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Recipharm strengthens high potency capabilities with new pilot and development investment

- *Investment in new high potency GMP pilot scale capabilities at Leganés, Spain, strengthening support from development through to commercial manufacture*
- *Builds on OEB 5 (0,1-1µg/m³) commercial high potency expertise, including the manufacture of oncology tablets*
- *Enhances Recipharm's global high potency network, combining experts with capabilities across multiple sites.*

Recipharm, a leading global contract development and manufacturing organisation (CDMO), today announced a strategic investment to further strengthen its high potency oral solid dose (OSD) capabilities at its Leganés site in Spain. The new high potency clinical and pilot capabilities, scheduled to be operational by the end of the year, will enhance the company's ability to support customers from development through to commercial supply.

The expansion of high potency clinical and pilot capabilities will enable efficient onboarding of customers with:

- High potency phase III clinical programmes, including process transfer and optimisation
- High potency pilot scale GMP projects
- Small-scale commercial production (10kg+), particularly suited for products such as paediatrics or orphan drugs where high potency containment is required

Coupled with Recipharm's ReciPredict™ modelling platform, the enhanced capabilities will support optimisation of formulation and process design space while safeguarding critical clinical supply milestones.

Leganés is already a cornerstone of Recipharm's high potency network, with commercial OEB 5 (0,1-1µg/m³) containment capability and proven experience supporting high potency oncology products for global customers. This flagship site in Leganes is an FDA-approved site, recognised internally as a key strategic asset based on its advanced technology, strong safety and sustainability culture and demonstrated ability to deliver high quality products reliably and on time.

The new investment will expand the site's capabilities upstream, enabling customers to accelerate late-stage development and clinical programmes, de-risk scale-up or Tech Transfer, and transition seamlessly into commercial manufacturing within the same high potency environment.

Importantly, the site now offers a fully integrated set of assets, including coater, roller compactor, in-process control (IPC) systems and associated analytical capabilities, located within a single high containment facility. This integrated setup, combined with experienced technical teams, enhances scale-up efficiency, supports dossier filings and strengthens the robustness of the commercial supply chain.

Greg Behar, CEO at Recipharm, said: "High potency oral solid dose manufacturing remains one of the most capacity-constrained and technically demanding areas in our industry. By adding dedicated high potency development and pilot capabilities at Leganés, we are strengthening our ability to partner with customers earlier and support them across late-stage development through clinic to commercialisation. Just as importantly, our experienced high potency experts work closely with customers to understand their specific requirements and to jointly identify the right technical and operational solutions for what can often be highly complex programmes."

In addition to its high potency offering in Leganés, Recipharm offers additional high potency capabilities across its global network, including:

- Commercial-scale OEB4 (1-10µg/m³) manufacturing capability, supporting a broad range of potent compounds;
- OEB4 capability for sterile fill and finish of Pre-Filled Syringes, liquid vials and Pre-Filled Cartridges, supporting advanced injectables drug products.

All sites operate under a strong execution framework, with industry-benchmark performance in safety, quality and delivery: a critical foundation for reliable high potency development and manufacturing.

This latest investment reinforces Recipharms' commitment to serving the growing demand for safe, scalable and high-quality high potency pharmaceutical development and manufacturing solutions.

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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, Italy, Portugal, Spain, Sweden and the US.

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

Media contact:

Guenaelle Holloway, Head of marketing and communications
Guenaelle.Holloway@recipharm.com
+44 7730 303 708