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Servier, Neurochlore initiates trial to evaluate bumetanide in ASD children

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The pediatric investigation plan, which involves the use of an oral liquid formulation for children, has beenapproved by the Pediatric Committee of the European Medicines Agency.

Servier, an independent, international pharmaceutical company, and Neurochlore, French biotechnology, announce the launch in Europe of phase 3 studies to evaluate the use of bumetanide in children suffering from Autism Spectrum Disorders (ASD).

The pediatric investigation plan, which involves the use of an oral liquid formulation for children, has been approved by the Pediatric Committee of the European Medicines Agency. Two multicenter, randomized, double-blind, placebo-controlled clinical trials conducted by Servier are underway and will evaluate the efficacy and safety of bumetanide administered twice a day to children suffering from ASD aged 2 to 6 years and 7 to 17 years.

The main aim of these trials is to evaluate the efficacy and safety of bumetanide, compared with placebo, on the core symptoms (persistent impairment in reciprocal social communication and interaction and restricted and repetitive patterns of behavior) of ASD after 6-month treatment. Overall the total duration of each of these two trials will be one year. Following the 6-month evaluation period versus placebo, all the patients will be treated with bumetanide for a period of 6 months. Each patient will thus have the opportunity to be on active treatment for at least 6 months.

Servier has obtained the required authorizations to conduct these clinical trials in some European countries (France, Spain, Hungary, Germany, Italy, Poland and United Kingdom). Following additional regulatory approval, other European countries and countries outside Europe should be included as well in these trials. The objective is to recruit approximately 200 patients in each study.

Bumetanide reduces the high concentrations of chloride observed in neurons in certain neurodevelopmental disorders like ASD. In 2017, Neurochlore published results supporting efficacy and safety from its phase 2b study with bumetanide in 6 centers in France in almost 90 children (aged2-18 years). Bumetanide’s favorable effects on several aspects of ASD allow to envision management of autism, particularly of its core symptoms.

Professor Ben-Ari, President of Neurochlore, commented: “We are pleased with the launch of these phase 3 studies which are in the continuum of our ongoing research into autism, for which there is still no drug treatment."

These clinical studies are in the frame of a partnership agreement signed in 2017 in which Servier will develop and commercialize bumetanide in Europe while Neurochlore will retain the rights for the rest of the world.