

BioLife Solutions Completes Safety Studies on HypoThermosol® and CryoStor™ Additional Safety Data Could Drive Product Adoption in High-Growth Cell Therapy Market

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BioLife Solutions, Inc. (BULLETIN BOARD: BLFS) , a leading developer and marketer of proprietary cGMP hypothermic storage and cryopreservation media products for cells, tissues, and organs, today announced that it has completed an initial series of small animal safety studies at the Seattle-based Fred Hutchinson Cancer Research Center on its biopreservation media products, HypoThermosol and CryoStor.

The effort, titled, "A Preclinical Safety Study of Intravenous Injection of Biopreservation Solutions as a Vehicle for Cellular Products," evaluated injections of HypoThermosol, CryoStor, or control phosphate buffered saline (PBS) into healthy rodents. The study was designed to mimic human clinical applications where stem cells isolated from cord or peripheral blood are re-suspended in a carrier solution and administered intravenously to treat patients suffering from a variety of diseases and disorders including leukemia, anemia, lymphoma, myeloma, and other cancers.

The results of these studies demonstrate that infusion of HypoThermosol and CryoStor present no safety risk within the parameters of this two-stage evaluation in a rodent model. No toxic deaths were noted in either Stage 1 or 2 at infusion or in the 7 day follow-up. Stage 1 involved infusion of carrier solutions alone with no cells, while Stage 2 evaluated freshly isolated umbilical cord blood-derived stem cells re-suspended in the various carrier solutions. Blood chemistries and organ pathologies were also evaluated, with no abnormalities found.

Mike Rice, chairman and CEO of BioLife stated, "In collaborating on the study design with leading clinicians at the Fred Hutchinson Cancer Research Center, we intentionally selected injection volumes and cell concentrations that significantly exceed typical human dosage equivalents, to establish a wide safety margin for our customers involved in human clinical cell therapy product development and commercialization, where our products are used in their production processes."

Currently, biopreservation media products are considered excipient materials used in the production of biologic products, and the manufacturer of a biologic product is responsible for validating the use, safety, and efficacy of all excipient materials and the final product. This includes therapies where cells are directly introduced into patients without removing excipient materials.

Rice continued, "While our current and prospective customers are required to complete their own studies to determine the safety of using our products within their clinical applications, we feel that our independent safety data will encourage more cell therapy companies and hospital-based stem cell and bone marrow transplant centers to consider adopting our products. To date, more than 120 cell therapy organizations have ordered our enabling biopreservation products, which have been shown to extend the shelf life and improve the post-preservation viability and functional yield of biologic source material and derived cell-based products. We anticipate completing additional animal studies to compare engraftment capabilities of cells preserved in HypoThermosol and CryoStor against cells preserved in other standard laboratory preservation media formulations."

BioLife has already taken important regulatory steps by submitting and maintaining separate FDA Master Files for HypoThermosol and CryoStor, and these will be updated to include data from the safety studies. A link to request a cross reference to the master files can be found here: <http://www.biolifesolutions.com/regulatory/mfrequest.htm>.

About BioLife Solutions, Inc:

BioLife Solutions develops and markets patented hypothermic storage/transport and cryopreservation media products for cells, tissues, and organs. The Company's proprietary HypoThermosol® and CryoStor™ platform of biopreservation media products are marketed to academic research institutions, hospitals, and commercial companies involved in cell therapy, tissue engineering, cord blood banking, drug discovery, and toxicology testing. BioLife's cGMP products are serum-free and protein-free, fully defined, and formulated to reduce preservation-induced, delayed-onset cell damage and death. BioLife's enabling technology provides research and clinical organizations significant improvement in post-preservation cell and tissue viability and function. For more information please visit www.biolifesolutions.com.

This news release contains forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These forward-looking statements include any statements that relate to the intent, belief, plans or expectations of the Company or its management, or that are not a statement of historical fact. Any forward-looking statements in this news release are based on current expectations and beliefs and are subject to numerous risks and uncertainties that could cause actual results to differ materially. Some of the specific factors that could cause BioLife Solutions' actual results to differ materially are discussed in the Company's recent filings with the Securities and Exchange Commission. BioLife Solutions disclaims any obligation to update any forward-looking statements as a result of developments occurring after the date of this press release.

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