

# **FDA Advisory Committee Unanimously Recommends Approval of XIAFLEX™ for Treatment of Dupuytren's Disease**

LYNBROOK, NY – September 16, 2009 - BioSpecifics Technologies Corp. (NASDAQ: BSTC), a biopharmaceutical company developing first-in-class collagenase-based products, today announced that the Arthritis Advisory Committee appointed by the U.S. Food and Drug Administration's (FDA) unanimously recommended by a vote of 12 to 0 that XIAFLEX™ (collagenase clostridium histolyticum), a novel, first-in-class, orphan-designated, biologic, be granted marketing approval by the FDA for the treatment of Dupuytren's disease, a debilitating disorder resulting from excessive collagen deposition that causes contractures of the fingers.

"We believe that the Advisory Committee's very supportive vote today for XIAFLEX represents a major advance for both the patients suffering from Dupuytren's disease, as well as for BioSpecifics and its shareholders," stated Thomas L. Wegman, President of BioSpecifics. "We congratulate our partner Auxilium on its thorough and thoughtful presentation today and look forward to the FDA's decision regarding the approval of XIAFLEX."

The Advisory Committee's recommendations are not binding, but will be considered by the FDA in its review of the XIAFLEX BLA. Auxilium Pharmaceuticals, Inc. has licensed the rights to XIAFLEX from BioSpecifics for three clinical indications: Dupuytren's disease; Peyronie's disease; and frozen shoulder (adhesive capsulitis). Auxilium filed its BLA for XIAFLEX for the treatment of Dupuytren's disease on February 27, 2009 and received a target date under the Prescription Drug User Fee Act (PDUFA) date of August 28, 2009, which has not been updated.

## **About BioSpecifics Technologies Corp.**

BioSpecifics Technologies Corp. is a biopharmaceutical company that has developed injectable collagenase for three clinical indications: Dupuytren's disease; Peyronie's disease; and frozen shoulder (adhesive capsulitis). Its strategic partner Auxilium Pharmaceuticals, Inc. has announced the acceptance of the Biologic License Application (BLA) and Priority Review by the U.S. Food and Drug Administration for injectable collagenase XIAFLEX™ in 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 June 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.

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