

BioLife Solutions Collaborates with Seattle Children's to Improve Viral Vector and Cell and Gene Therapy Manufacturing

Sexton Cell Processing tools and CryoStor cGMP Freeze Media Incorporated in Cell and Gene Therapy Workflows

BOTHELL, Wash., Jan. 4, 2022 /PRNewswire/ -- [BioLife Solutions](#), Inc. (NASDAQ: [BLFS](#)), a leading supplier of class-defining bioproduction tools and services for the cell and gene therapy and broader biopharma markets, today announced an extended collaboration with Seattle Children's Therapeutics, a venture at Seattle Children's, bringing cutting edge, curative technologies and therapies to defeat pediatric cancer and other diseases that impact children. The collaboration will focus on establishing best practices in biopreservation and closed-system manufacturing with the introduction and integration of Sexton's AF-500™ for closed-system processing for cell therapy manufacturing and viral vector delivery that will be used in Seattle Children's Therapeutics new lentiviral vector manufacturing facility called VectorWorks.

"This expanded collaboration is an exciting step for Seattle Children's Therapeutics as we work towards developing closed-system processes for cell therapy manufacturing," said Matt Selley, Director of GMP Manufacturing at Seattle Children's. "Lentiviral vector manufacturing is a critical component of the cell production process."

Seattle Children's has utilized BioLife's CryoStor® cGMP freeze media for several years, as an optimized excipient for improved post-thaw viability and functional recovery of cells used in clinical applications and trials. As cell and gene therapy manufacturers move toward closed-system processing, it is vital that upstream critical excipients and ancillary materials, such as viral vectors, are manufactured and packaged in containers suitable for closed-system integration. While some upstream bioprocesses have been successfully automated, the final steps of downstream bioprocess, namely fill-finish, are often performed manually in open systems with associated risks of contamination and user error. Furthermore, current packaging for viral vector intermediates demands that therapy developers operate in higher grade environments due to the open nature of this manufacturing step.

This continued collaboration will combine the Sexton off-the-shelf automated fill-finish system, AF-500, with Seattle Children's Therapeutics' expertise in viral vector manufacturing. Sexton's rapidly deployable AF-500 is capable of filling and sealing up to 560 CellSeal® vials in 90 minutes. The goal is to utilize the AF-500 to initiate high throughput fill-finish of vector intermediates. Vectors will be filled into Sexton's proprietary vials, CellSeal and CellSeal Connect™. CellSeal Connect builds on the original CellSeal cryogenic storage vial, which has been incorporated as the final drug packaging in commercial cell therapy products. The new version allows closed-system retrieval of intermediate products, such as viral vectors, thereby negating the need for therapy developers to operate in higher grade manufacturing suites for delivery of vectors and cargo.

The collaboration will result in detailed workflows, demonstrating the suitability of the CellSeal platform as a packaging container and closed system automation for viral vectors. It will include an assessment of the vial and fill system's usability and compatibility with high throughput fill-finish of viral vectors. In addition, post-fill activities such as high-density storage, shipping, distribution, thawing, and closed system retrieval will be assessed. As

Seattle Children's Therapeutics will be the end-user of the viral vector product, the workflow resulting from the collaboration will cover the movement of viral vectors from the point of packaging to the point of transduction and patient administration, when applicable.

"The development of these closed connection processes in small volume aliquots has the potential to streamline this element of cell therapy manufacturing," said Sean Werner PhD, Chief Technology Officer, Cell Processing at Biolife Solutions. "Developing tools to meet the unique needs of this emerging industry is the best way to bring these life changing therapies to patients."

About BioLife Solutions

BioLife Solutions is a leading supplier of class-defining bioproduction tools and services for the cell and gene therapy and broader biopharma markets. Our tools portfolio includes our proprietary [CryoStor®](#) and [HypoThermosol®](#) biopreservation media for shipping and storage, the [ThawSTAR®](#) family of automated, water-free thawing products, [evo®](#) cold chain management system, [high capacity cryogenic storage freezers](#), [Stirling Ultracold](#) mechanical freezers, [SciSafe](#) biologic storage services, and [Sexton Biotechnologies](#) cell processing tools. For more information, please visit www.biolifesolutions.com, www.scisafe.com, www.stirlingultracold.com, or www.sextonbio.com and follow BioLife on [Twitter](#).

About Seattle Children's

Seattle Children's mission is to provide hope, care and cures to help every child live the healthiest and most fulfilling life possible. Together, Seattle Children's Hospital, Research Institute and Foundation deliver superior patient care, identify new discoveries and treatments through pediatric research, and raise funds to create better futures for patients.

Ranked as one of the top children's hospitals in the country by U.S. News & World Report, Seattle Children's serves as the pediatric and adolescent academic medical center for Washington, Alaska, Montana and Idaho – the largest region of any children's hospital in the country. As one of the nation's top five pediatric research centers, Seattle Children's Research Institute is internationally recognized for its work in neurosciences, immunology, cancer, infectious disease, injury prevention and much more. Seattle Children's Foundation works with the Seattle Children's Guild Association, the largest all-volunteer fundraising network for any hospital in the country, to gather community support and raise funds for uncompensated care and research. Join Seattle Children's bold initiative – It Starts With Yes: The Campaign for Seattle Children's – to transform children's health for generations to come.

For more information, visit seattlechildrens.org or follow us on Twitter, Facebook, Instagram or on our [On the Pulse](#) blog.

Cautions Regarding Forward Looking Statements

Except for historical information contained herein, this press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, statements concerning our extended collaboration with Seattle Children's and the results of such collaboration. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. These statements are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described in the forward-looking

statements, including among other things, those factors described in our risk factors set forth in our filings with the Securities and Exchange Commission from time to time, including our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. We undertake no obligation to update the forward-looking statements contained herein or to reflect events or circumstances occurring after the date hereof, other than as may be required by applicable law.

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