Certara Announces New Versions of Biosimulation Software for Development of Novel Biologics

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New capabilities enhance clinical predictability for different compounds across more therapeutic areas

PRINCETON, N.J., June 21, 2022 (GLOBE NEWSWIRE) -- Certara, a global leader in biosimulation, today announced the release of new versions of its Immunogenicity (IG), Immuno-oncology (IO) and Vaccine Simulators to help predict how drugs work and address key questions in the development of novel biologic therapies.

"The latest versions of our simulators help tackle some of the toughest challenges in drug discovery and development with complex biologics," said William F. Feehery, Ph.D., CEO of Certara. "Our Simulators incorporate the latest advancements in biosimulation to determine the best strategies for developing safe and effective novel biologic therapies to address critical unmet patient needs."

The simulators are based on quantitative systems pharmacology (QSP), which combines computational modeling and experimental data to examine the relationships between a drug, the biological system, and the disease process. Researchers use the Simulators to create virtual patients, conduct computer-based trials and predict how drugs work in patients, before testing investigational drugs in clinical trials.

"Our continued innovation in QSP expands use cases of biosimulation and grows adoption by regulators and the pharmaceutical industry," said Piet van der Graaf, Ph.D., senior vice president, QSP at Certara. "The latest versions of the IG and IO Simulators enable better prediction of dosing regimens for more patient populations. The Vaccine Simulator accurately predicted the optimal timing for COVID-19 vaccine boosters and is now being used to assess next-generation mRNA vaccines."

Developed in partnership with eight leading pharmaceutical companies, Certara's IG Simulator is used to assess, predict and manage the immunogenicity of a wide range of biologic therapies in development. The latest version (Version 5.0) allows for the evaluation of many different types of biologics, including monoclonal antibodies, bi-and multi-specifics, complex proteins, cell, and gene therapies. Earlier this year, the U.S. Food and Drug Administration licensed Certara's IG Simulator to research and evaluate immunogenicity in protein-based therapeutics.

Certara's IO Simulator uses virtual patients to determine the optimal combination of different cancer therapies and dosing regimens. The latest version of the IO Simulator (Version 4.0) expands the number of targets in blood cancers and solid tumors to include 20 different cell types, such as cytotoxic, helper, regulatory T-cells and B-cells, and 10 immunomodulatory cytokine targets. The IO Simulator enables researchers to assess combination therapies, design trials, select patients, and link dosing regimens to biomarkers, which aligns well with Project Optimus, the FDA's initiative to reform the dose optimization and dose selection paradigm in oncology drug development.

Certara's Vaccine Simulator answers 'what-if' scenarios to determine the best vaccine dosing strategies for various patient populations, including children and the elderly. Version 1.0 of the Vaccine Simulator incorporates a novel lipid nanoparticle administration module and is being used to support the development of next-generation mRNA vaccines and gene therapies. Findings from the Vaccine Simulator have been published and discussed in leading scientific journals, including _Nature_.

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

About Certara
Certara accelerates medicines using proprietary biosimulation software, technology and services to transform traditional drug discovery and development. Its clients include more than 2,000 biopharmaceutical companies, academic institutions, and regulatory agencies across 62 countries.

Certara Contact
Jieun W. Choe
jieun.choe@certara.com

Media Contact
Ariane Lovell
Finn Partners
ariane.lovell@finnpartners.com

Investor Relations Contact
David Deuchler
ir@certara.com

Source: Certara