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PRESS RELEASE

Dipharma receives GMP certification from Brazilian ANVISA

The Baranzate site (Italy) is the first Dipharma manufacturing facility to receive Anvisa certification

Milan, Italy - Dipharma Francis S.r.I. (Dipharma), a leading Contract Development and Manufacturing Organization (CDMO) and a global manufacturer of Active Pharmaceutical Ingredients, announced today that its production site, located in Baranzate, just outside Milan (Italy), has received the Good Manufacturing Practice (GMP) certification, CBPF (Certificado de Boas Práticas de Fabricação), from the Regulatory Authority of Brazil, ANVISA (Agência Nacional de Vigilância Sanitária). It is the first Dipharma manufacturing facility to receive ANVISA certification.

This authorization certifies the strict adherence of Dipharma's quality system to GMP requirements and allows Dipharma to be the right choice for all customers who would like to register new applications at ANVISA.

The facility has already been regularly and successfully inspected by the US FDA and the Italian Ministry of Health (AIFA) for more than 50 years.

"We are very pleased to have obtained this first successful completion of the ANVISA certification — said Jorge Nogueira, Chief Executive Officer of Dipharma Francis S.r.l. — It represents a key regulatory milestone for the Dipharma Group and demonstrates our continuous commitment to providing high quality services and solutions to our global customers".

About the Dipharma Francis group

With revenues over €137 million, the 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 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. 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. 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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