New Policies to Advance Development of Cell and Gene Therapies Announced by FDA

FDA Cites Increases in IND Submissions and Anticipated Product Approvals that could benefit BioLife Solutions

New Guidance to Support Manufacturing Process Changes for Late-Phase Developers Without Necessarily Requiring New Clinical Trials

BOTHELL, Wash., Jan. 22, 2019 /PRNewswire/ -- BioLife Solutions, Inc. (NASDAQ: BLFS), the leading developer, manufacturer and marketer of proprietary biopreservation media products for cell and gene therapies, expects to benefit from new policies to advance the development of safe and effective cell and gene therapies as set forth in a statement issued by the U.S. Food and Drug Administration (FDA) on January 15, 2019.

In the statement, the FDA noted the critical challenges arising from the development of cell-based gene therapies such as CAR-T cells, "including the complexities associated with manufacturing these products in a safe, reliable and cost-effective way, and in a manner that allows for the efficient use of these products in the clinic." The statement continued, "Our new guidance will recommend parameters for how innovators can introduce advances in manufacturing that promote the more efficient development and application of CAR-T therapies without necessarily requiring costly new clinical investigations. We intend to propose ways to help ensure the safety and effectiveness of the resulting products through available technologies and examinations, and when limited clinical bridging studies may be needed prior to approval of a change, possibly followed by the submission of additional clinical information supplied by real-world data after the change is introduced."

Mike Rice, BioLife CEO, remarked, "We welcome this supportive statement from the FDA regarding new policies to advance development of safe and effective cell and gene therapies. To date, we believe our optimized CryoStor® and HypoThermosol® proprietary biopreservation media products have been used in more than 300 customer clinical applications. The new FDA guidance could help accelerate adoption of our products specifically with later-phase companies that still use non-optimized, generic 'home-brew' preservation media cocktails. We see the potential to convert these trial sponsors to our products. Oftentimes these companies perceived the risk of having to conduct new clinical studies as an obstacle to switching to our best-in-class biopreservation media."

Customers use BioLife's CryoStor cell freeze media and HypoThermosol cell storage and shipping media to preserve starting/source material such as apheresis collections and tumor biopsies, as well as for manufactured cell and gene therapies. In 2008, BioLife submitted Master Files to the FDA for CryoStor and HypoThermosol. This mechanism enables customers to declare their intended use of BioLife products in regulatory submissions to the FDA. In 2018, BioLife's Master Files were cross-referenced 57 times by customers planning to conduct new clinical trials. This compares with 27 cross-references in 2016 and 47 cross-references in 2017.

In their statement, FDA cited the surge of cell and gene therapy products entering early development, as well as anticipated increase in the number of product approvals in the coming year. The following projections were provided on approvals of new cell and gene therapies and FDA staffing to support the review of new applications:

- Based on a "surge of cell and gene therapy products entering early development, we anticipate that by

2020 we will be receiving more than 200 INDs per year, building upon our total of more than 800 active cell-based or directly administered gene therapy INDs currently on file with the FDA."

- "…by 2025, we predict that the FDA will be approving 10 to 20 cell and gene therapy products a year based on an assessment of the current pipeline and the clinical success rates of these products."

About BioLife Solutions

BioLife Solutions is the leading developer, manufacturer and supplier of proprietary biopreservation media for cells and tissues. Our HypoThermosol® hypothermic storage and CryoStor® cryopreservation freeze media are highly valued in the regenerative medicine, biobanking and drug discovery markets. These novel biopreservation media products are serum-free and protein-free, fully defined, and are formulated to reduce preservation-induced cell damage and death; offering commercial companies and clinical researchers significant improvement in shelf life and post-preservation viability and function. For more information please visit www.biolifesolutions.com, and follow BioLife on Twitter.

Except for historical information contained herein, this press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, statements concerning the company's anticipated business and operations, guidance for financial results in 2018, including achieving GAAP operating profit, EBITDA, adjusted EBITDA and cash flow from operations, the potential utility of and market for its products and services, potential revenue growth and market expansion, regulatory approvals and/or commercial manufacturing of our customers' products, and potential customer revenue. 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.

Media & Investor Relations
Roderick de Greef
Chief Financial Officer
(425) 686-6002
rdegreef@biolifesolutions.com

SOURCE BioLife Solutions, Inc.
