

Infant Bacterial Therapeutics AB secures partnership with Recipharm Advanced Bio for commercial production of drug substance

- *IBP-9414 targets mortality and gastrointestinal injury in premature infants*
- *With Breakthrough Therapy designation for gastro-intestinal mortality and Rare Paediatric Disease designations, IBP-9414 is on an accelerated path to commercialisation*
- *PPQ (Process Performance Qualification) runs for IBP-9414 begin at Recipharm Advanced Bio's Cuxhaven site, marking a major milestone on the path to regulatory approval.*

Recipharm Advanced Bio, a segment of Recipharm and a leading Contract Development and Manufacturing Organisation (CDMO), and Infant Bacterial Therapeutics AB (IBT), announced the initiation of Process Performance Qualification (PPQ) for IBT's lead product, IBP-9414. The PPQ programme will be conducted at Recipharm's microbial manufacturing facility in Cuxhaven, Germany.

Vikas Gupta, president of Recipharm Advanced Bio, said: "Partnering with Infant Bacterial Therapeutics on this breakthrough therapy underscores our shared commitment to addressing critical unmet needs in vulnerable patient populations. By combining IBT's innovative approach with Recipharm Advanced Bio's microbial expertise and accelerated path to manufacturing, we are ensuring PPQ and commercial readiness are delivered on a fast and reliable timeline, bringing this lifesaving treatment for premature infants fast to market. In addition, we are well positioned to support IBT's future growth with scalable capacity across both Europe and the USA."

Staffan Strömberg, CEO at IBT, said: "IBP-9414 will be the first LBP (Live Biotherapeutic Product) globally, and after careful consideration, we now proceed to Process validation for Drug substance with Recipharm Advanced Bio in Cuxhaven. With the possibility of Recipharm Advanced Bio being a future drug substance supplier, we are strengthening our commercial supply chain possibilities. We feel that we are in good hands for this work, given Recipharm Advanced Bio's deep expertise and understanding of pharmaceutical quality requirements for scalable commercial manufacturing."

Recipharm Advanced Bio's Cuxhaven site offers integrated bacterial capabilities covering the full product lifecycle, from pre-clinical development through commercial supply. The facility provides comprehensive support, including viral and bacterial cell bank production, development, scale-up, and production of virus-based therapies and vaccines (AAV, lentivirus, oncolytic virus), sterile fill and finish, analytical services, recombinant proteins and monoclonal antibodies (mAbs).

Through its network of Advanced Therapies Medicinal Products facilities and centres of excellence (Cuxhaven: Viral vectors and bacteria; Oeiras, Portugal: recombinant proteins and LBPs; and Watertown, USA: nucleic acids), Recipharm Advanced Bio enables comprehensive and accelerated manufacturing to support partners from early development through commercial supply.



For more information

About Recipharm

Recipharm is a leading Contract Development and Manufacturing Organisation (CDMO) employing over 5,000 employees worldwide. Recipharm provides manufacturing services of pharmaceuticals in various dosage forms, including sterile fill & finish, oral solid dosage and biologics; clinical trial material development and manufacturing services; and pharmaceutical product development. Its Recipharm Advanced Bio segment works with customers to develop and commercialise advanced therapy medicinal products (ATMPs): pre-clinical to clinical development, commercial development and manufacture for new biological modalities, encompassing technologies based on live viruses and viral vectors, live-microbial biopharmaceutical products, nucleic acid-based mRNA and plasmid DNA production.

Recipharm manufactures several hundred different products to customers ranging from big pharma to smaller research and development companies. It operates development and manufacturing facilities in France, Germany, India, Israel, Italy, Portugal, Spain, Sweden and the US.

Recipharm Advanced Bio's Cuxhaven site operates under the legal entity, Vibalogic GmbH. Regulatory documentation, including cGMP certification, is listed under this name.

For more information on Recipharm, please visit www.recipharm.com and www.Recipharm-ab.com

About IBT

Infant Bacterial Therapeutics AB ("IBT") is a public company domiciled in Stockholm. The company's Class B shares are since September 10, 2018, listed on Nasdaq Stockholm (IBTB).

IBT is a pharmaceutical company whose purpose is to develop and commercialize drugs for diseases affecting premature babies.

IBT's main focus is the drug candidate IBP-9414, a formulated bacterial strain naturally found in human breast milk. IBP-9414, is expected to be the first product in the new class of biologics called "Live Biotherapeutic Products" for premature infants. The drug development of IBP-9414 is currently in its final stages for this important product for premature babies.

In the recent Phase III Connection study in premature infants, the group treated with IBP-9414 demonstrated a significant 27% reduction in all-cause mortality compared with the placebo group, meaning that widespread use of IBP-9414 could save more than 1000 patients annually in the US alone. The therapy has received both Breakthrough Therapy Designation (March 2025) for gastrointestinal mortality and Rare Paediatric Disease Designation, reflecting its potential to address a significant unmet medical need.

The portfolio also includes additional drug candidates, IBP-1016, IBP-1118 and IBP-1122. IBP-1016, for the treatment of gastroschisis, a life-threatening and rare disorder in which children are born with externalized gastrointestinal organs. IBP-1118 to prevent retinopathy of prematurity (ROP), one of the leading causes of blindness in premature babies, and IBP-1122 to eliminate vancomycin-resistant enterococci (VRE), which cause antibiotic-resistant hospital infections.

Through the development of these drugs, IBT can address medical needs where no sufficient treatments are available.

Contacts

IBT

Staffan Strömberg, CEO

Maria Ekdahl, CFO

info@ibtherapeutics.com

+46 76 219 37 38



Recipharm

Guenaëlle Holloway, Head of communications

Guenaëlle.Holloway@recipharm.com

+44 7730 303 708