PRESS RELEASE 15 October 2025

Recipharm supports landmark trial of next generation pneumococcal vaccine developed by ImmBio and iiCON

- *Recipharm delivers cGMP manufacture of PnuBioVax® enabling progression to phase 2 clinical trials in Malawi.*
- *Demonstrates Recipharm's agility and flexibility, completing full tech transfer, scale-up and process optimisation within three months.*
- *Strengthens Recipharm's position as a trusted partner for innovative and global health collaboration, supporting the development of scalable, affordable vaccines for unmet medical needs.*

Recipharm, a leading global contract development and manufacturing organisation (CDMO), today announced the successful cGMP manufacture of PnuBioVax®, a new protein-based vaccine against pneumococcal disease developed by ImmunoBiology Ltd (ImmBio) and the Infection Innovation Consortium (iiCON). This milestone has enabled the start of Phase 2 clinical trials in Malawi, the largest human challenge trial ever conducted in the country.

The vaccine is being brought forward as part of a £3.2 million Medical Research Council (MRC) funded trial for the disease being delivered by the Infection Innovation Consortium: iiCON, a consortium led by Liverpool School of Tropical Medicine.

Pneumococcal disease, caused by *Streptococcus pneumoniae*, is a leading preventable cause of death in children worldwide, particularly in low- and middle-income countries (LMICs). Despite the existence of current vaccines, emerging resistance and limited serotype coverage have left significant gaps in protection. PnuBioVax® takes a novel approach by targeting proteins common across pneumococcal strains, including Serotype 3 pneumococcus (SPN3), which is driving a rise in severe disease globally.

Recipharm led the cGMP manufacture of PnuBioVax® for Phase 2 trials, following a seamless technology transfer from the Phase 1 CDMO. The team successfully scaled up production, introduced targeted improvements and optimised the process to meet Phase 2 requirements. Alongside this, Recipharm implemented rigorous quality control systems to support consistent, high-quality output, full compliance with stringent product specifications and reproducibility across manufacturing batches.

The results from the Phase 2a trial will inform the vaccine's potential to provide broad, cost-effective protection against multiple pneumococcal serotypes, paving the way for larger-scale trials and eventual commercialisation.

Vikas Gupta, President Recipharm Advanced Bio, said: "We are committed to enabling the development of innovative, accessible vaccines that can address urgent global health challenges. Supporting iiCON and ImmBio to bring PnuBioVax® into Phase 2 cGMP clinical supply is a testament to the strength of collaborative science and manufacturing excellence. We are proud to contribute to a project that has the potential to save lives and reduce the global burden of antimicrobial resistance."

Professor Janet Hemingway, iiCON's founding director, said: "Working to support and accelerate SME innovation is at the heart of iiCON's purpose and we're delighted to have reached this key

stage in the development of PnuBioVax with our collaborators. Our team has worked closely with ImmBio and our manufacturing partner, Recipharm Advanced Bio, to overcome R&D hurdles and enable a smooth tech transfer process to bring this vaccine forward and into clinical trials at our specialist testing facility in Malawi. We are incredibly excited about the potential this product holds to save lives and play a role in addressing a fast-growing global public health concern."

ImmBio developed PnuBioVax and successfully conducted Phase 1 safety and immunogenicity studies. iiCON has since collaborated with ImmBio to lead on the next phase of development of the vaccine, to bring it to Phase 2 clinical trials.

Dr Chris Bailey, Development Director at ImmBio, said: "Recipharm Advanced Bio impressed us with their technical competence in bacterial fermentation, protein purification and analysis. I would highlight the careful consideration of technical risks, building contingencies and delivering Phase 2 clinical grade PnuBioVax to a tight timeline. We are thrilled to see PnuBioVax moving forward through the development pathway with the potential to address a global medical need."

iiCON is now carrying out the Phase 2a clinical trial in Malawi with approximately 400 participants. The programme will trial ImmBio's protein-based pneumococcal vaccine on young healthy adults under a controlled human infection model (CHIM) trial delivered through iiCON's lead partner Liverpool School of Tropical Medicine (LSTM) in Malawi.

CHIM trials for pneumococcal disease have been well established at LSTM for many years and this trial will build on the current £4.5m MARVELS (Malawi Accelerated Research in Vaccines by Experimental and Laboratory Systems) programme at the Malawi Liverpool Wellcome Programme.

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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.

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

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