For Immediate Release
February 24th, 2020
Ref. E.C. 01/2020

PRESS RELEASE

Dipharma Francis S.r.l. completes construction of new cGMP Suite in USA

Located in Kalamazoo (MI), the New GMP-compliant Kilolab and QC Laboratory will manage supply for clinical Phase 1 and early Phase 2.

Milan, Italy - Dipharma Francis S.r.l. (Dipharma), a leading Contract Development and Manufacturing Organization (CDMO) and a global manufacturer of Active Pharmaceutical Ingredients, announces today the completion of the new cGMP Quality Control laboratory and c-GMP kilolab at its CDMO site located in Kalamazoo (MI), USA.

The new state-of-the-art cGMP manufacturing suite strengthens Dipharma's CDMO offering and completes the range of exclusive services, ensuring continuity across the whole lifecycle of Customers' molecules, from preclinical to commercial stage.

The QC laboratory is designed and equipped according to latest pharmaceutical quality standards, with full CFR21 compliance for Data Integrity management.

"*The new suite marks the achievement of a key milestone within the Exclusive Synthesis growth strategy and reinforces the company's value proposition to provide reliable innovative solutions to customers: Dipharma Group is now able to cover the whole pharmaceutical chemistry services spectrum, from discovery to marketed drugs –.* commented Mr. Jorge Nogueira, CEO of Dipharma Francis S.r.l. – *Furthermore, I am pleased to highlight that, with the construction of the new kilolab, Dipharma implements cGMP capability at its American subsidiary Kalexsyn Inc., enhancing its range of exclusive services from CRO to CDMO".*

With an engineering batch already scheduled for production, Dipharma is currently assembling all documents required by FDA for Drug Establishment Registration.

About the Dipharma Francis group
With revenues about €120 million, Dipharma is one of the leading family-owned Contract Development and Manufacturing Organisation (CDMO) and a global manufacturer of Active Pharmaceutical Ingredients, with commercial offices in Italy, U.S.A. and China. Its fully-equipped R&D Centers, located in the U.S.A. and in Italy, develop innovative chemical processes and crystalline forms for the most renowned pharmaceutical companies worldwide, and have originated in about 250 patents and patent applications and more than 1200 scientific papers. Its manufacturing sites have been successfully inspected by the major health authorities since 1970. They are equipped to supply from laboratory to industrial quantities, whilst complying fully with the most stringent quality standards.

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