

New Journal Articles Cite Expanded Use of BioLife Solutions Products in Clinical Cell Therapy Applications

CryoStor® Clinical Grade Cell Freeze Media Enabling Development of Novel Regenerative Medicine Therapies for Large Disease States

BOTHELL, Wash., Jan. 25, 2016 /PRNewswire/ -- [BioLife Solutions](#), Inc. (NASDAQ: BLFS), the leading developer, manufacturer and marketer of proprietary clinical grade cell and tissue hypothermic storage and cryopreservation freeze media and a related cloud hosted biologistics cold chain management app for smart shippers today announced that two recently published journal articles cite expanded use of the Company's CryoStor cell freeze media in pre-clinical safety studies and clinical trials of cellular therapies for liver transplantation and heart failure.

The article [Successful expansion of functional and stable regulatory T Cells for immunotherapy in liver transplantation](#) was published in the journal *Oncotarget* and completed at MRC Centre for Transplantation, Division of Transplantation Immunology and Mucosal Biology, King's College London, Guy's Hospital, Great Maze Pond, London, and the Institute of Liver Studies, King's College Hospital, Denmark Hill, London.

In this study, Treg cells were frozen in CryoStor, then thawed and assessed for viability and suppressive function. The authors concluded:

- We report the enrichment of a pure, stable population of Tregs (>95% CD4⁺CD25⁺FOXP3⁺), reaching adequate numbers for their clinical application.
- Our protocol proved successful in influencing the expansion of superior functional Tregs, as compared to freshly isolated cells, whilst also preventing their conversion to Th17 cells under pro-inflammatory conditions.
- We conclude with the manufacture of the final Treg product in the clinical research facility (CRF), a prerequisite for the clinical application of these cells.

In another article, [Widespread Myocardial Delivery of Heart-Derived Stem Cells by Nonocclusive Triple-Vessel Intracoronary Infusion in Porcine Ischemic Cardiomyopathy: Superior Attenuation of Adverse Remodeling Documented by Magnetic Resonance Imaging and Histology](#), a study using CryoStor was completed at Cedars-Sinai Heart Institute in Los Angeles, and Keio University School of Medicine in Tokyo, Japan. The authors concluded:

- We have addressed a number of issues that are central to the delivery of cell therapy (safety and efficacy of stop-flow versus continuous-flow, and of single- versus triple-vessel infusion).
- Our findings give reason to believe that global cell infusion may be a promising translational tool, particularly to treat generalized cardiac disorders.
- These data provide preclinical validation for nonocclusive multi-vessel cell delivery, as is being utilized in the phase 2a DYNAMIC (Dilated cardiomyopathy intervention with Allogeneic Myocardial Allogeneic Cells) trial of allogeneic CDCs in patients with ischemic and non-ischemic heart failure.

Mike Rice, BioLife's President & CEO, said, "We are pleased to see additional public disclosures about the use of our biopreservation tools used in the regenerative medicine market. Our proprietary biopreservation media products are now embedded in over 200 customer clinical validations and clinical trials of potentially life saving cellular therapies. With the recent launch of *biologistex*™ cloud based cold chain management app and *evo*™ Smart Shipper, we have tremendous opportunities to help our customers improve the quality and delivery logistics of their time and temperature sensitive biologic products."

BioLife Solutions is sponsoring, presenting, and exhibiting at the Cell & Gene Therapy World conference, January 25 – 27, at the Grand Hyatt in Washington, DC. Kevin O'Donnell, Vice President, Cold Chain Standards, Practices, and Compliance, will chair the session, *What Progress is Enabling the True Globalization of Cell & Gene Therapies?* occurring at 11:45AM on January 27th. For more information, please visit <http://www.bioleaders-forum.com>.

About biologistex Cold Chain SaaS App:

BioLife's [biologistex](#) cloud based cold chain management service is a new integrated logistics and track and trace web app used by shippers of time and temperature sensitive biologic materials. The [evo Smart Shipper](#) is a state of the art precision thermal shipping container with embedded payload monitoring, GPS location tracking, and cellular communication electronics that transmit critical shipment information to the cloud. This SaaS app enables users to monitor high value shipments during transit and configure actionable alerts for downstream recipients for location, approaching destination, delivery, package open, and remaining shelf life or stability via the patent pending StableAlert™ countdown timer.

About BioLife Solutions Addressable Markets

- In July 2015, Frost & Sullivan forecasted that the stem cell therapy market is expected to be worth \$40 billion by 2020 and \$180 billion by 2030.
- Pharmaceutical Commerce estimates that in 2015, \$10 billion was spent on cold chain logistics of pharmaceuticals, with \$7 billion for transportation and \$3 billion for specialized packaging and instrumentation. BioLife's addressable market is comprised of the demand for small payload shipping containers and related temperature monitoring and location tracking devices.
- Global Industry Analysts, Inc. estimates in their September 2015 Organ Preservation Solutions, A Global Strategic Business Report that the worldwide demand for organ cold storage solutions was \$85.5 million in 2014, and is expected to grow 109% to over \$175 million in 2020.

About BioLife Solutions:

The Company's proprietary HypoThermoso® and CryoStor® platform of solutions are highly valued in the biobanking, drug discovery, and regenerative medicine markets. BioLife's biopreservation media products are serum-free and protein-free, fully defined, and are formulated to reduce preservation-induced cell damage and death. BioLife's enabling technology provides commercial companies and clinical researchers significant improvement in shelf life and post-preservation viability and function of cells, tissues, and organs. BioLife also performs contract aseptic media formulation, fill, and finish services. For more information please visit www.biolifesolutions.com, and follow BioLife on [Twitter](#).

This press release contains forward-looking statements, including, but not limited to, statements concerning new products, the company's anticipated business and operations, the potential utility of and market for its products and services, potential revenue growth and market expansion, and, projected financial results and liquidity. 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, uncertainty regarding market adoption of products; uncertainty regarding third party market projections; market volatility; competition; litigation; and those other 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 and Quarterly Reports on Form 10-Q. 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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