Certara Awarded FDA Grant to Further Advance Virtual Bioequivalence Assessments of Generic Medicines Using Biosimulation

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Represents Fourth FDA Grant for Simcyp MechDermA™ Model for Virtual Bioequivalence

PRINCETON, N.J., Sept. 20, 2021 (GLOBE NEWSWIRE) -- Certara (Nasdaq: CERT), a global leader in biosimulation, today announced the Company has been awarded a grant from the U.S. Food and Drug Administration (FDA) to verify and expand biosimulation models for assessing virtual bioequivalence (VBE) to help enable safer, faster and more cost-effective generic drug product development.

Bioequivalence (BE) studies ensure that the rate and extent of absorption of the investigational product are not significantly different from those of the comparable reference drug product. Demonstrating BE is a key regulatory hurdle for generic drug approvals due to the high cost of conducting clinical trials. Modeling and simulation techniques, such as physiologically-based pharmacokinetic (PBPK) modeling, address this challenge by enabling drug developers to demonstrate *virtual* bioequivalence, helping to reduce or eliminate the need for clinical trials.

“We are elated to receive this grant and proud to collaborate with the FDA to help accelerate the drug development process of affordable generic medications,” said Rob Aspbury, Ph.D., President of Simcyp at Certara. “This project is aimed at further demonstrating the predictive performance, reliability and flexibility of Certara’s biosimulation models, which ultimately benefit patients.”

Sebastian Polak, Ph.D., will serve as principal investigator on the project titled, “Progressing integration of in vitro topical formulation characterisation, release and permeation data to the next level - PBPK based extrapolation to bioequivalence assessment in virtual populations.” This is the fourth grant that the FDA has awarded Certara for the development of Certara’s Simcyp MechDermA model. Furthermore, the Simcyp MechDermA model was used to demonstrate bioequivalence for the FDA approval of diclofenac sodium topical gel, a complex generic drug, in 2019 using the agency’s abbreviated new drug application pathway. This new project will allow for similar usage for complex, multi-phase formulations and advanced drug release technologies such as microspheres and liposomes and also focus on defining best practices for in vitro data usage.

“Demonstrating bioequivalence is especially complex for topical, dermatological generic treatments,” said Sebastian Polak, Ph.D., Senior Scientific Advisor & Head of Mechanistic Dermal Modelling at Certara. “I am excited to oversee this project, which will further optimize our biosimulation of topical drugs based on skin permeability. With this support, we can expand the applicability of our MechDermA model to demonstrate VBE and help to streamline or waive more clinical trials.”

Learn more about Simcyp Virtual Bioequivalence at https://www.certara.com/services/virtual-bioequivalence/.

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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