

## Press Release

Source: BioSpecifics Technologies Corp.

### BioSpecifics Technologies Corp. Announces Initiation of Phase IIb Trial for Peyronie's Disease

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LYNBROOK, N.Y. Sept. 17 /PRNewswire-FirstCall/ -- BioSpecifics Technologies Corp. (OTC Bulletin Board: [BSTC - News](#)), a biopharmaceutical company developing first in class collagenase based products, announced today the initiation of a U.S. Phase IIb clinical trial in Peyronie's disease for its injectable collagenase, XIAFLEX (TM), by its partner Auxlium Pharmaceuticals, Inc.

"We are very pleased that our partner has chosen to advance this trial into a Phase IIb based on our extremely encouraging IIa results that showed a statistically significant reduction of angle of penile curvature and improvement in sexual satisfaction," stated Thomas Wegman, President of BioSpecifics Technologies Corp. "Peyronie's disease affects over 1 million men worldwide and there are no currently effective pharmaceutical therapies. We are happy to be one step closer to making this minimally invasive therapy available for those that need it and we look forward to the anticipated trial results that will be announced by the end of 2009."

The Phase IIb study is a randomized, double-blind, placebo-controlled study that is 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), in subjects with Peyronie's disease. The study will involve at least 120 patients at approximately 11 sites throughout the U.S., and patients will be monitored for 36 weeks following the first injection.

The trial is also designed to validate a proprietary Peyronie's Patient Reported Outcome (PRO) questionnaire, which will measure several domains of patients' sexual quality of life, over a 36 week period. The four domains measured by the PRO are penile pain, Peyronie's disease bother, intercourse discomfort and intercourse constraint.

To qualify for the study, patients must be able to maintain a rigid erection and have a penile contracture between 30 and 90 degrees. Patients will be stratified by the degree of penile curvature (i.e. 30 degrees to 60 degrees versus > 60 degrees) and then randomized into 4 treatment groups to receive either XIAFLEX or placebo with or without modeling of the penile plaque. Modeling refers to massaging of the plaque after the second injection of a treatment series and is intended to maximize the enzymatic effect of the XIAFLEX injection in the plaque. Patients will be randomized in a 3:1 ratio of XIAFLEX to placebo and a 1:1 ratio to receive penile plaque modeling or no modeling.

#### About Peyronie's Disease

Peyronie's disease is characterized by the presence of a collagen plaque on the shaft of the penis, which can distort an erection and make intercourse difficult or impossible in advanced cases. The plaque is not elastic and it does not stretch during erection. In some

mild cases, the plaque can resolve spontaneously without medical intervention. The most common plaque forms on the top of the penis causing the penis to arc upward. In severe cases, the penis can be bent at a 90-degree angle during erection. Significant psychological distress has been noted in patients with Peyronie's disease who are sexually active. Frequent patient complaints include increased pain, painful erections, palpable plaque, penile deformity, and erectile dysfunction. Patients with Peyronie's disease have been reported to have an increased likelihood of having Dupuytren's disease, frozen shoulder, plantar fibromatosis, knuckle pads, hypertension and diabetes. Peyronie's disease typically affects males in the range of 40-70 years. The cause of Peyronie's disease is unknown, although some investigators have proposed that it may be due to trauma or an autoimmune component. A number of researchers have suggested that the incidence of Peyronie's disease has increased due to the use of erectile dysfunction drugs.

About BioSpecifics Technologies Corp.

BioSpecifics Technologies Corp. is a biopharmaceutical company that has developed and licensed injectable collagenase for three clinical indications: Dupuytren's disease, Peyronie's disease and frozen shoulder (adhesive capsulitis). It has a development and licensing agreement with Auxilium Pharmaceuticals, Inc. Positive top line results from the Phase III clinical trials with XIAFLEX(TM) for treatment of Dupuytren's disease were released in June 2008. More information about the company may be found on its website at [www.biospecifics.com](http://www.biospecifics.com).

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