Japan's Pharmaceuticals and Medical Devices Agency (PMDA) Renews Licenses of Certara's Biosimulation Software for Evaluating Regulatory Submissions

June 23, 2021

The PMDA enters 8th consecutive year of using Certara's biosimulation software

PRINCETON, N.J., June 23, 2021 (GLOBE NEWSWIRE) -- Certara, a global leader in biosimulation, today announced that the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) has renewed its licenses of Certara's Simcyp™ and Phoenix™ biosimulation software. The PMDA has been using Certara's biosimulation software since 2014.

The Simcyp Physiologically-Based Pharmacokinetic (PBPK) Simulator is used in drug development to determine first-in-human dose, design more efficient and effective clinical studies, and predict drug-drug interactions using virtual populations. The Phoenix Pharmacokinetic and Pharmacodynamic (PK/PD) Platform is used for pharmacokinetic, pharmacodynamic, and toxicokinetic modeling and simulation to help drug developers save time by streamlining data management.

"The continued growth in modeling and simulation approaches for new drug applications in Japan is helping to support the development of medicines for difficult-to-treat diseases and for much needed areas, including pediatrics," said Certara's CEO William Feehery, Ph.D. "Regulatory guidance and support are critical to expand new use cases for biosimulation to ultimately bring safe and efficacious therapies to patients."

Taking into account the increase in the use of exposure-response and PBPK analyses, two guidelines were issued by Japan's Ministry of Health, Labour, and Welfare for the use of modeling and simulation in 2020: "Guideline for Drug Exposure -Response Analysis" and "Guidelines for Analysis Reports Involving Physiologically based Pharmacokinetic Models."

According to a report presented in March 2021 at the PMDA Public Workshop of 'Role of Model Informed Drug Development', an increasing number of drug approval applications have used modeling and simulation to optimize dosing regimens and establish precautions in new drug application documents submitted to the PMDA. Certara works with more than 130 biopharmaceutical companies and research institutions in Japan, including all of the top 10 Japanese biopharmaceutical companies by R&D spend.

For more information on Certara's software platforms, please visit https://www.certara.com/software/.

About Certara

Certara accelerates medicines to patients using biosimulation software and technology to transform traditional drug discovery and development. Its clients include 1,650 global biopharmaceutical companies, leading academic institutions, and key regulatory agencies across 61 countries.

Investor Relations Contact:

David Deuchler
Gilmartin Group
ir@certara.com

Media Contact:

Ariane Lovell
Finn Partners
ariane.lovell@finnpartners.com

Source: Certara