



Certara Customers Received 90 Percent of US FDA Novel Drug Approvals for 8th Consecutive Year

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Asserts Certara's leadership in advancing the development and approval of new drugs for patients

PRINCETON, N.J., Feb. 15, 2022 (GLOBE NEWSWIRE) -- Certara, Inc. (Nasdaq: CERT), a global leader in biosimulation, today announced that 90 percent of new drug approvals by the U.S. Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) were received by Certara's customers in 2021, excluding diagnostic agents. This is the 8th consecutive year that Certara's customers, who use the Company's biosimulation software and technology-driven services, have had novel drugs approved by the FDA in a wide range of therapeutic indications, from oncology to rare diseases.

"We are proud of our contributions to advance new medicines using our biosimulation software and technology-driven services," said Certara's CEO William Feehery, Ph.D. "This past year, we worked with large pharmaceutical companies and biotechnology companies to support many first-in-class therapies, which have mechanisms of action different from those of existing therapies. Furthermore, our Simcyp[™] Simulator aided in providing prescribing information for 13 new drugs in 2021, helping to mitigate the cost and time required with clinical trials."

Certara's Simcyp PBPK Simulator has now been used to inform more than 250 drug label claims for nearly 90 novel drugs, in lieu of conducting clinical studies. Phoenix[™] PK/PD software is also used extensively by biopharmaceutical companies to understand how a drug moves through and out of the body. Both Simcyp and Phoenix software are used by the FDA to evaluate drug applications. Additionally, Certara's technology-driven services, including model-informed drug development and regulatory writing and submission support, contributed to 6 oncology drugs, 14 drugs for orphan diseases and 17 drugs that received priority review or accelerated approval in 2021.

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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