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

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The PMDA enters 9th consecutive year of using Certara’s software

PRINCETON, N.J., Oct. 19, 2022 (GLOBE NEWSWIRE) -- Certara, Inc., (Nasdaq: CERT) a global leader in biosimulation, today announced that the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) has renewed its licenses of Certara’s Simcyp™ Simulator, Phoenix™ biosimulation software, and Pinnacle 21™ Enterprise software.

“The adoption of biosimulation and technology to advance novel drug development continues to grow in Japan,” said Certara’s CEO William Feehery, Ph.D. “We are proud of our ongoing partnership with the PMDA and industry leaders in Japan, as we work together to drive the use of innovative approaches and deliver critical therapies to patients sooner.”

The PMDA has been using Certara’s biosimulation software since 2014. The PMDA also performs independent validation of clinical study data which CDISC compliance is required as part of sponsors’ regulatory submissions in their Pinnacle 21 Enterprise environment. Pinnacle 21 Enterprise software supports the PMDA’s new validation rules, which were introduced at the end of 2021.

Certara works with more than 140 biopharmaceutical companies and research institutions in Japan, including all of the top 20 Japanese biopharmaceutical companies by R&D spend.

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

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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