

BioSpecifics Technologies Corp. Announces Initiation of Global Phase 3 Trial of XIAFLEX[®] for Treatment of Peyronie's Disease

- Top-line Results Expected in First Half 2012 by Auxilium -

LYNBROOK, NY – October 12, 2010 - BioSpecifics Technologies Corp. (NASDAQ: BSTC), a biopharmaceutical company developing first in class collagenase-based products, today announced that its partner Auxilium Pharmaceuticals, Inc. (Auxilium) has dosed the first subject in the global Phase 3 program of XIAFLEX[®] (collagenase clostridium histolyticum) for the treatment of Peyronie's disease. Peyronie's disease is the development of scar tissue on the shaft of the penis that can cause the penis to curve during erection, often interfering with or preventing intercourse and resulting in psychological distress or bother for the patient. XIAFLEX is currently approved and marketed in the U.S. for the treatment of Dupuytren's contracture.

"The initiation of this Phase 3 trial is an important advance for XIAFLEX, moving it one step further as a treatment for Peyronie's disease. Currently, patients have only limited and undesirable treatment options available to them," commented Thomas L. Wegman, President of BioSpecifics. "We are very happy that XIAFLEX is progressing through the clinic as a second potential indication for the patients who could benefit immensely from a new treatment option. We look forward to these trial results in the first half of 2012."

Auxilium anticipates that it will complete enrollment for the double-blind studies in the first quarter of 2011 and will report top-line results in the first half of 2012.

Auxilium has announced that the late stage global development plan for XIAFLEX will consist of four clinical studies and will be known by the acronym IMPRESS - The Investigation for Maximal Peyronie's Reduction Efficacy and Safety Studies. There will be two randomized, double-blind, placebo-controlled Phase 3 studies, which are expected to enroll at least 600 patients at approximately 70 sites in the U.S. and Australia, with a 2:1 ratio of XIAFLEX to placebo. There also will be one open label study, which is expected to enroll at least 250 patients, at approximately 30 sites in the U.S., EU and New Zealand, and one pharmacokinetic study, which should enroll approximately 16 patients. XIAFLEX will be administered two times a week every six weeks for up to four treatment cycles (2 x 4). Each treatment cycle will be followed by a penile modeling procedure. Patients will be followed for 52 weeks post-first injection in the double-blind studies and for 36 weeks in the open label trial.

The trials' co-primary endpoints are the change from baseline in the Peyronie's disease bother domain of the Peyronie's Disease Questionnaire (PDQ) compared to placebo and percent improvement from baseline in penile curvature compared to placebo. The PDQ will have at least three domains, which will include Peyronie's disease bother, severity of psychological and physical symptoms of Peyronie's disease, and penile pain. Safety measurements will include adverse event monitoring, immunogenicity testing and clinical labs.

Auxilium stated that over the last six months, its team, in conjunction with the U.S. Food and Drug Administration (FDA), outside experts and men with Peyronie's disease, has spent a considerable amount of time and effort to refine the PDQ, which has now been accepted for use in the Phase 3 clinical trials by the FDA's Study Endpoint and Label Development Division.

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 is common among sexually active patients with Peyronie's disease. Currently, there are no FDA approved pharmaceutical therapies for this disease.

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 contracture; Peyronie's disease; and frozen shoulder (adhesive capsulitis). Its strategic partner Auxilium Pharmaceuticals, Inc. has gained approval of XIAFLEX in the U.S. for the treatment of Dupuytren's contracture. Pfizer, Inc. is responsible for marketing XIAFLEX in Europe. More information about the Company may be found on its website at www.biospecifics.com.

Forward Looking Statements

This press release contains 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 statements made by BioSpecifics and by its partner Auxilium regarding the ability to obtain regulatory approval of XIAFLEX in the U.S. for Peyronie's disease; and other risk factors identified in the Company's Form 10-K for the year ended December 31, 2009 filed with the SEC. There may be additional risks that BioSpecifics does not currently know or that BioSpecifics currently believes are immaterial that could also cause actual results to differ from those contained in the forward-looking statements. Given these risks and uncertainties, any or all of these forward-looking statements may prove to be incorrect; therefore, any such factors or forward-looking statements should not be relied upon. 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.

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