INFANT BACTERIAL THERAPEUTICS

Press Release February 10, 2021

Infant Bacterial Therapeutics announces that the recruitment to the first stage of the Phase III Connection Study is completed - an update about the clinical development of IBP-9414

Infant Bacterial Therapeutics (IBT) announces that the company has reached an important milestone after recruiting 300 premature infants to the ongoing clinical Phase III study of IBP-9414. This in part means that a safety analysis of these infants will take place in order to also recruit infants with a very low birth weight, which in turn is expected to significantly increase the recruitment rate. Furthermore it means that IBT has an opportunity to validate the study's second primary endpoint, feeding tolerance, and redefine this if necessary.

IBTs clinical Phase III study of its drug candidate IBP-9414 for the prevention of necrotizing enterocolitis and improvement of feeding tolerance in premature infants, the Connection Study, started in July 2019. There are currently 68 neonatal intensive care units (NICUs) open for recruitment in the study. These NICUs are located in France, Hungary, Israel, Spain, the UK and the USA. The clinical trial application has further recently been approved in Bulgaria and Poland and submitted in Romania and Serbia. IBT expects that approximately 20 NICUs will open for recruitment in the coming months in these newly added countries.

The majority of the infants intended to be recruited to the Connection Study will be extremely low birth weight (ELBW) premature infants, i.e they have birth weights of 1000 grams or below. These are the most vulnerable preterm infants and as a precautionary measure the study was designed to include 300 infants with birth weights between 750 and 1000 g in the first stage of the study. After the ongoing safety analysis of these infants the recruitment is intended to be broadened to include infants with a birthweight down to 500 g. This is expected to double the number of infants available for inclusion in the study and we anticipate a significant increase the speed of recruitment in the study.

Prior to commencing the Connection Study, IBT agreed with the FDA to perform a pilot analysis of the first 300 patients with the purpose of qualitatively and quantitatively assessing the clinical meaning of the premature infants ability to, as soon as possible, receive enteral feeding without complication. Together with the external neonatology expert group we will analyze the correlation between sustained feeding tolerance and, for example, the incidence of sepsis in the infants. In accordance with the agreement with the FDA, the purpose of the pilot analysis is to validate the second primary endpoint of the study and if necessary redefine it.

At the beginning of 2020 and prior to the COVID 19 pandemic, recruitment rates were close to those expected and IBT predicted reaching 300 patients during 2020. However, due to the effects of the pandemic, reaching this milestone has been delayed by a number of months. As previously communicated, IBT now anticipates to complete the study in 2022.

Through extensive cooperation with the investigating NICUs, IBT has been able to mitigate the pandemics effects on recruitment, and patients have been recruited during the duration of the pandemic. All patients included in the Connection Study are in-hospital patients and therefore no formal outpatient visits are required. Due to this, hospital restrictions on visiting have not affected the Connection Study. Through for example the use of virtual study monitoring, it has also been possible to maintain study quality in relation to patient data capture.

The pandemic has however affected recruitment to the study in several ways. Firstly, certain hospitals stopped recruitment to all clinical research studies and new studies were not allowed to start as the relevant research staff were allocated other responsibilities. Further, the staff on duty in the NICUs have in some cases been transferred to COVID-related intensive care departments. In addition, neonatologists in the study as well as scientific journals are reporting a dramatic drop in the numbers of premature infants born into their NICUs during the pandemic. Recruitment rates are expected to significantly increase once the pandemic is under control.

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Clinical trial supply is functioning well and the IBP-9414 product is well-accepted by hospital pharmacies involved in the Phase III study. IBT is also pleased that the ongoing stability program for the physical product IBP-9414 is going according to plan.

The cost estimates for the Connection Study performed prior study start correspond to the actual incurred expenses. As previously communicated, IBT estimates that it has sufficient capital to complete the Phase III Study.

The pandemic has in various ways affected the possibility to recruit patients to the study, not least when a limited weight group interval range was chosen as a precautionary measure for the first 300 patients in the study. The first phase of the study is being evaluated at the same time that we can conclude that the study quality is sufficient and that the study can be completed with IBTs current capital. IBT expects that the recruitment rate will increase during 2021 due to the combination of lower impact from the COVID pandemic, continued opening and activation of new hospitals and the fact that the study is expected to include infants with a birth weight down to 500 grams. The medical need for preventive treatment for necrotising enterocolitis and to improve feeding tolerance in preterm infants remains very high.

About Infant Bacterial Therapeutics AB
Infant Bacterial Therapeutics AB (publ) is a pharmaceutical company with a product in clinical stage with a vision to develop drugs influencing the infant microbiome, and thereby prevent or treat rare diseases affecting infants.

IBT is currently developing the drug candidate IBP-9414, for the prevention of necrotizing enterocolitis ("NEC") and improvement of feeding tolerance in premature infants. IBP-9414 contains the active substance *Lactobacillus reuteri,* which is a human bacterial strain naturally present in breast milk. The product portfolio also includes another project, IBP-1016, for the treatment of gastroschisis, a severe and rare disease affecting infants. By developing these drugs, IBT has the potential to fulfill unmet needs for diseases where there are currently no prevention or treatment therapies available.

Infant Bacterial Therapeutics AB ("IBT") is a public company domiciled in Stockholm. The company's class B-shares shares are listed on Nasdaq Stockholm, Mid-cap (IBT B).

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