

Danaher Launches Collaboration with Cincinnati Children's Hospital Medical Center Aiming to Improve Patient Safety in Early Drug Development

- *Danaher Beacon for Preclinical Drug Safety seeks to address major cause of failure in clinical trials*
- *Program will leverage automated liver organoid technology for drug toxicity screening*
- *Aims to expand genetic diversity of screening, accelerate therapy development, and help ensure patient safety*

WASHINGTON, Feb. 5, 2024 /PRNewswire/ -- Danaher Corporation (NYSE: DHR), a global science and technology innovator, today launched a strategic collaboration with Cincinnati Children's Hospital Medical Center, with the goal of improving patient safety by addressing a leading cause of failure in clinical trials. As part of the Danaher Beacons program, the multi-year collaboration aims to improve liver organoid technology as a drug toxicity screening solution for safeguarding patients, which could accelerate development of new therapies and potentially save billions of dollars in wasted research and development productivity each year.

More than 20% of clinical trials fail due to drug-induced liver injury (DILI)¹, leading to as much as \$3 billion annually in lost effort². Widely used *in vitro* models for toxicity testing that rely on immortalized cell lines or primary cells frequently fall short in accurately predicting human responses such as DILI. Emerging alternatives, such as liver organoids – complex multicellular models that have been shown to be highly predictive of human responses – can offer a more physiologically complex and personalized replication of human biology, proving valuable in predicting individual patient reactions to drugs and therapeutic interventions.

However, liver organoids have not been adopted widely because they are challenging to manufacture consistently at large scale and are typically sourced from a small number of samples that represent a highly limited patient population. As a result, biotech and pharmaceutical companies often struggle to accurately predict the risk of DILI in preclinical stages of drug development – especially in genetically diverse human populations that are not adequately represented by current model systems.

Molecular Devices, a Danaher subsidiary and leading high-performance life science solutions provider, will build on a long-standing relationship with Cincinnati Children's to lead the Beacon's work. Molecular Devices is a pioneer of end-to-end solutions for organoid development, and recently launched the CellXpress.ai™ Automated Cell Culture System – an AI-enabled solution that automates demanding production schedules to produce reliable, reproducible, and streamlined organoids at scale. The Cincinnati Children's Center for Stem Cell & Organoid Medicine (CuSTOM) -- a cross-departmental multi-disciplinary center of excellence leveraging advances in developmental biology and stem cell technologies to create complex, physiologically functioning human tissues – has been producing organoids using Molecular Devices technology since 2019.

William Blake, PhD, Chief Technology Officer, Human-Based R&D, Danaher, said:

"Predictive, human-relevant drug safety testing is one of the most pressing needs to reduce clinical trial attrition. We are delighted to partner with Cincinnati Children's with the goal of developing more streamlined, scalable, and genetically diverse liver organoid technology that could help get better, safer therapeutics to more patients faster."

Collaborative project work will be performed in a state-of-the-art facility known as the CuSTOM Accelerator (CA) lab that focuses on process, prototype development and de-risking proprietary technology to facilitate clinical translation and commercialization. Magdalena Kasendra, PhD, Director of Research and Development at CuSTOM and Takanori Takebe, MD, PhD, Director for Commercial Innovation at CuSTOM and an associate professor in the University of Cincinnati Department of Pediatrics, will co-lead the Beacon's efforts.

Kasendra said: "The recent modification in FDA regulations, eliminating the mandatory testing of therapies on animals before commencing clinical trials, has created opportunities for the widespread adoption of alternative methods. The Beacon project is designed to adapt human liver organoids to align with industry standards and regulatory practices. This adaptation could facilitate their more accessible integration into drug discovery processes, addressing current gaps in predictive and equitable toxicity testing."

Takebe said: "Our ongoing commitment to comprehending patient diversity and susceptibility to drug-related adverse events finds a synergistic match in our strategic collaboration with Danaher. This joint endeavor will bring together our collective expertise and aim to make strides in robust technology with the potential to impact countless patients waiting for safe new drugs."

The collaboration with Cincinnati Children's is the latest addition to the Danaher Beacons program, which funds product-driven pioneering scientific research with globally recognized academic investigators. The ultimate objective of this program is to develop innovative technologies and applications that can improve human health, with focus areas in genomic medicines, precision diagnostics, next-generation biomanufacturing, human systems and data sciences.

ABOUT DANAHER

Danaher is a leading global life sciences and diagnostics innovator, committed to accelerating the power of science and technology to improve human health. Our businesses partner closely with customers to solve many of the most important health challenges impacting patients around the world. Danaher's advanced science and technology – and proven ability to innovate – help enable faster, more accurate diagnoses and help reduce the time and cost needed to sustainably discover, develop and deliver life-changing therapies. Focused on scientific excellence, innovation and continuous improvement, our approximately 63,000 associates worldwide help ensure that Danaher is improving quality of life for billions of people today, while setting the foundation for a healthier, more sustainable tomorrow. Explore more at www.danaher.com.

ABOUT CINCINNATI CHILDREN'S HOSPITAL MEDICAL CENTER

Cincinnati Children's ranks #1 in the nation in U.S. News & World Report's 2023-24 listing of Best Children's Hospitals. In addition, Cincinnati Children's was recognized as one of America's Most Innovative Companies by Fortune in 2023 – and ranks the highest of any children's hospital in the nation. Cincinnati Children's also was recognized by Forbes as one of America's Best Employers for Diversity for 2023, and the only children's hospital recognized in the Top 20 by DiversityInc. Established in 1883, Cincinnati Children's is a nonprofit academic health system that is internationally recognized for improving child health and transforming delivery of care through research, education, and innovation. Nearly one-third of the more than 18,000 employees are engaged in research, and Cincinnati Children's is one of the top recipients of pediatric research grants from the National Institutes of Health.

FORWARD-LOOKING STATEMENTS

Statements in this release that are not strictly historical, including any statements regarding events or developments that DanaHER believes or anticipates will or may occur in the future are "forward-looking" statements within the meaning of the federal securities laws. There are a number of important factors that could cause actual results, developments and business decisions to differ materially from those suggested or indicated by such forward-looking statements and you should not place undue reliance on any such forward-looking statements. These factors include, among other things, potential future, adverse impacts on DanaHER's business, results of operations and financial condition related to the COVID-19 pandemic, the impact of our debt obligations on our operations and liquidity, deterioration of or instability in the economy, the markets we serve and the financial markets, uncertainties relating to national laws or policies, including laws or policies to protect or promote domestic interests and/or address foreign competition, contractions or growth rates and cyclicalities of markets we serve, competition, our ability to develop and successfully market new products and technologies and expand into new markets, the potential for improper conduct by our employees, agents or business partners, our compliance with applicable laws and regulations (including rules relating to off-label marketing and other regulations relating to medical devices and the health care industry), the results of our clinical trials and perceptions thereof, our ability to effectively address cost reductions and other changes in the health care industry, our ability to successfully identify and consummate appropriate acquisitions and strategic investments and successfully complete divestitures and other dispositions, our ability to integrate the businesses we acquire (including the acquisition of Abcam) and achieve the anticipated growth, synergies and other benefits of such acquisitions, contingent liabilities and other risks relating to acquisitions, investments, strategic relationships and divestitures (including tax-related and other contingent liabilities relating to past and future IPOs, split-offs or spin-offs), security breaches or other disruptions of our information technology systems or violations of data privacy laws, the impact of our restructuring activities on our ability to grow, risks relating to potential impairment of goodwill and other intangible assets, currency exchange rates, tax audits and changes in our tax rate and income tax liabilities, changes in tax laws applicable to multinational companies, litigation and other contingent liabilities including intellectual property and environmental, health and safety matters, the rights of the United States government with respect to our production capacity in times of national emergency or with respect to intellectual

property/production capacity developed using government funding, risks relating to product, service or software defects, product liability and recalls, risks relating to fluctuations in the cost and availability of the supplies we use (including commodities) and labor we need for our operations, our relationships with and the performance of our channel partners, uncertainties relating to collaboration arrangements with third-parties, the impact of deregulation on demand for our products and services, the impact of climate change, legal or regulatory measures to address climate change and our ability to address stakeholder expectations relating to climate change, labor matters and our ability to recruit, retain and motivate talented employees representing diverse backgrounds, experiences and skill sets, non-U.S. economic, political, legal, compliance, social and business factors (including the impact of military conflicts), disruptions relating to man-made and natural disasters, pension plan and healthcare costs, inflation and the impact of our By-law exclusive forum provisions. Additional information regarding the factors that may cause actual results to differ materially from these forward-looking statements is available in Danaher's SEC filings, including our 2022 Annual Report on Form 10-K and Quarterly Report on Form 10-Q for the third quarter of 2023. These forward-looking statements speak only as of the date of this release and except to the extent required by applicable law, Danaher does not assume any obligation to update or revise any forward-looking statement, whether as a result of new information, future events and developments or otherwise.

Sources:

- <https://www.sciencedirect.com/science/article/pii/S0168827823000727>
- <https://nature.com/articles/s43856-022-00209-1>

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