

BioLife Solutions Announces FDA Master File Acceptance for CryoStor™ Pre-formulated Cryopreservation Media

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 its Master File for CryoStor cryopreservation media has been accepted by the United States Food and Drug Administration (FDA).

BioLife Chairman and Chief Executive Mike Rice commented: "We believe that the FDA Master File for CryoStor will provide clinical researchers and commercial partners easier access to our best-in-class cryopreservation media and facilitate faster product development of cell and tissue based products. Although classified as excipient materials, our sterile products are manufactured under medical device quality regulations and are made from only USP or the highest available grade components.

"We're optimistic that having an FDA Master File will also help accelerate product adoption in our key clinical markets, including cell therapy and cord blood and cell banking," Rice continued. "Our value proposition centers on providing the highest quality off-the-shelf and ready-to-use biopreservation media products with what is now the best regulatory footprint in the industry. Referencing our Master File should take some of the regulatory burden off our customers, so they can focus more time and resources on product development and clinical therapies."

More than 100 development-stage cell therapy companies have evaluated or adopted HypoThermosol® and/or CryoStor in the production of novel cell-based products targeting a multitude of diseases and disorders such as cancer, heart failure, vision loss, and neurologic disorders. In addition, TriMark Publications, LLC, a global leader in market research and intelligence for biotechnology, healthcare and life sciences, forecasts the global market for stem cell products and services to \$104 billion by 2012. PA Consulting Group, a global consulting firm with expertise in life sciences and healthcare, estimates the worldwide market for media to preserve cells, tissues, and organs for research and clinical applications will grow from \$200 million in 2007 to nearly \$350 million by 2011.

Rice added: "We have a growing body of internal and external data clearly illustrating that our novel biopreservation media formulations extend shelf- life and improve post-preservation viability and function of numerous biologic source materials as well as manufactured cell and tissue products and therapies. With this data and our FDA Master File, we are striving to raise the regulatory standards for biopreservation media products and are committed, through our proprietary products, to enabling our customers' successful development and commercialization of new cell and tissue-based products and therapies."

About the CryoStor FDA Master File:

The FDA Master File for CryoStor provides specific quality information and specifications for the components used to manufacture CryoStor, the cGMP quality and manufacturing system, and the release criteria for the product. Traditional cryopreservation media are typically mixed in small batches on- site in a clinical laboratory using variable quality components and often

under conditions that prove challenging for maintaining the integrity of the formulation. CryoStor requires no mixing of components or other on-site manipulation of the product by the clinician.

To request a cross reference to the Master File for CryoStor please contact the Company.

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 preservation media products are marketed to academic research institutions, clinical care provider organizations, and commercial companies involved in cell therapy, tissue engineering, cord blood banking, drug discovery, and toxicology testing. BioLife 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 and viability and function. For more information please visit <http://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.

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

Web site: <http://www.biolifesolutions.com/>

<https://investors.biolifesolutions.com/2008-05-08-BioLife-Solutions-Announces-FDA-Master-File-Acceptance-for-CryoStor-Pre-formulated-Cryopreservation-Media>