BioLife Solutions CryoStor® Cell Freeze Media Embedded in Invossa™: First Approved Cell and Gene Therapy for Osteoarthritis

Korean Approval Received by Kolon Life Science, TissueGene's Exclusive Licensee

BOTHELL, Wash., July 13, 2017 /PRNewswire/ -- BioLife Solutions, Inc. (NASDAQ: BLFS), the leading supplier of pre-formulated, clinical grade cell and tissue hypothermic storage and cryopreservation freeze media ("BioLife"), today announced that Kolon Life Science, TissueGene's exclusive licensee for Asia, including Korea, has received marketing approval for Invossa-K Inj., the world's first cell and gene therapy for degenerative arthritis from the Korea Ministry of Food and Drug Safety (MFDS).

The manufactured Invossa cell and gene therapy will be frozen and shipped in BioLife's CryoStor cell freeze media to extend the shelf life until arrival at the clinic for injection into the patient.

Invossa is a first-in-class cell and gene therapy 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 in the US have demonstrated pain relief, increased mobility, and potentially game-changing improvements in joint structure – offering substantial relief and convenience for osteoarthritis patients who would otherwise be in need of surgery.

In December 2016, BioLife executed a ten year supply agreement with TissueGene to supply clinical grade CryoStor for use in the Invossa manufacturing process. Kolon Life Science filed for a Biologics License Application (BLA) for Invossa-K Inj. with the MFDS in August 2016 based on efficacy results from its Phase III clinical trials conducted at 12 major university hospitals in Korea.

Mike Rice, BioLife CEO, commented, "This initial geographic approval of Invossa in Korea is a major accomplishment for TissueGene and Kolon. We are very pleased that our CryoStor cell freeze media is integrated into the storage and distribution protocol for this approved cell-mediated gene therapy. This approval confirms the value of our regenerative medicine customer base and the enabling role our proprietary products play in helping to commercialize novel cell and tissue based therapies. Furthermore, we anticipate that additional customers will receive regulatory marketing approvals in the near future, which we anticipate will increase demand for our proprietary, clinical grade biopreservation media products."

Worldwide, an estimated 150 million people suffer from knee osteoarthritis. BioLife estimates that just 1% of the worldwide addressable patient population represents at least $5 million in revenue.

In November last year, Kolon Life Science signed a license agreement with Mitsubishi Tanabe Pharmaceutical Corporation, and Mitsubishi Tanabe Pharma is proceeding with the preparation of clinical trials through its exclusive development and commercialization rights in Japan. Through its national US Phase III clinical trials, TissueGene will be using the results to seek a Disease Modifying Osteoarthritis Drug (DMOAD) designation for Invossa™ from the US Food and Drug Administration (FDA), potentially making Invossa™ the first and only cell and gene therapy for osteoarthritis of the knee.

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. 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 the company's anticipated business and operations, and expected revenue growth from customer regulatory approvals or approved therapies. 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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