For Immediate Release
15 October 2024
Ref. E.C. 03/2024

PRESS RELEASE

Dipharma granted first CADIFA by Brazilian ANVISA for the Ursodeoxycholic Acid

The recognition highlights Dipharma's commitment to quality and strengthens its presence in the Brazilian market

Milan, Italy - **Dipharma Francis S.r.l.** (Dipharma), a leading Contract Development and Manufacturing Organization (CDMO) and a global manufacturer of Active Pharmaceutical Ingredients and advanced intermediates, **announced today the granting of its first CADIFA** (Carta de Adequação de Dossiê de Insumo Farmacêutico Ativo) **by the Regulatory Authority of Brazil, ANVISA** (Agência Nacional de Vigilância Sanitária) related to the **ursodeoxycholic acid** active pharmaceutical ingredient. The product has been manufactured almost thirty years in the **production site of Caronno Pertusella (Italy),** which received the **ANVISA's Good Manufacturing Practice (GMP) certification, CBPF (Certificado de Boas Práticas de Fabricação) in 2023.**

The granting of this CADIFA marks another significant milestone in Dipharma's expansion into the Brazilian pharmaceutical market. This journey began with the first ANVISA authorization in 2022 for the Dipharma's Baranzate production site in Milan, Italy, and is part of the company's strategic effort to strengthen its presence and offerings in Brazil.

"*We are extremely proud to have received our first CADIFA from ANVISA for ursodeoxycholic acid, a cornerstone product in our portfolio* – **said Sabrina Furin, Director of Corporate QA & RA of Dipharma Francis S.r.l.** –. *This achievement underscores Dipharma's world-class quality systems, which have been consistently recognized by major regulatory bodies for over 50 years. Attaining CADIFA is a challenging process that involves comprehensive assessments of our manufacturing processes and quality controls. This approval is not only a regulatory milestone but a testament to our ongoing commitment to delivering high-quality API solutions globally*."

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:

Paola Clerici
Communication Manager
Dipharma Francis S.r.l.
paola.clerici@dipharma.com
www.dipharma.com