U.S. FDA Licenses Certara's Immunogenicity Simulator

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Affirms the advancements of innovative biosimulation technology and its growing impact in R&D

PRINCETON, N.J., Feb. 23, 2022 (GLOBE NEWSWIRE) -- Certara, Inc. (Nasdaq: CERT), a global leader in biosimulation, today announced that the U.S. Food and Drug Administration (FDA) has licensed Certara's Immunogenicity (IG) Simulator to research and evaluate immunogenicity in protein-based therapeutics. Certara's IG Simulator predicts the immune response of therapeutics in development, which is important to guide clinical and regulatory decision-making.

"The FDA's decision to license our IG Simulator affirms the importance of biosimulation for addressing the most important challenges in drug development," said Piet van der Graaf, PharmD, Ph.D., senior vice president of Quantitative Systems Pharmacology (QSP) at Certara. "For the past five years, we have invested, developed and validated our IG Simulator with a high level of rigor. We are excited by this opportunity to expand the impact of our Simulator to quickly assess immunogenicity risk, addressing pressing questions and guiding study design for better clinical outcomes."

Immunogenicity, or the tendency of a molecule to trigger an immune response, is a major problem with protein-based therapeutics such as antibody-based drugs or biological medicines that are engineered versions of naturally occurring human proteins. Immunogenicity has long been an area of keen research interest by the FDA and biopharmaceutical companies as it can be challenging to predict and can negatively impact drug development projects late in the process that may be costly to rectify. As a part of its pilot model-informed drug development (MIDD) program, the FDA held a workshop on immunogenicity in June of 2021 with more than 2,000 registrants, where Certara scientists and partners presented on the rapid advances of the IG Simulator and its use cases.

Certara's IG Simulator is used to assess, predict and manage immunogenicity of a wide range of biologics, including monoclonal antibodies, bi-and multi-specifics and cell and gene therapies. Using the Simulator, researchers can create virtual patients and conduct computer-based trials. The IG Simulator was developed in partnership with eight leading pharmaceutical companies in Certara's IG QSP Consortium. The IG Simulator has been validated in 20 clinical case studies, including mono and combination therapies.

To learn more about the IG Simulator, please visit https://www.certara.com/software/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.

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