Certara Announces FDA Renewal and Expansion of Certara's Biosimulation Software for Reviewing Regulatory Submissions

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FDA holds more than 400 Simcyp™ and Phoenix™ software licenses across 12 divisions and offices

PRINCETON, N.J., Dec. 21, 2021 (GLOBE NEWSWIRE) -- Certara, Inc. (Nasdaq: CERT), a global leader in biosimulation, today announced that the U.S. Food and Drug Administration (FDA) has renewed and expanded its licenses of Certara's proprietary biosimulation software, with more than 400 user licenses of Simcyp and Phoenix software. In total, there are 12 divisions and offices of the FDA using Certara's software for internal research and to independently analyze, verify and review regulatory submissions.

Certara's Simcyp Simulator, an industry-leading platform for physiologically-based pharmacokinetic (PBPK) modeling and simulation, is used throughout the drug development process to evaluate new drug formulations, determine first-in-human dosing, optimize clinical study design and predict drug-drug interactions. The FDA has renewed its licenses for the Simcyp Simulator, Simcyp Paediatric and Simcyp Cardiac Safety Simulator, which the agency uses to independently analyze, verify and review investigational therapies, new drug applications and generic drug applications.

"It is a privilege to continue providing software that global regulatory agencies can rely on to inform their reviews of regulatory submissions," said William F. Feehery, Ph.D., CEO of Certara. "We are pleased that more scientists at the FDA are using our biosimulation software to support the development of safe and effective medicines."

Additionally, the FDA has renewed and expanded its user licenses of Certara's Phoenix Software, which is widely used for pharmacokinetic, pharmacodynamic and toxicokinetic modeling and simulation. Phoenix is used extensively to perform data analyses for new drug and biologics license applications by drug developers, including 37 of the top 40 global pharmaceutical companies by R&D spend. The FDA uses Certara's Phoenix software including WinNonlin, NLME and *In Vitro-In Vivo* Correlation (IVIVC) toolkit as well as the Company's Trial Simulator software.

For more information on Certara's software platforms, please visit https://www.certara.com/software/.

About Certara
Certara accelerates medicines using proprietary biosimulation software and technology to transform traditional drug discovery and development. Its clients include more than 1,650 global biopharmaceutical companies, leading academic institutions, and key regulatory agencies across 61 countries.

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