Certara Releases New Versions of Its Preeminent Quantitative Systems Pharmacology (QSP) Simulators for Expediting Development of Biologics and Immuno-oncology Therapies

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Expanded capabilities in company's Immunogenicity and Immuno-oncology QSP Simulators broaden applicability for addressing safety and efficacy challenges

PRINCETON, N.J., May 13, 2021 (GLOBE NEWSWIRE) -- Certara, Inc. (Nasdaq: CERT), the global leader in biosimulation, today announced the launch of new versions of its Immunogenicity (IG) and Immuno-oncology (IO) Quantitative Systems Pharmacology (QSP) Simulators to help address the challenges in the development of biologics and cancer therapies. These new versions further expand applications of QSP and advance the field of using virtual patients to conduct computer-based trials throughout drug discovery and development.

"We have seen an increasing interest in the potential of QSP to guide regulatory decisions and anticipate that this will only continue to grow, much like physiologically-based pharmacokinetic (PBPK) modeling, which is now a critical component in many regulatory submissions," said William F. Feehery, Ph.D., CEO of Certara.

QSP addresses the most complex challenges in drug development by combining computational modeling and experimental data to examine the relationships between a drug, biological system, and disease process. Immunogenicity is a key challenge for developing biologics, including novel modalities such as gene and cell therapies. Researchers use Certara's IG Simulator to simulate immunogenicity in virtual patients. Version 4.0 of the IG Simulator now allows for the extrapolation of *ex vivo* patient assays in addition to *in vitro* assays to better inform the model and predict clinical outcomes. The IG Simulator has now been used in more than 20 case examples. Certara and its customers will be presenting several of these case examples at an upcoming FDA workshop in June.

In immuno-oncology, the sheer number of possible therapy combinations requires a quantitative framework to integrate the complex and dynamic factors that determine efficacy and historically have led to the selection of suboptimal combinations. Certara's IO Simulator uses virtual patients to quickly test these different combinations to determine the optimal combination of therapies and dosing regimens. Version 3.0 of the IO Simulator vastly expands the number of targets and cell types including cytokines, immune cell types, and tumor neoantigens. It can also now test combinations of chemotherapy and radiotherapy. The IO Simulator has correctly predicted therapeutic outcomes of using drugs in various cancer types, including solid tumors and blood cancers.

"QSP is demonstrating its capacity to improve biopharmaceutical R&D, improving confidence in both the drug compound and target to increase the likelihood of success," said Piet van der Graaf, Ph.D., Senior Vice President, QSP at Certara. "The IG Simulator can use first-in-human data to design Phase II/III trials, predict impact of disease and co-medication, extrapolate to new populations, and predict if IG can be managed via dosing regimens. In tandem with the rise of IO therapeutics, we've expanded the number of drug targets and cell types in our IO Simulator enabling us to better predict optimal drug combinations and dosing regimens for more patient populations."

In recent years, the emergence of QSP has attracted increasing interest and is now becoming an essential part in model-informed drug discovery and development. The U.S. Food and Drug Administration (FDA) has seen an increase in evaluating QSP approaches in regulatory submissions.

For more information about Certara's QSP services and regulatory support, please visit: https://www.certara.com/services/quantitative-systems-pharmacology/.

About Certara

Certara accelerates medicines using 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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