Certara Simcyp® Simulator Becomes First and Only Software Platform to Receive EMA Qualification Opinion for PBPK Modeling

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RADNOR, Pa., Aug. 04, 2025 (GLOBE NEWSWIRE) -- Certara, Inc., a global leader in biosimulation, today announced that the European Medicines Agency (EMA) has formally qualified the Simcyp® Simulator for use in regulatory submissions across the EU. Certara is the first company to receive EMA qualification for a PBPK modeling platform, and Simcyp is the only software to hold this designation. The recognition follows a rigorous multi-year, collaborative engagement between Certara and the EMA.

With this qualification in place, sponsors can now use the Simcyp Simulator in regulatory submissions across the EU to assess drug-drug interaction (DDI) risk without needing to re-establish the platform's credibility for the specified context of use (COU) scenarios. Simcyp has long been the leading biosimulation software used in submissions to the EU and other regulatory agencies, and this qualification makes the drug submission process easier and faster. "This first of its kind qualification by EMA regulators of a new approach methodology further demonstrates the scientific value biosimulation provides to drug development scientists," said William F Feehery, Chief Executive Officer. "This milestone reflects the value of Certara's scientific leadership, innovation, and technical expertise."

Drug-drug interaction (DDI) studies typically involve the co-administration of two or more drugs, where one acts as a substrate and the other as a perpetrator. The qualification opinion covers various scenarios (3 COUs) where Simcyp simulations can replace clinical DDI studies using a range of verified substrates and perpetrators integrated within the platform. The COUs span 6 CYP enzymes and 2 inhibition mechanisms, thereby significantly reducing the number of clinical studies a sponsor has to conduct.

"We're at an inflection point in drug development as the industry and regulators increasingly prioritize model-informed drug development (MIDD). This recognition and regulatory trust from the EMA further solidify the future we've been working towards for numerous years," said Rob Asbury, President, Certara Predictive Technologies. "This is yet another exciting stepping stone as we continue to empower drug developers to utilize mechanistic modeling to speed decision making, further scientific insights, and bring innovative medicines to patients faster."

To learn more about the Simcyp Simulator and how it supports MIDD strategies, visit www.certara.com/simcyp.

About Certara

Certara accelerates medicines using biosimulation software, technology, and services to transform traditional drug discovery and development. Its clients include more than 2,400 biopharmaceutical companies, academic institutions, and regulatory agencies across 70 countries. Learn more at certara.com.

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