

BioLife Solutions Submits FDA Master File on HypoThermosol® Preservation and Storage Media for Cells, Tissues

Materials, Components and Manufacturing Process Documentation for Customer Clinical Applications

PRNewswire-FirstCall
BOTHELL, Wash.

BioLife Solutions Inc. (BULLETIN BOARD: BLFS), a leading developer and marketer of proprietary hypothermic storage and cryopreservation media products for cells, tissues, and organs, today announced that it has submitted a Master File to the United States Food and Drug Administration (FDA) for the Company's HypoThermosol preservation media product.

An FDA Master File provides key information about the quality of components, materials and manufacturing processes involved in producing medical devices and human drugs, including related products such as media to preserve and store biologic materials like cells, tissues and organs.

In May 2008 the FDA accepted the Company's submission of a Master File for its CryoStor™ cryopreservation media product platform.

BioLife Chairman and Chief Executive Mike Rice remarked, "This Master File submission for HypoThermosol completes our stated corporate objective of offering the easiest to use biopreservation media products with the best regulatory footprint in the industry."

Currently, biopreservation media products are considered excipient materials (inert or inactive compounds or reagents) used in the production of biologic products, and a manufacturer of a biologic product is responsible for validating the use, safety, and efficacy of all excipient materials. An FDA Master File is therefore a key information source for end-users of BioLife products.

Rice added that the FDA Master File is expected to drive even stronger product adoption by shortening the qualification process for customers in BioLife's markets. The Company plans to take further steps in raising the bar for the quality of key ancillary and excipient compounds related to the production of cell and tissue-based therapies.

Mark Sandifer, director of quality at BioLife, added: "This submittal is another step in our continuous quality improvement initiative, and it supports our goal of offering the highest quality biopreservation media products to our customers. Our team did a great job assembling the required documentation for the HypoThermosol Master File, and our scientific advisors again provided key input."

About BioLife Solutions:

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 fully defined serum-free and protein-free products are manufactured under current Good Manufacturing Practices and are formulated using only USP or highest available grade components to reduce preservation-induced, delayed-onset cell damage and death. BioLife's enabling technology provides research and clinical organizations significant yield improvement in post-preservation cell and tissue and viability and function.

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 U.S. 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.

Media Relations:	Investor Relations:
Len Hall	Dan Matsui
Allen & Caron Inc.	Allen & Caron Inc.
(949) 474-4300	(949) 474-4300
len@allencaron.com	d.matsui@allencaron.com

First Call Analyst:

FCMN Contact:

SOURCE: BioLife Solutions Inc.

CONTACT: Media, Len Hall, len@allencaron.com, or Investors, Dan Matsui, d.matsui@allencaron.com, both of Allen & Caron Inc., +1-949-474-4300, for BioLife Solutions Inc.

<https://investors.biolifesolutions.com/2008-11-05-BioLife-Solutions-Submits-FDA-Master-File-on-HypoThermosol-Preservation-and-Storage-Media-for-Cells-Tissues>