Biota Commences Dosing in Phase 2 Trial of Antiviral Therapy BTA074 for Topical Treatment of Condyloma

ATLANTA, Feb. 08, 2016 (GLOBE NEWSWIRE) -- Biota Pharmaceuticals, Inc. (NASDAQ:BOTA), a biopharmaceutical company focused on the discovery and development of direct-acting antivirals that address infections that have limited therapeutic options, announced today that the first patient has been dosed in a Phase 2 double-blind, randomized, placebo-controlled trial to evaluate the safety, tolerability and efficacy of BTA074 5% gel in male and female patients with condyloma, or anogenital warts, caused by human papillomavirus (HPV) types 6 & 11.

"We are excited to progress BTA074 into a well-powered proof-of-concept study. The currently approved topical treatments for condyloma lack consistent efficacy and cause a considerable amount of undesirable local skin reactions, such as erosions and edema, often leading to the need to stop treatment. With this larger Phase 2 study, we hope to further validate the clinical activity of BTA074 seen in its earlier Phase 2 trial, which showed evidence of overall clearance and a benign side effect profile," remarked Joseph M. Patti, PhD, president and chief executive officer at Biota. "We now have three direct-acting antiviral programs in the clinic, each of which has the potential to help patients by attacking the root cause of their viral infections."

BTA074 is a potent and selective inhibitor of the interaction between two viral proteins from HPV6 and HPV11, and is designed to prevent HPV DNA replication. The Phase 2 trial is expected to enroll approximately 210 patients with anogenital warts and will have a 2-to-1 randomization of BTA074 5% gel to placebo gel. The patients will be dosed twice daily for up to 16 weeks. The primary efficacy objective is to determine the complete clearance rate for baseline anogenital warts from the commencement of therapy to the end of the treatment period. Secondary efficacy endpoints include various assessments of clearance and wart area reduction for both baseline warts and post-baseline emergent warts.

About Condyloma (Anogenital Warts)

Condyloma infections from human papillomavirus (HPV) represent the most frequent viral sexually transmitted disease in adults worldwide. In the United States, approximately one to two percent of sexually active adults between the ages of 15 to 49 develop condyloma as the primary clinical manifestation of HPV infection. Currently available treatments for anogenital warts typically are divided into two categories, ablative/destructive therapies and topical therapies. Existing topical therapies are associated with significant mucosal toxicities manifesting as erosions and ulcerations, which can result in therapy discontinuation. Ablative options can be painful and scarring, and can lead to sexual dysfunction. Another significant limitation with current therapies is a high incidence of recurrence after successful primary treatment.

About Biota Pharmaceuticals, Inc.

Biota Pharmaceuticals is focused on the discovery and development of direct-acting antivirals to treat infections that have limited therapeutic options and affect a significant number of patients globally. The Company has three product candidates in active clinical development: These include vapendavir, an oral treatment for human rhinovirus infections in moderate-to-severe asthmatics, currently being evaluated in the Company's ongoing Phase 2b SPIRITUS trial; BTA585, an oral fusion protein inhibitor in Phase 1 development for the treatment and prevention of respiratory syncytial virus (RSV) infections; and BTA074, a topical antiviral treatment in Phase 2 development for condyloma caused by human papillomavirus types 6 & 11. For additional information about the Company, please visit www.biotapharma.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve known and unknown risks and uncertainties concerning Biota's business, operations and financial performance. Any statements that are not of historical facts may be deemed to be forward-looking statements, including the potential efficacy of the Company's three programs in the clinic. Various important factors could cause actual results, performance, events or achievements to materially differ from those expressed or implied by forward-looking statements, including: the Company, the U.S. Food and Drug Administration (FDA) or a similar regulatory body in another country, a data safety monitoring board, or an institutional review board delaying, limiting, suspending or terminating the clinical development of BTA074 or any of the Company's product candidates at any time for a lack of safety, tolerability, regulatory or manufacturing issues, or any other reason whatsoever; the Company's ability to secure, manage and retain qualified
third-party clinical research data management and contract manufacturing organizations upon which it relies to assist in the
design, development, implementation and execution of the clinical development of all its product candidates and those
organizations ability to successfully execute their contracted responsibilities; the Company's ability to comply with applicable
government regulations in various countries and regions in which we are conducting, or expect to conduct, clinical trials; and
other cautionary statements contained elsewhere in this press release and in our Annual Report on Form 10-K, Quarterly
Report on Form 10-Q and our other reports filed with the Securities and Exchange Commission. There may be events in the
future that the Company is unable to predict, or over which it has no control, and the Company's business, financial
condition, results of operations and prospects may change in the future. The Company may not update these forward-
looking statements more frequently than quarterly unless it has an obligation under U.S. Federal securities laws to do so.

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