

BioLife Solutions Executes 10 Year Supply Agreement with TissueGene for CryoStor® Use in Invossa™ Osteoarthritis Cell-Mediated Gene Therapy

BOTHELL, Wash., Dec. 20, 2016 /PRNewswire/ -- [BioLife Solutions](#), Inc. (NASDAQ: BLFS), a 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](#) ("BioLife" or the "Company"), today announced that it has entered into a ten year supply agreement with TissueGene, a leading developer of regenerative therapies for the treatment of various orthopedic diseases.

BioLife's CryoStor clinical grade cell freeze media is incorporated into TissueGene's manufacturing process for Invossa, a first-in-class osteoarthritis drug designed to conveniently and effectively treat osteoarthritis of the knee through a single intra-articular injection. Clinical trials completed in Korea and on-going trials in the US have demonstrated pain relief, increased mobility, and improvements in joint structure – offering substantial convenience for osteoarthritis patients who would otherwise need surgery.

Upon completion of its clinical trials in Korea in July of this year, which successfully verified the safety and efficacy of Invossa, TissueGene's marketing partner, Kolon Life Science, filed for a biologics license application with the Korea Ministry of Food and Drug Safety (MFDS). Similarly, Mitsubishi Tanabe will proceed with Japanese clinical trials and regulatory filings and Kolon Life Science will be responsible for manufacturing activities. Market forecasts predict that the number of osteoarthritis patients in Japan aged 40 and older amounts to more than 25 million and is expected to accelerate with the aging population.

For the US market, TissueGene has completed U.S. Phase 2 trials of Invossa and received a Special Protocol Assessment ("SPA") designation for Phase 3 trials scheduled to begin in the second quarter of 2017. The US Phase 3 will aim for approval from the US Food and Drug Administration (FDA) as the first disease-modifying osteoarthritis drug (DMOAD). Additional Information can be found at the NIH registry, www.clinicaltrials.gov.

Mike Rice, BioLife President & CEO, commented, "We are very pleased to support TissueGene and Kolon with this long term supply agreement, which further supports our growth potential of the franchise we have built in the high growth cell therapy industry. We believe that CryoStor and HypoThermosol are incorporated into more than 230 customer pre-clinical validation projects and clinical trials of cell-based therapies targeting blood cancers, solid tumors, vision loss, heart disease, stroke, and movement disorders such as osteoarthritis. 2017 should be a pivotal year for BioLife, as we expect further customer progress in late stage clinical trials and regulatory approval submissions. This momentum in the regenerative medicine market should drive increased demand for CryoStor and HypoThermosol."

About TissueGene

TissueGene, Inc. is a biopharmaceutical company based in Rockville, Maryland, specializing in regenerative therapies for the treatment of various orthopedic diseases. TissueGene has completed Phase 2 trials and has reached an agreement with the U.S. Food and Drug Administration regarding a Special Protocol Assessment (SPA) on the design, endpoints and statistical analysis plan for a Phase 3 clinical trial for Invossa, an allogeneic cell therapy for osteoarthritis of the knee. Related information can be found at the NIH registry,

<http://www.clinicaltrials.gov/>. For additional information about TissueGene, please visit <http://www.tissuegene.com/>.

About BioLife Solutions

BioLife Solutions develops, manufactures and markets biopreservation media products and smart shipping containers connected to a cloud hosted cold chain management app to improve the quality of delivery logistics for cells, tissues, and organs. The Company's proprietary HypoThermosol® 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.

The [biologistex](#) cloud based cold chain management service is an integrated logistics and tracking 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. 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, market adoption of biologistex, commercial manufacturing of our customers' products, potential proceeds from the credit facility, and projected financial results, cash flow and liquidity, including the potential for reaching positive cash flow from operations next year. 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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