

## **BioSpecifics Technologies Corp. Announces Top-Line Phase 2b Results for XIAFLEX™ for Treatment of Peyronie's Disease**

LYNBROOK, NY – December 16, 2009 - BioSpecifics Technologies Corp. (NASDAQ: BSTC), a biopharmaceutical company developing first in class collagenase-based products, today announced top-line efficacy and safety results from a Phase 2b clinical trial of XIAFLEX™ for the treatment of Peyronie's disease. Peyronie's disease is characterized by the presence of inelastic collagen on the shaft of the penis, which can distort an erection and make sexual intercourse difficult or impossible in advanced cases. The Phase 2b study, conducted by the Company's partner, Auxilium Pharmaceuticals, Inc., was designed to measure efficacy endpoints of improvement in penile curvature and improvement in patients' sexual quality of life using the Peyronie's disease Patient Reported Outcome (PRO) questionnaire. Overall, XIAFLEX demonstrated a statistically significant change compared to placebo at 36 weeks in both improvement in penile curvature ( $p=0.001$ ) and the PRO Peyronie's disease bother domain ( $p=0.046$ ). There was no statistically significant change in mean scores between XIAFLEX and placebo in the PRO penile pain, intercourse discomfort or intercourse constraint domains. XIAFLEX was well-tolerated and the most common treatment related adverse events in the Phase 2b study were consistent with adverse events reported in previous Peyronie's disease trials with XIAFLEX, which included injection site bruising, edema and pain.

"Peyronie's disease can be psychologically devastating and patients have very limited and undesirable treatment options today," commented Thomas L. Wegman, President of BioSpecifics. "We look forward to progress in the clinical program for XIAFLEX in Peyronie's disease in 2010."

In patients who received XIAFLEX, a mean improvement of 29.7% in penile curvature from baseline to 36 weeks was seen (54.4 to 38.2) vs. an 11.0% mean improvement in curvature seen in placebo patients (50.6 to 45.1); ( $p=0.001$ ). In patients who received XIAFLEX, 60.5% of patients achieved the endpoint of at least a 25% reduction in angle of curvature vs. 25.0% of placebo patients achieving at least a 25% reduction in angle of curvature. In the PRO Peyronie's disease bother domain, the overall XIAFLEX treatment arm experienced a benefit in mean change in score from baseline to 36 weeks that was significantly better than the overall placebo arm benefit ( $p=0.046$ ). Auxilium Pharmaceuticals Inc. expects to meet with the U.S. Food and Drug Administration (FDA) in the second quarter of 2010 to further discuss these results.

The Phase 2b study was a randomized, double-blind, placebo-controlled trial that was designed to assess the safety and efficacy of XIAFLEX when administered two times a week, every six

weeks, for up to three treatment cycles (2 x 3). The study was conducted at 12 sites throughout the U.S., and 145 patients were monitored for 36 weeks following the first injection, with 109 patients receiving XIAFLEX as a series of intralesional injections and 36 receiving placebo (3:1 ratio) in the study. The treatment and placebo arms were also randomized to test for a benefit with the addition of penile modeling versus no modeling (1:1). Modeling refers to massaging of the plaque and is intended to maximize the enzymatic effect of the XIAFLEX injection in the plaque.

The trial was designed to measure the improvement in penile curvature and complete the validation of disease PRO, which measured four domains of patients' sexual quality of life over a period of 36 weeks: penile pain, Peyronie's disease bother, intercourse discomfort and intercourse constraint.

To qualify for the study, patients must have been diagnosed with Peyronie's disease for longer than six months, have stable disease, be able to maintain a rigid erection and have a penile contracture between 30 and 90 degrees. Patients were stratified by the degree of penile curvature (i.e. 30 degrees to 60 degrees versus 60 to 90 degrees).

### **About Peyronie's Disease**

Peyronie's disease is characterized by the presence of inelastic collagen on the shaft of the penis, which can distort an erection and make sexual intercourse difficult or impossible in advanced cases. Significant psychological distress has been noted in sexually active patients with Peyronie's disease. Currently, there are no effective pharmaceutical therapies for this ailment.

### **About BioSpecifics Technologies Corp.**

BioSpecifics Technologies Corp. is a biopharmaceutical company that has developed injectable collagenase for eleven clinical indications, three of which include: Dupuytren's disease, Peyronie's disease, and frozen shoulder (adhesive capsulitis). Its partner Auxilium has announced the acceptance of the Biologic License Application and Priority Review by the FDA's Arthritis Advisory Committee for injectable collagenase XIAFLEX in the treatment of Dupuytren's disease, and on September 16, 2009, the Arthritis Advisory Committee unanimously recommended, by a vote of 12 to 0, that the FDA approve XIAFLEX for the treatment of Dupuytren's disease. Pfizer, Inc. is responsible for marketing XIAFLEX product in Europe.

## **Forward Looking Statements**

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact, including statements regarding the company's strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, its expected revenue growth, and any other statements containing the words "believes", "expects", "anticipates", "plans", "estimates" and similar expressions, are forward-looking statements. There are a number of important factors that could cause its actual results to differ materially from those indicated by such forward-looking statements, including the ability of its partner Auxilium to obtain regulatory approval of XIAFLEX™ in the United States for Dupuytren's disease and Peyronie's disease and the ability of Pfizer to obtain regulatory approval of XIAFLEX™ in its territory for these same indications, which will determine the amount of milestone, royalty and sublicense income payments it may receive; the amount of earn out payments it may receive from DFB Biotech Inc. and its affiliates; whether Auxilium exercises its option under the companies' license agreement for additional indications; the potential benefits of its existing license and development agreements; its estimates regarding expenses, future revenue, capital requirements and needs for additional financing; and other factors identified in the Company's Form 10-K for the year ended December 31, 2008 and the Form 10-Q for the quarter ended September 30, 2009 and any subsequent reports filed with the SEC. The Company disclaims any intention or obligation to update any forward-looking statements as a result of developments occurring after the date of this press release.

### **Contact:**

BioSpecifics Technologies Corp.

Thomas L. Wegman, President

(516) 593-7000

thomas\_wegman@biospecifics.com