PRESS RELEASE 3 October 2024

Recipharm strengthens pharmaceutical development capabilities with strategic investments

- *New investments include expanded capabilities in Oral Solid Dosage (OSD), Sterile Fill & Finish (SFF) and complement existing development capabilities.*
- *New product development lab for sterile liquids and lyo products, as well as GMP pilot scale lines for BFS, PFS and vials.*
- *Expanded labs and new GMP pilot scale equipment for product development.*
- *Investment in analytical labs' Extractables and Leachables, Nitrosamines and Elemental Impurities capabilities.*
- *Group offering now covers all phases of product development, from API route scouting and synthesis, to commercial manufacturing, including early- and late-stage development and clinical supply.*

3rd October 2024 – Recipharm, a leading global pharmaceutical contract development and manufacturing organisation (CDMO), is expanding its pharmaceutical development capabilities, through targeted investments and the integration of cutting-edge technologies. This investment bolsters its services for early- and late- stage product development, including clinical study supply at small and pilot scales and wide range of commercial technologies.

Following this investment, Recipharm's fully integrated services will cover the whole life cycle of a molecule from APIs route scouting to commercial manufacturing of pharmaceutical products.

Recipharm's development centres, strategically located in Europe, the US and India, are equipped with state-of-the-art tools and infrastructure to deliver science-driven solutions. Guided by the Quality by Design (QbD) principle, Recipharm's experts leverage the innovative ReciPredict platform, which combines material- and process- sciences, statistical tools, modelling and simulation to drive the development of robust products.

Expanding small molecule development capabilities

Recipharm's centre of excellence for small molecules (NCEs and generics) in Bengaluru, India, is expanding its capabilities with a new lab for sterile product development. This is in addition to the new Extractables and Leachables, Nitrosamines and Elemental Impurities laboratories, which have become Recipharm flagship location for comprehensive analytical services.

In Zwickau, Germany, Recipharm's pilot-scale development centre focuses on dry granulation, tableting and hard capsule filling, with expertise in combination products.

In addition, recent investments at both Bengaluru and Zwickau include advanced material characterisation equipment, a compression and compaction simulator, a Mini-Pactor for dry granulation, a pilot-scale capsule filler and a small-scale tablet press.

Enhancing sterile product development

Recipharm has strengthened its pre-clinical, clinical and pilot scale sterile development capabilities for both small and large molecules, including liquid vials, pre-filled syringes, blow-fill-seal and lyophilised products. Significant investments include the establishment of a development lab for

sterile formulations for small molecules in Bengaluru, the installation of a GMP VarioSys line for vials and pre-filled syringes at the Wasserburg site and a GMP LAB+ equipment at the Kaysersberg site.

Leading the way in Biologics and ATMPs

ReciBioPharm, Recipharm's biologics and ATMP development segment, operates from sites in Watertown in the US, Cuxhaven in Germany and Lisbon in Portugal. The Group's capabilities in biologics include monoclonal antibodies and recombinant proteins, while in the ATMP space, it is at the forefront of developing innovative medicines and supporting clinical trials for microbiome, oncolytic viruses, nucleic acid (xRNA/LNP), viral vectors (AAV, Lentivirus) and bacterial vaccines and therapeutics.

API capabilities

Recipharm's site in Yavne, Israel, continues to offer integrated services from route scouting for new chemical entities up to small scale API for tox studies, first in man studies and early clinical supplies. In addition, related impurity management and analytics are part of the integrated offering.

Commitment to global standards and regulatory excellence

All Recipharm development centres are equipped to support clinical trials across the US, EU and other relevant regions, adhering to the highest regulatory standards. With fully integrated analytical capabilities, Recipharm continues to support the development of new medicines with a commitment to quality and innovation.

Flexibility and agility thanks to experts strategically placed across the Group

Recipharm achieves flexibility and agility through teams of experts strategically positioned across its sites. In Bengaluru, India, its centre of excellence for small molecules (NCE and generics) employs over 60 scientists dedicated to developing oral solids, semi-solids and liquid dose forms, while its analytical services include a team of over 150 scientists, delivering comprehensive expertise. These teams, along with development experts at Wasserburg, Kaysersberg and across all ReciBioPharm sites, work together to provide global support and expertise.

About Recipharm

Recipharm is a leading Contract Development and Manufacturing Organisation (CDMO) employing over 5,200 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 ReciBioPharm division 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 and is headquartered in Stockholm, Sweden.

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

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