FDA approves Infant Bacterial Therapeutics' request for a new orphan drug designation

Building upon Infant Bacterial Therapeutics AB's (IBT) unique expertise in developing treatment solutions for preterm infants, IBT is at an early stage of investigating the possibilities of developing a drug to prevent retinopathy of prematurity, a growing and serious condition that often leads to blindness among prematurely born babies. The FDA granted orphan drug designation for IBT's product on Sep 20th .

Retinopathy of prematurity affects 50-70% of preterm infants weighing less than 1,500 grams at birth, in several cases leading to patients becoming legally blind. Current treatments do not sufficiently address the medical need with severe cases growing significantly from 1.7 to 14.8 per 1,000 preterm infants between the years 1990 and 2011.

Orphan drugs are either drugs or biologics intended for the treatment, diagnosis or prevention of rare diseases or disorders affecting less than 200,000 patients in the US per year. An orphan drug designation qualifies the company applying for it to receive certain benefits from the US government, such as tax reductions and long term market exclusivity, in exchange for developing the drug.

The approval does not change the standard regulatory requirements and processes for obtaining marketing approval for a product. Consequently, all aspects of the development must be investigated, including the clinical safety and efficacy documentation required for a market authorisation.

The drug candidate is a dipeptide developed under the leadership of Dr. Josef Neu, Professor at University of Florida Health, Department of Pediatrics, Division of Neonatology and Dr. Maria Grant, Professor at University of Florida Health, Department of Endocrinology, Diabetes and Metabolism.

“Advances in neonatal intensive care include survival of extremely preterm infants that are highly susceptible to retinopathy of prematurity (ROP), a major cause of blindness in children. Current treatment strategies are based on prevention of progression once an early stage of the disease is diagnosed. These are invasive and involve interventions that are often difficult for these infants to tolerate. Studies in animal models of retinopathy support the preventative potential of arginyl-glutamine dipeptide. Our goal is to determine whether this agent can be provided at a stage that will prevent even the early onset of this disease, thereby eliminating or decreasing the need for future invasive procedures and most importantly, progression to blindness”, says Professor Josef Neu.

“We are honored to be working with Professor Josef Neu on this initiative and pleased that the FDA has granted the product orphan drug designation. We are now investigating if, and how, we can contribute to the care of these patients. IBT has established unique competencies by pursuing treatment solutions for preterm infants, new pathways through

pharma grade probiotics as well as enabling a healthy microbiome across the gastroenterology field. These competencies allow us to assess potential portfolio expansion opportunities. Retinopathy of prematurity aligns with our core focus in developing the drug candidate IBP-9414, for the prevention of necrotizing enterocolitis ("NEC") and improvement of feeding tolerance in premature infants. We continue to expect to complete IBP-9414 recruitment with existing capital and are concurrently investigating this new opportunity with minimum financial exposure", says Staffan Strömberg, Chief Executive Officer, IBT.

For additional information please contact

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