PRESS RELEASE

OM Pharma successfully submitted an IND application to the FDA

OM Pharma announces that the U.S. Food and Drug Administration (FDA) has cleared the Investigational New Drug (IND) application for a phase IIb study of OM-85 in the United States in recurrent wheezing episodes in children aged 6 months to 5 years with recurrent wheezing.

Geneva, Switzerland, XX December 2022 - OM Pharma announced today that the U.S. Food and Drug Administration (FDA) has cleared its IND application for the phase IIb clinical study, a randomised placebo-controlled, double-blind, multicenter study to assess the efficacy and safety of OM-85 versus placebo given on top of routine treatment in children aged from 6 months to 5 years with recurrent wheezing episodes randomised.

OM-85, an extract of different bacterial species, is already marketed in 64 countries under the trademark Broncho-Vaxom® for the prevention of recurrent respiratory tract infections. It has not yet been authorised for commercialisation in the United States.

Wheezing is a high-pitched whistling sound made while breathing, often associated with difficulty in breathing. Recurrent wheezing episodes are common in the early years of life; one in three children has at least one episode of acute wheezing before the age of three, with a prevalence of 50% at the age of 6 years[1,2], and in the United States they are among the leading causes of hospital admission.[3]

“We are extremely pleased with the FDA’s acceptance of the initiation of our OM-85 Phase IIb trial in preschool children with wheezing. This is an important milestone for OM Pharma towards addressing this high unmet need in paediatric population”, said Dr Mathias Knecht, Chief Medical Officer at OM Pharma.

Josef Troxler, CEO of OM Pharma, commented: “This is an important step in the company's ambition to expand its global presence, particularly in the United States, and to continue to develop as a global biopharmaceutical company, addressing the unmet needs of a growing number of patients”.

This successful submission further underscores OM Pharma's ability to become a leading global biopharmaceutical company focused on improving the lives of patients by building on its unique heritage in bacterial lysates.

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[1] Martinez FD, Wright AL, Taussing LM, Holberg CJ, Haloen M, Morgan WJ. Asthma and wheezing in the first six years of life. *N Engl J Med* 1995;332:133-8.
[2] Bisgaard H, Szefler S. Prevalence of asthma-like symptoms in young children. *Pediatr Pulmonol* 2007;42(8):723-8.
[3] Mansbach JM, Camargo CA, Jr. Respiratory viruses in bronchiolitis and their link to recurrent wheezing and asthma. *Clin Lab Med* 2009;29(4):741-55.

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About OM-85

OM-85 is an extract of several different bacterial species, indicated in the prevention of recurrent respiratory tract infections for both adults and children. Administered orally, it modulates the immune system to help defend against respiratory pathogens.

The first marketing authorisation of OM-85 was obtained in Switzerland in 1979. OM-85 is currently marketed in 64 countries worldwide, under various trademarks, the best-known being Broncho-Vaxom®. It is currently indicated for the prophylaxis of recurrent respiratory tract infections in adults and children from 6 months of age in several European countries and worldwide. OM-85 is currently not authorised for commercialisation in any indication in the United States.

About the OM-85 Phase IIb clinical study

The objective of the Phase IIb clinical study is to demonstrate the efficacy and safety of daily OM-85 versus placebo given in paediatric patients aged 6 months to 5 years with recurrent wheezing episodes. Subjects will be treated with the paediatric formulation of 3.5 mg capsule of OM-85 or placebo, daily for 6 consecutive months (a total of 180 dosing days) with an additional 3-month follow-up period without treatment, to provide a preliminary estimate of the efficacy of OM-85 and to assess the safety of this dosing regimen.

About OM Pharma

OM Pharma is a global Geneva-based biopharmaceutical company. It is a leader in the prevention of recurrent respiratory and urinary tract infections and is also active in the treatment of vascular diseases.

It operates in about 100 countries thanks to a strong network of international partners and invests its profits in R&D to develop microbial derived immunotherapeutic products to treat acute and chronic immunological disorders resulting from inflammation and infections.

On 30 September 2020, Etienne Jornod, former Executive Chairman of Vifor Pharma and Galenica, acquired the company together with entrepreneurs, with the ambition to continue its global expansion and to invest CHF 250 million in R&D and manufacturing capacity expansion.

The company strives to improve the quality of life of patients around the world by providing access to better treatment of immunological imbalances.

For more information, visit the website: www.ompharma.com

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