

## **Fujifilm and Predictive Oncology Announce Collaboration to Reduce Protein Interference in Bacterial Endotoxin Detection Testing of Biopharmaceuticals**

**RICHMOND, VA, and PITTSBURGH, April 25, 2024** – FUJIFILM Wako Chemicals U.S.A. Corporation (Fujifilm), a supplier of high purity chemicals and reagents, and Predictive Oncology Inc., (NASDAQ: POAI), a leader in AI-driven drug discovery and biologics, announced today that the companies have entered into a collaboration and co-marketing agreement to reduce protein interference in bacterial endotoxin testing of biopharmaceutical products. Per the terms of the agreement, Predictive Oncology will utilize its novel EndoPrep™ sample treatment technology (EndoPrep), together with Fujifilm's PYROSTAR™ bacterial endotoxin detection reagent (PYROSTAR), to [detect residual endotoxins more accurately in biopharmaceuticals](#) by eliminating protein interference from the drug product in the detection assay.

Endotoxins – also known as lipopolysaccharides (LPS) – are components of the outer cell membrane of gram-negative bacteria and are released when intact bacteria are disrupted. Sub-nanogram levels of endotoxins can trigger immune responses such as inflammation and fever in patients, even leading to systemic shock and death. Endotoxins are highly resistant to sterilization processes, and accurate detection and removal of endotoxins in biopharmaceuticals are required before entering animal trials or human clinical trials.

The Limulus Amebocyte Lysate (LAL) test is recognized by the U.S. Pharmacopeia (USP) for determining endotoxin levels in many biopharmaceuticals. Fujifilm's PYROSTAR ES-F LAL reagent is designed for the specific determination of gram-negative bacterial endotoxins, while also remaining unreactive to (1,3)-β-D-glucan. The PYROSTAR ES-F LAL reagent accurately detects residual endotoxins in the presence of interfering glucans and, when paired with Predictive Oncology's EndoPrep, reduces interference of most biologic products with the detection assay. In a proof-of-concept study, the companies achieved reproducible and accurate measurements of endotoxin in the presence of specific interfering proteins in biologics.<sup>1</sup> The study results indicate that 3 of 4 tested biologics went from not falling in the 50-200% detection range of challenge endotoxin to falling in the 50-200% detection range required by the FDA.

“We have a very powerful opportunity through this collaboration with Predictive Oncology to make a significant impact on drug safety by enabling the more accurate detection of residual endotoxins associated with biologic drug products,” said Lisa Komski, general manager, LAL Sales and Export Department, FUJIFILM Wako Chemicals U.S.A. Corporation.

“There is no question that Fujifilm has one of the best detection systems for measuring endotoxin levels in biologic drug products,” said Dr. Larry DeLucas, senior vice president, of Biologics for

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<sup>1</sup> Compared to traditional industry standards of utilizing heat-treatment or dilution to remove the interference of high protein.

Predictive Oncology. “We have developed an advanced sample treatment product that allows pharmaceutical companies to prevent drug product interference with endotoxins, a technique which allows for a more accurate measurement of endotoxins that would have been masked by binding to the drug product itself.”

According to a recent report by [Future Market Insights, Inc.](#), the injectable drug market is estimated to be approximately US\$ 6.0 billion in 2024. During the period from 2024 to 2034, the market is expected to progress, registering a compounded annual growth rate of 5.8%. By 2034, the injectable drug market is anticipated to reach a value of US\$ 10 billion. By bringing together Fujifilm’s PYROSTAR endotoxin detection technology with Predictive Oncology’s EndoPrep treatment kit, the companies will together be able to offer unique endotoxin solutions for injectable pharmaceuticals and biological products.

For more information, please visit <http://www.Predictive-Oncology.com/Fujifilm>.

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## **About Fujifilm**

FUJIFILM Wako Chemicals U.S.A. Corporation, headquartered in Richmond, Virginia, is recognized around the world as a trusted supplier of high purity chemicals and reagents for the Specialty Chemicals, Laboratory Chemicals, and Diagnostics business sectors. The company offers a wide range of products including the PYROSTAR™ ES-F series of reagents and the Toxinometer® ET-7000 measurement system, a computer-operated kinetic incubating tube reader, to help its customers detect endotoxins. FUJIFILM Wako Chemicals U.S.A. Corporation develops and sells products dedicated to the health, welfare, and safety of its customers, as well as, the protection of the environment. For more information, please visit: <https://www.wakopyrostar.com>.

FUJIFILM Holdings Corporation, Tokyo, leverages its depth of knowledge and proprietary core technologies to deliver Value from Innovation in our products and services in the business segments of healthcare, materials, business innovation, and imaging. Our relentless pursuit of innovation is focused on providing social value and enhancing the lives of people worldwide. Fujifilm is committed to responsible environmental stewardship and good corporate citizenship. For more information about Fujifilm’s Sustainable Value Plan 2030, [click here](#). For the year ended March 31, 2023, the company had global revenues of approximately 2.9 trillion yen (21 billion \$USD at an exchange rate of 134 yen/dollar). For more information, please visit: [www.fujifilmholdings.com](http://www.fujifilmholdings.com).

## **About Predictive Oncology**

Predictive Oncology (NASDAQ: POAI) is on the cutting edge of the rapidly growing use of artificial intelligence and machine learning to expedite early drug discovery and enable drug development for the benefit of cancer patients worldwide. The company’s scientifically validated AI platform, PEDAL, is able to predict with 92% accuracy if a tumor sample will respond to a certain drug compound, allowing for a more informed selection of drug/tumor type combinations for subsequent

in-vitro testing. Together with the company's vast biobank of more than 150,000 assay-capable heterogenous human tumor samples, Predictive Oncology offers its academic and industry partners one of the industry's broadest AI-based drug discovery solutions, further complimented by its wholly owned CLIA lab and GMP facilities. Predictive Oncology is headquartered in Pittsburgh, PA.

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