Press conference - Bio International Convention

San Diego - from June 3rd to 6th, 2024

This year, Boehringer Ingelheim will use ELEM Biotech's platform V.HEART to evaluate the cardiac safety of five new research compounds following a conclusive evaluation of ELEM's supercomputer-based virtual human trial technology.

Boehringer Ingelheim is working on breakthrough therapies that transform lives today and for generations to come. As a leading research-driven biopharmaceutical company, the company creates value through innovation in areas of high unmet medical need.

With V.HEART-SAFETY, Boehringer can safely test new compounds in virtual exposure-QTc studies in diverse virtual human populations of female, male, and pediatric hearts at the click of a button as soon as in vitro data becomes available for that compound. As the model parameters are all human, translation to clinical outcomes is straightforward compared to animal experiments requiring translational analysis.

BI's adoption of V.HEART-SAFETY follows a two-year internal evaluation of ELEM's full heart computational models to predict the concentration-response relationship of changes in the QT interval using a high-performance computing approach.

> *"These cardiac models reproducing human cardiac populations were comparable to human clinical data based on a set of well-characterized compounds with clinical QT interval data. We conclude that exposure-QT modelling with a virtual population of whole hearts to predict the outcome of clinical studies can be used to support decision-making in pharmaceutical research"* - **Jan Kriegl Global Computational Biology and Digital Sciences,** Boehringer Ingelheim.

From now on, having observed good agreement between simulation and clinical studies, BI plans to routinely use ELEM's Virtual cardiac trial platform in research for:

- Strengthening proof of concepts and estimating label-critical concentrations (>10ms DDQTc prolongation)
- Exploring unlimited exposures within and beyond medical ranges (accidental or intended overdosing)
- Assisting clinical go/no-go decision-making for new compounds

Anticipating potential adverse cardiac effects induced by a new molecule early prevents wasting valuable resources and can save up to 80% of the projected development cost, depending on the point in time of discontinuation.

The scope for V.HEART-SAFETY at BI will include:

- Investigating the impact of metabolic deficiencies on QT prolongation
- Extending exposure-QTc testing to more diverse populations and patient groups that are difficult to recruit
- Retrospectively verify adverse occurrences in marketed compounds
- Explore alternative uses of marketed compounds for other therapeutic areas

The availability of V.HEART-SAFETY on-demand, the speed, the ease of use of the platform, and the flexibility to define their trials are some of the additional benefits from ELEM's virtual trial technology that BI finds compelling. Virtual studies with V.HEART-SAFETY are cost-effective and reduce business and innovation risks.

Furthermore, the collaboration between BI and ELEM extends beyond routine applications. Our teams work hand in hand to develop new features, guide the choice of virtual sub-populations (e.g. with comorbidities), and more. The objective is to make virtual human trials even more real and inclusive, adding significance to what can be achieved with current clinical trial practice.

> *"Our clients perform hundreds of virtual assays in just days. At ELEM, we create medical avatars or Virtual Humans based on patient data, develop the most advanced supercomputer-based biomedical simulation software, and produce virtual populations of female, male and children hearts to test drugs and medical devices safely V.HEART-SAFETY is our first commercial application, and more are on their way in cardio and for new organs" -* ***Mariano Vazquez, ELEM Biotech's CTSO and originator of the technology.***

In time, we aim to present sufficient evidence to the regulatory bodies to obtain Thorough QT (TQT) waiver approval supported by V. HEART-SAFETY studies. Our first result, published on March 5th in the Journal of Pharmacology and Toxicology Methods, marked a key step on this journey. *[Virtual clinical QT exposure-response studies - A translational computational approach J Pharmacol Toxicol Methods. 2024 Mar-Apr:126:107498. doi: 10.1016/j.vascn.2024.107498.]*

> "For the first time, a pharmaceutical laboratory has strongly committed to virtual patients in drug development. This concept of modelling patients, diseases, and treatments all at once to deliver (new) scientific evidence in testing was introduced by Tina Morrison in 2015 at the FDA Center for Devices and Radiological Health. Today, Boehringer Ingelheim has decided to embrace it for drug development and has chosen ELEM Biotech. We are very excited about this partnership between BI and ELEM. It is a testament to BI's commitment to innovation and care, as well as to the ELEM team and our solutions. ELEM's Virtual Humans and virtual populations open a new dimension towards de-risking innovation for the biomedical industry, and for all of us to

receive better and safer treatments." – **Chris Morton, ELEM Biotech's co-founder and chief executive.**

For more details see also our case study.

About ELEM Biotech
ELEM Biotech provides on-demand cardiac safety assessments to pharmaceutical companies, CROs, and medical device manufacturers through ELEM's cloud-based platform, V.HEART-SAFETY.

ELEM Biotech is creating the fastest and most accurate Virtual Human and Virtual Trials technology for the biomedical therapeutics industry. By harnessing the power of supercomputers and accurate, predictive patient and disease modelling, ELEM is helping customers generate unparalleled new medical evidence to drive innovation safely. ELEM's goal is to enable companies and regulators to extend their capacity to test human models and virtual populations on an unprecedented scale and, in doing so, lower risk and create better conditions for successful outcomes from clinical trials.

Learn more at https://elem.bio/

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