Fortrea & Emery Pharma Announce Strategic Collaboration to Deliver FDA Compliant Drug-Drug-Interaction Studies Using Rifampin

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Collaboration enables testing of nitrosamine impurities, allowing sponsors to demonstrate acceptable use of rifampin in drug-drug interaction studies

DURHAM, N.C., June 24, 2025 (GLOBE NEWSWIRE) -- Fortrea (Nasdaq: FTRE) (the "Company"), a leading global contract research organization (CRO), today announced a strategic collaboration with Emery Pharma, a leading analytical and bioanalytical CRO providing testing services under current Good Manufacturing Practice (cGMP) and Good Laboratory Practice (GLP), to provide rapid lot-by-lot, 1-methyl-4-nitrosopiperazine (MNP) testing of rifampin, the preferred drug for drug-drug interaction (DDI) studies, to certify impurities are below the Acceptable Intake (AI) Limit set by U.S. Food and Drug Administration (FDA) guidelines.

Fortrea has selected Emery Pharma due to its strong capabilities in analytical and bioanalytical testing in support of Fortrea's global clinical programs. Emery Pharma's expertise in this area supports Fortrea's ability to offer rifampin as an agent for inducing the CYP3A4 isoenzyme in DDI studies. The collaboration announced today allows sponsors to conduct DDI assessments using rifampin, which is frequently named as the preferred agent in these studies, due to its safety and tolerability profile.

"This collaboration reflects our shared commitment to smarter study design and greater participant safety," said Oren Cohen, M.D., chief medical officer and president of Clinical Pharmacology Services at Fortrea. "By enabling use of rifampin through our collaboration with Emery Pharma, we're helping sponsors de-risk early-phase trials, accelerate timelines and enhance data quality. Emery Pharma's deep expertise in bioanalytical sciences, coupled with their GLP and GMP capabilities, combined with Fortrea's industry-leading clinical conduct capabilities makes this an ideal collaboration for the testing of rifampin for use in our DDI studies. The collaboration strengthens our ability to generate high-quality data that will benefit patients worldwide."

Ron Najafi, Ph.D., chief executive officer of Emery Pharma, added, "We're honored to partner with Fortrea in advancing critical early-phase studies. Our team's strength lies in solving complex analytical challenges and ensuring studies meet the highest regulatory and scientific standards. We're excited to contribute to safer, faster and more effective drug development."

DDI studies are a cornerstone in the development of new therapeutics. Rifampin, a widely used antibiotic and traditionally a key tool in DDI studies, has faced scrutiny due to the discovery of MNP, a nitrosamine impurity. In 2021, the FDA found that all tested rifampin batches contained MNP levels exceeding previously accepted limits, prompting researchers to explore alternative drugs. However, these substitutes come with safety concerns and slower activation times. In 2023, the FDA updated its guidance, raising the acceptable MNP limit for rifampin.

This innovative approach of testing rifampin impurity levels is now available to Fortrea customers conducting clinical pharmacology trials, with flexible study designs that meet FDA requirements.

About Fortrea

Fortrea (Nasdaq: FTRE) is a leading global provider of clinical development solutions to the life sciences industry. We partner with emerging and large biopharmaceutical, biotechnology, medical device and diagnostic companies to drive healthcare innovation that accelerates life changing therapies to patients. Fortrea provides phase I-IV clinical trial management, clinical pharmacology and consulting services. Fortrea's solutions leverage three decades of experience spanning more than 20 therapeutic areas, a passion for scientific rigor, exceptional insights and a strong investigator site network. Our talented and diverse team working in about 100 countries is scaled to deliver focused and agile solutions to customers globally. Learn more about how Fortrea is becoming a transformative force from pipeline to patient at Fortrea.com and follow us on LinkedIn and X (formerly Twitter).

About Emery Pharma

Emery Pharma is a leading analytical and bioanalytical contract research organization based in Alameda, California, recognized for its scientific leadership in impurity analysis and regulatory compliance. Specializing in GLP- and cGMP-compliant analytical testing, the company provides a comprehensive suite of services that support every stage of drug development—from early discovery through clinical trials and commercialization.

A pioneer in the development and validation of sensitive and specific assays for nitrosamine detection, Emery Pharma has played a key role in helping pharmaceutical sponsors and manufacturers navigate evolving FDA and ICH guidelines. The company's cutting-edge capabilities in liquid chromatography-mass spectrometry (LC-MS/MS) and high-resolution mass spectrometry (HRMS) enable the precise quantification of trace-level nitrosamine impurities, including NDSRIs, NDMA and MNP, in complex matrices.

Emery Pharma also offers antibiotic screening, robust stability testing programs for both research-stage and commercial products,

along with advanced analytical platforms such as nuclear magnetic resonance (NMR) and gas chromatography-mass spectrometry (GC-MS). Its team of interdisciplinary scientists delivers problem-solving, method development and investigational services with a strong focus on regulatory readiness and data integrity.

Driven by a commitment to scientific excellence and public health, Emery Pharma continues to advance the field of impurity profiling—ensuring safer medicines and contributing to industry-wide efforts to mitigate the risks associated with nitrosamines and other genotoxic contaminants.

For more information, visit us at emerypharma.com and follow us on LinkedIn.

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