Certara's Simcyp Consortium Celebrates 25th Anniversary

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The pre-competitive scientific research consortium of top pharmaceutical companies remains a critical force in advancing qualified PBPK modeling and simulation to further drug development and regulatory decisions

RADNOR, Pa., Sept. 24, 2024 (GLOBE NEWSWIRE) -- Certara, Inc. (Nasdaq: CERT), a global leader in model-informed drug development, today announces the celebration of the 25th anniversary of the Simcyp® Consortium.

The Simcyp Consortium has become a global authority on mechanistic physiologically-based pharmacokinetic (PBPK) modeling and simulation. With members from 35 leading biopharmaceutical companies, the Simcyp® Consortium was created to guide the development of best practices, identify the most critical use areas, and fill the scientific gaps that were needed for studying drug handling by the body in computer-generated, virtual patients and beyond the limited framework of clinical trials.

The Simcyp Simulator is used by pharmaceutical and biotech companies, academia and has been adopted by all the leading regulatory agencies, including the US FDA, Europe's EMA, and Japan's PMDA. Modeling and simulation results from the Simcyp Simulator have informed dosing decisions for more than 375 label claims for more than 115 drugs in lieu of clinical studies. Of all novel drugs approved by the FDA between 2019 and 2023 that leveraged PBPK, more than 80% used Simcyp Simulator.

"The Simcyp Consortium has accelerated the pace of progress, innovation, and adoption of biosimulation across drug discovery and development over the last 25 years," said William F. Feehery, CEO of Certara. "Hitting this remarkable anniversary is a reminder of the successful collaboration we've had as we continue to serve and advance the scientific community."

The Simcyp Simulator accurately predicts drug behavior within the human body, aiding in various stages of drug development. It supports decision-making from dosing and optimizing clinical study designs to evaluating new drug formulations, predicting drug-drug interactions, and conducting virtual bioequivalence analyses.

"Very few scientific consortiums have shown as dynamic an impact as the Simcyp Consortium over the years, especially on the PBPK applications in model-informed drug discovery and development," said Kunal Tasker, Director, Global Head PBPK Modeling at GSK and chair of the Simcyp Consortium Members Discussion Group (SMDG). "The inputs from various industry consortium members have led to relevant advances in the Simulator. We all, along with the Certara Simcyp scientists, should be very proud of our collective impact on the wellbeing of patients around the globe."

"It is an honor to witness the Simcyp Consortium achieve this 25th anniversary milestone and to be one of the longest-running consortia focused on a specific area," said Amin Rostami, PharmD, PhD, Chief Scientific Officer at Certara. "We are proud that our work is helping not only better understand therapeutics and optimize their chance of success in the clinic, but also to support simulations of therapies in understudied and difficult-to-reach populations including pediatric, pregnancy, lactation, renal-impaired, and other important populations. The ultimate goal of technology is to extend our ability beyond what is currently possible. Our collaboration in the consortium has helped us achieve that goal, and we will continue to drive innovation and new scientific understanding in coming years together."

Simcyp Consortium Awards & Grants

To recognize research excellence and give back to the scientific community, the Simcyp Consortium presents awards as well as funding for either a PhD or a post-doctoral research program annually. The Simcyp Consortium's 2024 Most Informative Scientific Report Award is awarded to the National Taiwan University for the paper titled: 'Physiologically based mechanistic insight into differential risk of valproate hepatotoxicity between children and adults: A focus on ontogeny impact.'

The Simcyp Grant and Partnership Scheme has awarded over $1.4 million in grants to support 13 PhD and postdoctoral researchers and has provided Simcyp licenses to hundreds of academic institutions, fostering the growth of future scientific leaders.

In addition to its annual awards and funding, Simcyp provides academic teaching and research licenses to more than 110 universities and research institutions around the world. Further, Simcyp publications (including articles, meeting abstracts, reviews, letters, and book chapters) have been cited more than 8,000 times in scientific literature.

For more information about Certara's Simcyp Simulator, please visit: https://www.certara.com/software/simcyp-pbpk/

About Certara
Certara accelerates medicines using proprietary 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

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