



Certara Customers Received 90 Percent of US FDA Novel Drug Approvals for 9th Consecutive Year

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

PRINCETON, N.J., April 27, 2023 (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 2022. * This is the 9th 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.

"Our biosimulation platform continues to have an extraordinary impact on our client's drug development programs and the industry at-large," said Certara's CEO William Feehery, Ph.D. "We remain committed to our mission of safely accelerating the drug development process by lowering the cost and increasing the probability of success in trials, to improve the health and well-being of millions of people, globally."

Certara's Simcyp™ PBPK Simulator has now been used to inform more than 300 drug label claims for over 100 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. Certara's technology-driven services, including model-informed drug development and regulatory writing and submission support, contributed to eight oncology drugs, two drugs for orphan diseases, two drugs that received priority review or accelerated approval in 2022, and one EUA for treatment of moderate/severe COVID-19.

[View FDA Approvals for 2022](#)

*excludes diagnostic agents

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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