

Press Release

December 06, 2022



Shenandoah Biotechnology Introduces Expanded Range of CTGrade Recombinant Proteins Manufactured Following cGMP Practices

- *Portfolio of CTGrade cytokines and growth factors contain no animal- or human-derived materials*
- *Expansion of CTGrade portfolio resulting from the acquisition by FUJIFILM Irvine Scientific earlier this year*

Warminster, Pa., December 06, 2022: Shenandoah Biotechnology Inc., a FUJIFILM Irvine Scientific company and leading manufacturer of recombinant proteins, today announced it has expanded its CTGrade portfolio of cytokines and growth factors for cell and gene therapies manufactured following cGMP guidelines. The expanded range, which is now available directly through FUJIFILM Irvine Scientific, includes CTGrade cytokines IL-2, IL-3, IL-6, IL-7, IL-10, IL-15, IL-21, and FLT-3 ligand, with additional proteins in development that optimize cell proliferation and function for new cell and gene therapies applications.

Cytokines and growth factors are signaling molecules that regulate cell growth, differentiation, and motility, as well as immune and inflammatory responses, and are therefore used for the expansion, differentiation, and maintenance of cells in most cell therapies. As manufacturers move towards clinical trials, using raw materials manufactured following cGMP guidelines is optimal to minimize variability and ensure predictable workflow performance. Designed to support basic, translational, and clinical research, as well as commercial applications, the CTGrade products are produced from *E. coli* and are manufactured in a facility that does not use or process beta-lactam containing materials. No animal- or human-derived materials were used during manufacturing or as ingredients. These products are manufactured, tested, and released in an ISO 9001:2015 certified facility following cGMP practices. USP chapter <1043> for ancillary materials has been considered in the manufacture of these products.

The Shenandoah products are developed harnessing FUJIFILM Irvine Scientific's extensive regulatory expertise and quality control to ensure lot-to-lot consistency, reproducibility in

downstream cell culture processes, and the smooth transition of biological therapies from preclinical to clinical phases.

Erik Vaessen, chief business officer, FUJIFILM Irvine Scientific, said: *“The predictability and performance of CTGrade recombinant proteins help cell and gene therapy developers accelerate delivery of life-changing therapies to market. The biological activity of these high-performing proteins adheres to WHO International standards, where applicable, providing consistent, lot-to-lot biological activity and performance, and ultimately successful progression to the clinic.”* **He added:** *“The availability of this expanded range directly through FUJIFILM Irvine Scientific provides our customers worldwide with a single point of access for cGMP cell culture solutions, following our acquisition of Shenandoah Biotechnology in March this year.”*

All products are available from [Shenandoah Biotechnology](#) and [FUJIFILM Irvine Scientific](#) in multiple package sizes of 50 µg, 100 µg, and 1 mg, as well as with custom sizing and packaging. To view the entire range of Shenandoah Biotechnology recombinant proteins that support early research to further manufacturing visit www.shenandoah-bt.com.

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Notes to Editors

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. Our 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 visit www.irvinesci.com

FUJIFILM Holdings Corporation

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.

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