



The Year 2020 Marks the 7th Consecutive Year Certara Customers Received 90 Percent of US FDA Novel Drug and Biologic Approvals

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Affirms continued regulatory and industry adoption of biosimulation and technology to bring new drugs to patients

PRINCETON, N.J.--(BUSINESS WIRE)--Feb. 25, 2021-- Certara, Inc. (Nasdaq: CERT), a global leader in biosimulation, today announced that 2020 marked the seventh consecutive year where 90% of new drug and biologic approvals by the US Food and Drug Administration (FDA), excluding diagnostic agents, were received by Certara's customers. Certara's customers use its biosimulation software and tech-enabled services to increase confidence in decisions across the entire R&D lifecycle. The data generated from Certara's platforms helps to advance the safety and efficacy of therapies, accelerating critical medicines to patients.

In 2020, the FDA's Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research approved 54 medicines, excluding diagnostic agents. The majority of new drug approvals had orphan drug designation, and approximately half had breakthrough therapy designation.

Certara's Simcyp™, Phoenix™ and GlobalSubmit™ software platforms have been broadly adopted by the biopharmaceutical industry and global regulatory agencies for drug development and regulatory review. The Simcyp Simulator has now been used to provide approximately 250 drug label claims for more than 75 novel drugs, in lieu of conducting clinical studies. In 2020, the Simcyp Simulator was included in the regulatory submissions for therapies to treat breast cancer, a rare pediatric disease, and gastrointestinal tumors, among others.

"This milestone is indicative of Certara's impact in transforming the traditional drug development process, which can be costly and take many years," said Certara's CEO William Feehery, PhD. "We are proud to be at the forefront of a long-term trend of computer-based modeling that has advanced new treatments in a wide range of therapeutic areas, such as oncology, neurology, and rare diseases. In particular, our unique Simcyp Simulator has allowed our sponsor partners to expand prescribing information for novel drugs with regulatory-accepted science based on biosimulation."

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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