LYNBROOK, N.Y., Oct. 7, 2013 /PRNewswire/ -- BioSpecifics Technologies Corp. (NASDAQ: BSTC), a biopharmaceutical company developing first in class collagenase-based products marketed as XIAFLEX® in the U.S. and XIAPEX® in the EU, announced today that data from multiple trials evaluating the use of XIAFLEX ("collagenase clostridium histolyticum" or "CCH") in adult patients with Dupuytren's contracture with a palpable cord were presented by BioSpecifics' partner Auxilium Pharmaceuticals, Inc. (Auxilium) at the 68th Annual Meeting of the American Society for Surgery of the Hand ("ASSH") that took place in San Francisco, California, on October 3 – 5, 2013.

"We believe the data presented at ASSH on XIAFLEX further validates that XIAFLEX is a safe and efficacious treatment for adult patients with Dupuytren's contracture and it remains the only non-surgical option available today," commented Thomas L. Wegman, President of BioSpecifics. "We continue to support Auxilium in their commercialization efforts for this product and look forward to potentially adding a second FDA-approved indication by the end of the year for Peyronie's disease."

Auxilium presented results at ASSH from Year 4 of the Collagenase Optimal Reduction of Dupuytren's - Long-term Evaluation of Success Study ("CORDLESS"). CORDLESS is a five-year observational study designed to assess the rates of recurrence following treatment with XIAFLEX, as well as long-term safety and progression of disease in patients from earlier Auxilium studies. These data indicated that 57.9 percent of patients previously successfully treated with XIAFLEX did not experience disease recurrence based on the study's definition of recurrence, which is a 20 degree change of contracture with a palpable cord, or the joint undergoing medical or surgical intervention. Of the 623 joints assessed, only 12.8 percent of those joints received medical or surgical intervention through Year 4 and of these patients, most were retreated with XIAFLEX. The data also reveal no new long-term adverse events. Of the 86 serious AEs reported through four years of follow-up, only one was considered related to XIAFLEX (decrease in ring finger circumference due to Dupuytren's contracture resolution).

Additional data highlights from the CORDLESS study can be found in Auxilium's press release issued today.

CORDLESS study authors also presented an update on XIAFLEX safety data following three years of post-approval use and determined that after an estimated 49,078 XIAFLEX injections were administered to approximately 36,500 adult patients in the U.S. for the treatment of Dupuytren's contracture with a palpable cord, there was no clinically meaningful change in the nature of events reported relative to the one year post-marketing safety profile.[1] Adverse events were most commonly localized, non-serious reactions to XIAFLEX injections, including skin tears, contusion (bruising), peripheral edema (swelling), extremity pain and injection site reactions.

Based on data from a previous Phase 3b trial, Stephen Coleman and his colleagues at the Brisbane Hand and Upper Limb Clinic provided an analysis on the use of local anesthesia (LA) prior to Dupuytren's contracture correction procedures. Sixty adult patients with Dupuytren's contracture with a palpable cord were enrolled and treated, with 120 treated joints (75 metacarpophalangeal (MP), 45 proximal interphalangeal (PIP). Overall 27/60 patients received LA prior to finger extension; the remaining patients had finger extension procedures without LA. As presented in the poster [2], it was determined that the use of LA prior to a finger extension procedure following XIAFLEX injection led to greater improvement in the correction of contracture (82.6% vs. 69.8%), despite the patients having more severe contracture (total fixed flexion contracture (FFC) 90.3˚ vs 84.2˚). It was also demonstrated that PIP joints tended to show a better response than MP joints. Percent changes from baseline including FFC for PIP joints were 74.7% with LA and 59.7% without while MP joints were 77.8% and 74.4%, respectively. LA was not utilized in earlier Phase 3 trials but may allow physicians to use more force during the finger extension procedure without significant added pain to the patient.

[1] Peimer CA et al. Nonsurgical treatment of Dupuytren's contracture: 1-year US post-marketing safety data for collagenase clostridium histolyticum. Hand. 2012;7:143-146.

[2] Coleman S et al. Use of Local Anesthesia Prior to Finger Extension Following Injection of Collagenase Clostridium Histolyticum for Dupuytren's Contracture. Poster presented at ASSH 2013, the 68th Annual Meeting of the American Society for Surgery of the Hand. 2013 Oct 3-5; San Francisco CA.

**About BioSpecifics Technologies Corp.**

BioSpecifics Technologies Corp. is a biopharmaceutical company that has developed injectable collagenase for twelve clinical indications to date. Injectable collagenase is currently marketed as XIAFLEX® (collagenase clostridium histolyticum (CCH)) in the U.S. for the treatment of adult Dupuytren's contracture patients with a palpable cord in the palm by BioSpecifics' partner, Auxilium Pharmaceuticals, Inc. (Auxilium) and marketed in Europe and approved in Canada. Swedish Orphan Biovitrum AB has marketing rights for XIAPEX ® (the EU tradename for CCH) for the treatment of Dupuytren's contracture and Peyronie's disease in 71 Eurasian and African countries. Asahi Kasei Pharma Corporation has development and commercialization rights for XIAFLEX for the treatment of Dupuytren's contracture and Peyronie's disease in Japan and Actelion Pharmaceuticals Ltd. has development and commercialization rights for XIAFLEX for these two indications in Canada , Mexico , Brazil and Australia . CCH is in clinical development for the treatment of several additional promising indications. Under the Prescription Drug User Fee Act (PDUFA), the FDA has set an action date for XIAFLEX for Peyronie's disease of December 6 , 2013. Auxilium is testing CCH for frozen shoulder syndrome and cellulite and expects to initiate a Phase II trial of CCH for cellulite and next stage trials of CCH for frozen shoulder syndrome in the fourth quarter of 2013. BioSpecifics is currently managing the development of CCH for the treatment of human and canine lipomas, both of which are in Phase II trials, and expects to report top-line data from these trials by the end of 2013. For more information, please visit www.biospecifics.com .

**Forward-Looking Statements**

This release includes "forward-looking statements" within the meaning of, and made pursuant to

the safe harbor provisions of, the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical fact are "forward-looking statements". The forward-looking statements include statements concerning, among other things, the timing of the review and potential approval by the FDA of XIAFLEX as a treatment for Peyronie's disease; the extent to which additional indications are promising; the timing for Auxilium to initiate a phase II trial of CCH as a treatment for cellulite and next stage trials of CCH as a treatment for frozen shoulder; and the timing of reporting top-line data from BioSpecifics' trials of CCH for the treatment of human lipoma and canine lipoma. In some cases, you can identify these statements by forward-looking words such as "believe," "expect," "anticipate," "plan," "estimate," "likely," "may," "will," "could," "continue," "project," "predict," "goal," the negative or plural of these words, and other similar expressions. These forward-looking statements are our predictions based on our current expectations and our projections about future events. There are a number of important factors that could cause our actual results to differ materially from those indicated by such forward-looking statements, including the ability of Auxilium and its partners to achieve their respective objectives for XIAFLEX in their applicable territories; the uncertainties inherent in the initiation of future clinical trials; Auxilium or any of its partners modifying their respective objectives and/or allocating resources other than to XIAFLEX; the potential market for XIAFLEX in a given indication being smaller than anticipated; the potential of XIAFLEX to be used in additional indications and the initiation, timing and outcome of clinical trials of XIAFLEX for additional indications; the timing of regulatory filings and action; the receipt of any applicable milestone payments from Auxilium; and other risk factors identified in our Annual Report on Form 10-K for the year ended December 31, 2012, our Quarterly Reports on Form 10-Q for the quarters ended
March 31, 2013
and
June 30, 2013
, and our Current Reports on Form 8-K filed with the SEC. All forward-looking statements included in this release are made as of the date hereof, and we assume no obligation to update these forward-looking statements.

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