PRESS RELEASE
30 August 2024 18:38:00 CEST

IBT'S PHASE III STUDY SHOWS NO SIGNIFICANT EFFECTS ON THE PRIMARY ENDPOINTS BUT A SIGNIFICANT REDUCTION IN THE SECONDARY ENDPOINT, ALL-CAUSE MORTALITY

IBT has conducted a phase III study comprising 2153 premature infants for five years. The objective of the study has been to show that the company's drug candidate IBP-9414, a bacterial strain found naturally in human breast milk, can improve the health of premature infants by preventing necrotizing enterocolitis (NEC) and improve premature infants' gastrointestinal function (measured as time to Sustained Feeding Tolerance, SFT) and, as a secondary objective, reduce death. The results of the study have now been analyzed according to the pre-specified statistical analysis plan. Although these analysis showed positive trends, there were no statistical significance for the two primary endpoints: prevention of necrotizing enterocolitis (NEC), active group: 8.7% vs placebo group: 10.2% (p=0.24) and SFT, active group: 16 days vs placebo group: 17 days (p=0.07). Importantly, there was a significant reduction in the secondary endpoint of all-cause mortality, active group: 6.2% vs placebo group: 8.5% (p=0.04), corresponding to a significant risk reduction of 27%, which meant that in reality 23 infants' lives were spared by the administration of IBP-9414 in the study.

IBT will continue the development towards pharmaceutical registration, considering that the study showed statistical significance on all-cause mortality. The previous communicated timeline for the registration might be affected and IBT will revert with an update if any changes will occur. The risk reduction of 27% in mortality is a substantial effect size and comparable to currently available pharmaceutical products, for example, surfactants used in the neonatal intensive care units. The effect of IBP-9414 could potentially save the lives of thousands of infants per year and is the only Live Biopharmaceutical candidate that has shown a strong advantage in saving premature infants' lives.

Furthermore the study shows that giving IBP-9414 to these very vulnerable premature infants does not cause any safety issues, including the risk of sepsis which has been a concern expressed by the FDA for the use of probiotic products in preterm infants.

"It is becoming clear to the scientific community that NEC is a poorly defined diagnosis representing several different processes. This is the likely reason for the results obtained on the NEC endpoint. Regarding the SFT endpoint, feeding patterns between intensive care units differed more than expected, which could explain the SFT results. The observed difference of 27% in lowered mortality in the active group is exciting and cannot be ignored," says Josef Neu, Professor of Pediatrics at the University of Florida and principal investigator of the study.

"Over the years, neonatal intensive care has significantly improved the survival of preterm infants. Fifty years ago, only 5-10% of the smallest babies survived. Today, the corresponding survival rate is much higher at 80%. Several factors, such as mechanical ventilation and pharmaceuticals like

surfactants, have significantly contributed to this positive development. With our study data, I expect that IBP-9414 could be the next major improvement targeting the gut, as it is now established that the product increases the survival rate of premature infants. I believe the extraordinary and unexpected large effect on survival is even more important than potential improvements in NEC and SFT.

We are extremely grateful for all the excellent work done by our employees and the medical teams in approximately 100 hospitals involved in the study and special thank you to all families who have allowed us to include their infants in the study," says IBT's CEO, Staffan Strömberg.

"Because mortality is considerably lower in the active group, we have decided to pursue our endeavors to register IBP-9414 as a drug. IBT's financial situation is such that we have sufficient resources to continue our development work. IBT's cash position was SEK 272 million at the end of the second quarter. I am confident our competent staff led by Staffan Strömberg will spare no effort to register the product as a pharmaceutical thereby helping many premature infants in the future," says Peter Rothschild, IBT's chairman.

This information is information that Infant Bacterial Therapeutics is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2024-08-30 18:38 CEST.

Attachments

IBT's phase III study shows no significant effects on the primary endpoints but a significant reduction in the secondary endpoint, all-cause mortality