of phase 2 for its lead compound Litoxetine, a “first in class” treatment for urinary incontinence.

Tuesday 14 May, 2019

Toulouse (31) / Archamps (74),May 14th, 2019 – **Ixaltis** is pleased to announce successful completion of the phase 2 of clinical development in urinary incontinence for its lead compound Litoxetine. Litoxetine is an SSRI (Selective Serotonin Reuptake Inhibitor) and serotonin agonist-antagonist with specific activities on some receptor subtypes

The positive results pave the way to progress to phase 3 for this compound with the potential of being “first in class” for treating mixed urinary incontinence, a disease for which there is no approved medical treatment on the market.

The clinical phase 2 program included two studies:

- the first one, a double-blind placebo-controlled dose finding trial, recruited about 200 women with mixed urinary incontinence in several European countries and Canada. Results after 12 weeks of treatment showed a clinically meaningful and dose dependent reduction in episodes of incontinence, which was even greater and statistically significantly better than placebo in the more severe subgroup and for the dose of 40mg bid. The active treatment was also shown to markedly improve quality of life as measured by three different specialized questionnaires.

- The second one, conducted exclusively in the USA, explored safety and efficacy after 8 weeks of treatment with a forced dose escalating schedule up to 30 mg bid; about 90 patients, men and women with urinary incontinence, were recruited. Litoxetine caused a reduction of incontinence episodes which was both clinically meaningful and statistically larger than placebo.

Both studies showed very good safety and tolerability, with side effects typical of this class of drugs appearing at a low rate. Only one severe side effect was registered in the total of nearly 300 patients.

These results led Prof R. Dmochowski (Vanderbilt University, Nashville, USA) to comment: “*I find this data truly exciting as this compound may represent a novel effective and safe therapy for patients with mixed and stress predominant incontinence, given that no effective pharmacotherapy yet exists for these patients*”.

On the basis of these encouraging results, Ixaltis is planning to meet the regulatory authorities and finalize plans for phase 3, while in parallel exploring different strategic options for pursuing this development.

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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 Lluel, 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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