BioLife Solutions Provides Update on Customer Cell Therapy Clinical Trials and Development Programs

BOTHELL, Wash., March 14, 2016 /<u>PRNewswire</u>/ -- <u>BioLife Solutions</u>, Inc. (NASDAQ: BLFS), a developer, manufacturer and marketer of proprietary clinical grade cell and tissue <u>hypothermic storage</u> and <u>cryopreservation freeze media</u> and a related <u>cloud hosted</u> <u>biologistics cold chain management app</u> for <u>smart shippers</u>, today provided an update on several customer clinical trials and development programs using cellular therapies and cellular immunotherapies in human regenerative medicine applications. Key developments include:

- Vericel: Announces Positive Top-Line Results From Phase 2b ixCELL-DCM Clinical Trial of Ixmyelocel-T in Patients With Heart Failure Due to Ischemic Dilated Cardiomyopathy. BioLife's clinical grade HypoThermosol[®] cell and tissue storage and shipping medium is embedded in the manufacturing process and is used to preserve the Ixmyelocel-T cellular product during transport to the clinic. For more information please visit <u>http://investors.vcel.com/releasedetail.cfm?releaseid=959878</u>.
- TiGenix: Announces positive 52-week Phase III results of Cx601 in complex perianal fistulas in Crohn's disease patients. HypoThermosol will be used in commercial manufacturing of Cx601 allogeneic expanded stem cells for complex perianal fistula in Crohn's Disease patients. For more information please see http://www.nasdaq.com/press-release/tigenix-announces-positive-52week-phase-iii-results-of-cx601-in-complex-perianal-fistulas-in-crohn-20160307-00847.
- Adaptimmune Therapeutics: Incorporated BioLife's clinical grade CryoStor[®] in a third clinical program utilizing CryoStor in the manufacturing and delivery processes for manufactured cellular products in clinical trials. BioLife's previous announcement of a relationship with Adaptimmune can be viewed here: http://www.prnewswire.com/news-releases/adaptimmune-integrates-biolife-solutions-cryostor-cell-freeze-media-in-cancer-immunotherapy-clinical-trial-253524191.html.
- bluebird bio: Announced that interim data from the ongoing Phase 2/3 Starbeam Study (ALD-102) for the treatment of cerebral adrenoleukodystrophy (CALD) will be presented in an oral presentation during the Clinical Trials plenary session on April 20, 2016 at the American Academy of Neurology (AAN) 2016 Annual Meeting. CryoStor is used in the manufacturing process for the Lenti-D drug product used in the clinical trial. See: <u>https://clinicaltrials.gov/ct2/show/NCT01896102?term=bluebird+bio&rank=8</u>
- TxCell SA: Successfully concluded the most important milestone in the transfer of its manufacturing technology to MaSTherCell, its contract manufacturing organization ("CMO") for the European manufacturing of TxCell's product portfolio, including its lead product Ovasave®. CryoStor is used in the manufacturing process for OvaSave. More information can be viewed here: <u>http://www.prnewswire.com/news-releases/biolife-solutions-cryostor-freeze-media-adopted-by-txcell-forovasave-regulatory-t-cell-based-personalized-immunotherapy-263259651.html.</u>
- Several undisclosed customers continue to progress various CAR T-cell and other T cell therapies in clinical trials for cancer. Based on customer communication and public disclosures, management believes BLA submissions may commence in the last half of this year and first half on 2017.

Mike Rice, BioLife's President & CEO, remarked, "This is a very exciting time for BioLife as many of our valued regenerative medicine customers continue to make excellent progress with their clinical programs assessing safety and efficacy of cellular therapies targeting the leading causes of disability and death. We anticipate increased demand for our best in class biopreservation media products as trial enrollments are expanded in later phases and once commercial manufacturing commences after regulatory approvals are obtained by our customers. We have the manufacturing capacity and expertise to continue to deliver high quality products and excellent customer support."

About the T Cell Immunotherapy Market:

The Roots Analysis Private Ltd November 2015 market research report estimates that the T Cell Immunotherapy market T-cell therapy market will be worth USD 30 billion by 2030. BioLife serves this market by providing best in class biopreservation media products and the biologistex[™] cloud based cold chain logistics solutions to improve stability, yield, and distribution practices for time and temperature sensitive biologic materials.

About BioLife Solutions:

Our proprietary HypoThermosol[®] and CryoStor[®] biopreservation media products are critical enabling reagents used in the biobanking, drug discovery, and regenerative medicine markets. Our products are serum-free and protein-free, fully defined, and are formulated to reduce preservation-induced cell damage and death. These products provide commercial companies and clinical researchers significant improvement in shelf life and post-preservation viability and function of cells, tissues, and organs. Our related biologistex <u>cloud hosted</u> <u>biologistics cold chain management app</u> for evo[™] <u>Smart Shippers</u> offers enhanced track, trace, and notification services for shipments of time and temperature sensitive biologic materials. We also perform contract aseptic media formulation, fill, and finish services. For more information please visit <u>www.biolifesolutions.com</u>, and follow BioLife on <u>Twitter</u>.

This press release contains forward-looking statements, including, but not limited to, statements concerning potential growth, business opportunities and the potential utility of and market for its products and services. 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 the performance of customers' clinical trials; 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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