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PRESS RELEASE

Dipharma's cGMP Pilot plant, expansion proceeding according to plan

With an investment of €2.7 Million, the company continues to consolidate its position to be among the leading small molecule CDMOs

Milan, Italy – Dipharma Francis S.r.l. (Dipharma), a global CDMO and leading manufacturer of Active Pharmaceutical Ingredients and Intermediates, announced today **that the expansion of its cGMP small production pilot plant, at its Italian site in Mereto di Tomba (UD), is proceeding as planned and it will be commissioned by late November this year.**

The new production line doubles the capacity of the existing pilot plant with a total investment of € 2.7 Million.

The plant will be equipped with 2 glass-lined reactors, 2 stainless steel reactors, a Hastelloy C-22 filter dryer with continuous liner discharge and closed system operation; loading of raw material through an isolator and coupling with Split Butterfly valves allow for an extreme containment level. Furthermore, new equipment will increase the capacity of the utilities (scrubber, vacuum pump, chiller, etc.) serving the pilot plant.

In addition to this, the new plant will include clean rooms on all the three floors involved in the expansion, with pressure gradient control in rooms and airlocks for personnel and material. **This layout allows for the production of HPAPI up to OEB4 and will include a clean room for finishing activities** (filter dryer room). The HVAC systems are 100% fresh air.
The overall small-scale pilot plant is in full compliance with the highest cGMP standards and it is also equipped with 1 Stainless steel Centrifuge, 1 Stainless steel Tray Vacuum Dryer; it is capable of milling and of producing different batch sizes including:

- **from 5 kg to 50 kg on the first line**
- **from 5 kg to 25 kg on the second line (HPAPI)**

"*This investment is another important step forward on the strategic path towards the strengthening of our small molecule CDMO offer* — said **Jorge Nogueira, Chief Executive Officer** of **Dipharma Francis S.r.l.** —. *The new cGMP pilot plant expansion will enhance our CDMO scale-up capabilities for early-stage drug development and clinical trials, allowing Dipharma to better meet our customers' needs and expectations by systematically providing integrated, innovative and sustainable service solutions to their challenges".*

About the Dipharma Francis group

With a turnover of approximately €130 million, Dipharma Group is a global CDMO and a leading manufacturer of APIs and Intermediates, with more than 500 skilled and highly committed employees, 4 cGMP plants, located in the U.S.A. and Italy, plus sales offices in Italy, the U.S.A. and China. The fully equipped R&D Centres develop innovative chemical processes and crystalline forms for the most prominent pharmaceutical companies worldwide. Since 1970, Dipharma has managed to achieve a positive unbroken record of inspections by the main Regulatory Agencies and its cGMP manufacturing sites are equipped to supply quantities from laboratory to industrial scale, covering the entire lifecycle of a pharmaceutical substance. Dipharma has the right size and variety of scale-up capabilities to act as a global player and manage processes efficiently, while offering flexibility and agility to promptly solve any challenge. **Experience you can trust.**

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