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PRESS RELEASE

Successful FDA Inspection at Dipharma Facility in Kalamazoo, MI, USA

The Company expands its range of CGMP services to include small-scale commercial APIs

Milan, Italy - Dipharma Francis S.r.l. (Dipharma), a global Contract Development and Manufacturing Organization (CDMO) and leading manufacturer of New Chemical Entities (NCE), Generic Active Pharmaceutical Ingredients and Advanced Intermediates, **proudly announced that Dipharma Inc., its US facility located in Kalamazoo, MI, has been inspected by the U.S. Food and Drug Administration (FDA) and has received the Establishment Inspection Report (EIR), satisfactorily closing the inspection process.**

The rigorous inspection took place in the second week of January this year. At the closing meeting **the inspectors congratulated the Dipharma team members on the Current Good Manufacturing Practices (CGMP) Systems they created and their overall commitment to quality.**

Since 1970, Dipharma Group has achieved an **unbroken positive record of inspections by the major international Regulatory Agencies** and this new achievement demonstrates the Company's extensive experience in ensuring compliance with the highest global quality standards.

With this accomplishment, **Dipharma Inc. expands the range of services offered to its international clients to include commercial deliveries. Furthermore, it enhances the vertical integration of all Dipharma's CGMP manufacturing processes**, in all four facilities, from preclinical to commercial scale.

"*The successful closure of the FDA's Pre-Approval Inspection (PAI) marks a significant achievement for our US facility, Dipharma Inc. Congratulations to the whole team for this great accomplishment*" stated **Jorge Nogueira, Chief Executive Officer of Dipharma Francis**. "*This inspection, the first conducted by the FDA at our US facility, underscores the Dipharma Group's unwavering commitment to continuously improve our GMP Systems and uphold the highest quality standards. It reflects our dedication to ensuring that our products meet stringent quality benchmarks for patients worldwide".*

Dipharma Inc.'s Kalamazoo facility provides world-class CDMO services and API supplies for the Group's pre-clinical and clinical customers. The facility has undergone significant expansion in recent years with the aim of supporting and growing its services to meet the growing demands of the U.S. market. Staffed by highly skilled employees, Dipharma Inc. is equipped with a world-class R&D laboratory and a state-of-the-art CGMP facility including a Kilolab with dedicated QC laboratory and warehouses. The latest significant investment, in 2023, added a second cutting-edge CGMP line, capable of running larger-scale reactions in the Kilolab in reactors of up to 105 L volume. With this investment, Dipharma Inc. more than triples its capacity to process projects for customers, both in the generics and CDMO arena, while enhancing operational safety and isolation technologies.

About the Dipharma Francis group

With revenues of €160 million, the Dipharma Group is a global CDMO and a leading manufacturer of APIs and Intermediates, with about 600 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 Centers develop innovative chemical processes and crystalline forms for the most prominent pharmaceutical companies worldwide. As a third-generation family-owned company, Dipharma has a long history of stability, commitment, and financial solidity. 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.**

For more information:

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