Certara Simcyp® Simulator Results Replace Ten Human Trials for Chronic Myeloid Leukemia (CML) Therapy asciminib

March 3, 2026

Biosimulation results highlight how model-informed approaches for drug development and regulatory decision-making save time and money.

RADNOR, Pa., March 03, 2026 (GLOBE NEWSWIRE) -- Certara, Inc. (Nasdaq: CERT), a global leader in model-informed drug development, today announced its Simcyp® Simulator enabled physiologically-based pharmacokinetic (PBPK) modeling predictions accepted by the U.S. FDA in lieu of clinical studies to support the new drug application (NDA) for asciminib (Scemblix®). PBPK modeling uses virtual biological systems to predict how drugs are absorbed, distributed, metabolized, and eliminated by the body, and is increasingly being applied in place of certain clinical studies where appropriate. The results published in "*Physiologically Based Pharmacokinetic Modeling and Simulations in Lieu of Clinical Pharmacology Studies to Support the New Drug Application of Asciminib*" (Loisios-Konstantinidis et al.), highlight the growing impact and business benefits of model-informed drug development approaches for regulatory decision-making.

Asciminib is the first-in-class allosteric inhibitor that specifically binds the BCR::ABL1 myristoyl pocket used to treat patients with Chronic Myeloid Leukemia (CML). The global incidence rate of CML was close to one case in 100,000 population in 2018,[1] and it accounts for approximately 15% of newly diagnosed cases of leukemia in adults. Given its potential for drug-drug interactions and the need to evaluate multiple dosing regimens, PBPK modeling with the Simcyp Simulator enabled a mechanistic assessment of asciminib's pharmacokinetics across diverse patient populations, dosing regimens and clinical scenarios. These simulations provided evidence that complemented and, in some cases, replaced clinical pharmacology studies in the NDA.

"As a member of the Simcyp Consortium, we have firsthand experience with Simcyp's capabilities and value its leading scientific rigor essential for enabling regulatory acceptance of PBPK models," said Ioannis Loisios-Konstantinidis, Senior Principal Scientist, PK Sciences, Novartis Biomedical Research.

Key results from the PBPK modeling included:

- Bridging between clinically tested and untested scenarios
- Replacement of at least ten dedicated clinical pharmacology studies
- Accurate characterization of asciminib pharmacokinetics across healthy volunteers and cancer patients
- Predicting how medicines work in real-life patients taking other medications

"This collaboration exemplifies the scientific partnership that the Simcyp Simulator enables," said Rob Aspbury, President, Certara Predictive Technologies. "The modeling work for asciminib evolved over a decade and contributed to richer understanding its optimal dosing regimen and drug interaction profile, ultimately supporting regulatory approval and an important new treatment for patients with CML."

Learn more about the asciminib case study here.

About Certara
Certara accelerates medicines using biosimulation software, technology and services to transform traditional drug discovery and development. Its clients include more than 2,600 biopharmaceutical companies, academic institutions, and regulatory agencies across 70 countries. Visit us at www.certara.com.

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[1] https://ascopubs.org/doi/pdfdirect/10.1200/GO.21.00194