



Certara Announces Release of Simcyp™ Simulator Version 21, Expanding Capabilities to Align with Recent Regulatory Guidances

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PRINCETON, N.J., Dec. 02, 2021 (GLOBE NEWSWIRE) -- Certara, Inc. (Nasdaq: CERT), a global leader in biosimulation, today announced the release of [Simcyp Simulator](#) Version 21, which updates the Company's population-based modeling and simulation platform. The Simcyp Simulator 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.

Certara's Simcyp physiologically-based pharmacokinetic (PBPK) Simulator models describe the behavior of drugs in different body tissues and include genetic, physiological and epidemiological databases that facilitate simulations in virtual populations. The Simcyp Simulator has been used to inform more than 250 label claims for 85+ novel drug approvals by the US Food and Drug Administration (FDA). These were achieved virtually, using PBPK modeling and simulation in lieu of performing clinical trials.

"We are excited to offer new capabilities to advance modern drug development with the launch of our latest Simcyp Simulator," said William F. Feehery, Ph.D., CEO of Certara. "Certara's Simcyp Simulator and modeling expertise have already supported more than 850 peer-reviewed scientific publications, demonstrating its significant impact in drug development. This latest update aligns with recent regulatory guidances, so that we can help accelerate the development and approval of crucial therapies to patients."

New capabilities of the Simcyp Simulator include:

- Updates to renal- and hepatic-impaired population models to align with recent FDA guidance on pharmacokinetics and support dosing and labelling decisions
- Expansion of the human brain model to a five-compartment model, enabling the prediction of drug concentrations in cerebrospinal fluid and interstitial and intracellular brain fluid compartments
- Additions to the compound library to facilitate drug-drug interaction analysis on a wider range of compounds, including progestins in support of the FDA's recent oral contraception guidance
- Updates to Simcyp Animal to help increase confidence in translating from animals to humans and refine the design of subsequent studies
- Incorporation of 11 new or updated genotype and phenotype frequency and abundance values across several populations to improve gene variant-dependent drug exposure predictions, which can aid decision-making in clinical studies

"The application of Simcyp modeling continues to grow in formulation development, drug-drug interactions and special populations for novel drugs," said Masoud Jamei, Ph.D., senior vice president of Simcyp research and development at Certara. "We're proud to further support the development of advanced medicines by providing to our industry, academic and regulatory partners the latest innovations in biosimulation to efficiently and ethically evaluate drug performance, dosing regimens and drug interactions and help bring safer and more effective therapeutics to all patients."

Version 21 also features updates to Simcyp modules for pediatrics, pregnancy, lactation, biologic drugs, virtual bioequivalence and *in vitro-in vivo* correlation.

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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