

Press Release  
19 October 2022



## **FUJIFILM Irvine Scientific PRIME-XV Stem FreezIS DMSO-Free Cryopreservation Medium to be Used in FDA-Authorized Clinical Trial**

*Conducted by Vitro Biopharma, the trial aims to investigate the safety and efficacy of intravenous infusions of its stem cell therapy product*

**SANTA ANA, Calif., October 19, 2022--** FUJIFILM Irvine Scientific, Inc., a world leader in the development and manufacture of serum-free and chemically defined cell culture media for bioproduction and cell therapy manufacturing, today announced that its PRIME-XV Stem FreezIS DMSO-Free\* cryopreservation medium is to be used as an excipient in a FDA-authorized clinical trial conducted by Vitro Biopharma.

Vitro Biopharma is an innovative biotechnology company targeting autoimmune diseases and inflammatory disorders that are derived from culture-expanded mesenchymal stem cells (“MSCs”) sourced from the Wharton’s jelly of umbilical cords. In the United States, Vitro Biopharma is authorized to conduct a clinical trial under a U.S. Food and Drug Administration (“FDA”) Investigational New Drug (“IND”) application to assess the safety and efficacy of AlloRx Stem Cell therapy in Pitt Hopkins syndrome (“PTHS”). The PTHS trial will utilize FUJIFILM Irvine Scientific’s PRIME-XV Stem FreezIS DMSO-Free\* cryopreservation medium as an excipient during the process.

The use of DMSO during cell therapies has historically been a process critical step used to maintain cell viability during cryopreservation, however DMSO toxicity has been well characterized in cells throughout the human body and can cause a wide range of undesirable side effects following stem cell therapy. FUJIFILM Irvine Scientific’s PRIME-XV Stem FreezIS DMSO-Free\* cryopreservation medium is a complete and ready-to-use, chemically defined, animal component- and protein-free solution that does not contain DMSO. The medium is validated for use in mesenchymal stromal cells and CD34<sup>+</sup> cells, and optimized cryopreservation protocols for peripheral blood mononuclear cells and T cells have also been published. It is manufactured under GMP conditions and has a drug master file registered with the FDA.

**Erik Vaessen, chief business officer at FUJIFILM Irvine Scientific, said** *"We are pleased to support Vitro Biopharma’s clinical trial via the provision of our PRIME-XV Stem FreezIS DMSO-Free cryopreservation medium. The recent FDA authorization of this trial represents an exciting step forward in cell therapy pipelines, with the potential to remove the DMSO requirement from workflows. We are committed to developing and supplying products that help our customers fully realize the potential of new advanced therapies and improved patient outcomes."*

For more information on FUJIFILM Irvine Scientific’s PRIME-XV Stem FreezIS DMSO-Free\* cryopreservation medium, please visit <https://www.irvinesci.com/prime-xv-stem-freezis-dmso-free.html>

\* PRIME-XV Stem FreezIS DMSO-Free is for research use or further manufacturing use only.

**ENDS**

**Notes to Editors**



*Image: FUJIFILM Irvine Scientific's PRIME-XV Stem FreezIS DMSO-Free Medium*

For a high-resolution image please contact Zyme Communications.

## **About FUJIFILM**

### **FUJIFILM Irvine Scientific**

FUJIFILM Irvine Scientific, Inc. is a global leader in the innovation and manufacture of cell culture solutions for Life Science and Medical markets, providing products and services that assist our customers in advancing healthcare initiatives. Working across discovery research, cell and gene therapy, reproductive medicine and cytogenetics, as well as the large-scale production of biotherapeutics and vaccines, the Company is trusted by researchers, manufacturers, and clinicians. For over 50 years, our Mission has been to set the standard for excellence in our products and custom solutions to enable our customers to advance healthcare. Its facilities adhere to both ISO and FDA regulations, with manufacturing facilities that follow cGMP guidelines in the USA, Japan, and the Netherlands, and a media optimization center in China. All sites prioritize strategies that adhere to the FUJIFILM Sustainability Value Plan 2030 for sustainable growth. FUJIFILM Irvine Scientific, Inc. is a subsidiary of FUJIFILM Holdings America Corporation reporting to FUJIFILM Holdings Corporation.

For more information, please visit: [www.irvinesci.com](http://www.irvinesci.com).

### **FUJIFILM Holdings Corporation**

FUJIFILM Holdings America Corporation is the regional headquarters for the Americas. It is comprised of more than 20 affiliate companies across North and Latin America that are engaged in the research, development, manufacture, sale and service of FUJIFILM products and services. The company's portfolio represents a broad spectrum of industries including medical and life sciences, electronic, chemical, graphic arts, information systems, industrial products, broadcast, recording media, and photography. For more information, please visit: <https://www.fujifilm.com/us/en/about/region>.

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, 2022, the company had global revenues of approximately 2.5 trillion yen (21 billion \$USD at an exchange rate of 122 yen/dollar). For more information, please visit: [www.fujifilmholdings.com](http://www.fujifilmholdings.com).

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