Certara & Ichnos Glenmark Innovation Collaboration Optimizes Dosing Strategy for Potential First-In-Class Cancer Drug

September 18, 2024

Preclinical research on the trispecific antibody, ISB 2001, published in Nature Cancer leveraged virtual trials to select a higher starting dose that would lower costs and reduce cycle times

RADNOR, Pa., Sept. 18, 2024 (GLOBE NEWSWIRE) -- Certara, Inc. (Nasdaq: CERT), a global leader in model-informed drug development, today shared the results from its collaboration with Ichnos Glenmark Innovation (IGI) on the first-in-human dose prediction and selection for ISB 2001. IGI's drug candidate is a trispecific T-cell engager (TCE) being studied as a potential cancer treatment. Preclinical research and biosimulation findings were recently published in *Nature Cancer*. This publication highlighted ISB 2001's therapeutic potential for relapsed/refractory multiple myeloma patients.

Difficulties translating data from animals to patients traditionally limit first-in-human (FIH) dose selection to the most conservative approach. IGI sought to optimize the FIH dose of ISB 2001 to maximize patient safety and efficacy. They turned to Certara to develop an innovative virtual clinical trial platform leveraging their expertise in QSP (quantitative systems pharmacology) and PBPK (physiologically-based pharmacokinetics).

"We were honored to work with IGI to develop a comprehensive biosimulation approach that allowed the team to successfully test ISB 2001 in virtual trials," said Piet van der Graaf, PharmD, Ph.D., Senior Vice President and Head of Applied Biosimulation, Certara. "Our unique expertise and experience using virtual patients plus mechanistic modeling solutions allowed us to accelerate the speed at which ISB 2001 gets to patients. Virtual patient technology is the future of optimizing dosing for human patients."

As a result of this collaboration, the clinical starting dose increased by approximately 50-100 fold over the conventional starting dose. Using this higher dose reduces the likelihood of exposing cancer patients to ineffective doses. Accepted by the U.S. FDA and Australian HREC, this approach paves the way for determining FIH dosing for ISB 2001 and other TCEs.

In addition, leveraging virtual trials to optimize ISB 2001 dosing saves time and costs. This efficiency is key as the industry faces mounting pressure to get drugs to patients faster. Using a more optimized dose eliminates time spent dosing patient cohorts with sub-therapeutic doses. This approach also minimizes the quantity of animal studies needed aligning with U.S. and European regulatory goals including the FDA Modernization Act 2.0.

"The collaboration with Certara was important for the success of ISB 2001," said Mario Perro, Ph.D., Head of Biologics Research, IGI. "With the innovative QSP model adapted for our trispecific T cell engager, we could predict a first-in-human dose with an acceptable safety margin that will expose fewer patients to sub-therapeutic dosing."

To learn more about this research collaboration, please read this article, "ISB 2001 trispecific T-cell engager shows strong tumor cytotoxicity and overcomes immune escape mechanisms of multiple myeloma cells."

To learn more about the phase 1 clinical trial informed by this research, please refer to "Study of ISB 2001 in Relapsed/Refractory Multiple Myeloma."

About Certara
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