AnaptysBio Reports Positive ANB019 Top-line Phase 1 Clinical Trial Results

November 6, 2017

Robust Half-Life and Extended Pharmacodynamic Activity Following a Single Dose of ANB019

Supports Advancement of ANB019 into Phase 2 Trials for IL-36-Associated Orphan Inflammatory Diseases

SAN DIEGO, Nov. 06, 2017 (GLOBE NEWSWIRE) -- AnaptysBio, Inc. (Nasdaq:ANAB), a clinical-stage biotechnology company developing first-in-class antibody product candidates focused on unmet medical needs in inflammation, today announced positive top-line results from an interim analysis of an ongoing single and multiple ascending dose Phase 1 trial of ANB019, its investigational anti-interleukin-36 receptor (IL-36R) therapeutic antibody, in healthy volunteers. Top-line data demonstrated favorable safety, pharmacokinetics and pharmacodynamic properties that support advancement of ANB019 into patient Phase 2 studies.

In the double-blind, placebo-controlled healthy volunteer Phase 1 trial, 36 subjects were administered a single subcutaneous or intravenous dose of ANB019 ranging between 10 mg and 750 mg, 18 subjects were administered multiple ascending doses of ANB019 intravenously ranging between 40 mg and 300 mg weekly for four consecutive weeks and 18 subjects were dosed with placebo. All subjects in the single and multiple ascending dose cohorts have completed dosing. This interim analysis was conducted after the 85-day, post-dosing monitoring period has been completed for the single ascending dose cohorts while monitoring is on-going for the multiple ascending dose cohorts.

ANB019 was well-tolerated by all subjects and no dose-limiting toxicities were observed to date. The most frequent treatment-emergent adverse events observed in the single ascending dose cohorts were mild upper respiratory tract infections in 10 of 36 (28%) subjects dosed with ANB019 versus six of 12 (50%) subjects dosed with placebo. No serious adverse events were reported among the single ascending dose cohorts through completion of monitoring, and none have been observed in the multiple ascending dose cohorts to date.

The *in vivo* half-life of ANB019 was approximately 28 days for both subcutaneous and intravenous routes of administration, with bioavailability of approximately 90%. A single dose of ANB019 at certain dose levels was able to completely suppress IL-36 cytokine function for 85 days, as measured using an *ex vivo* pharmacodynamic assay.

AnaptysBio plans to report detailed data from this Phase 1 trial at a future medical conference. The company also plans to initiate Phase 2 clinical trials of ANB019 in Generalized Pustular Psoriasis (GPP) and Palmo-Plantar Pustular Psoriasis (PPP) patients during 2018.

“We are thrilled to advance the development of ANB019 for patients suffering from the debilitating effects of GPP and PPP,” said Hamza Suria, president and chief executive officer of AnaptysBio. “This program extends AnaptysBio’s vision of building a first-in-class antibody pipeline for severe inflammatory diseases.”

GPP is a life-threatening, rare, systemic inflammatory disorder that, based on analysis of publicly available data sources and interviews with physicians and key opinion leaders in the field, AnaptysBio estimates affects approximately 3,000 patients in the United States with no approved therapies. Studies have shown that GPP can be associated in some patients with mutations that lead to abnormally high signaling through the IL-36R, which the company believes may be addressed by treatment with ANB019 irrespective of whether a GPP patient has a mutated IL-36R signaling pathway. PPP is a non-fatal form of pustular psoriasis that the company estimates affects approximately 150,000 patients in the United States alone. PPP is believed to be caused by increased systemic levels of interleukin-36 resulting in inflammatory pustules on the hands and feet of patients that cause significant inability to stand, walk or do manual work, which the company believes may be addressed by treatment with ANB019.

About AnaptysBio

AnaptysBio is a clinical-stage biotechnology company developing first-in-class antibody product candidates focused on unmet medical needs in inflammation. The company’s proprietary anti-inflammatory pipeline includes its anti-IL-33 antibody (ANB020) for the treatment of moderate-to-severe adult atopic dermatitis, severe adult peanut allergy and severe adult eosinophilic asthma; its anti-IL-36R antibody (ANB019) for the treatment of rare inflammatory diseases, including generalized pustular psoriasis and palmo-plantar pustular psoriasis; and a portfolio of checkpoint receptor agonist antibodies for the treatment of certain autoimmune diseases where immune checkpoint receptors are insufficiently activated, which have demonstrated efficacy in an animal model of graft-versus-host disease. AnaptysBio’s antibody pipeline has been developed using its proprietary somatic hypermutation (SHM) platform, which uses *in vitro* SHM for antibody discovery and is designed to replicate key features of the human immune system to overcome the limitations of competing antibody discovery technologies. AnaptysBio has also developed multiple therapeutic antibodies in an immuno-oncology partnership with TESARO and an inflammation partnership with Celgene, including an anti-PD-1 antagonist antibody (TSR-042), an anti-TIM-3 antagonist antibody (TSR-022) and an anti-LAG-3 antagonist antibody

(TSR-033), which are currently under clinical development with TESARO, and an anti-PD-1 checkpoint agonist antibody (CC-90006) currently in the clinic with Celgene.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to: the anticipated timing of the release of detailed results from ANB019's Phase 1 clinical trial, and the possibility and timing of commencement of Phase 2 clinical trials of ANB019 for the treatment of generalized pustular psoriasis and palmo-plantar pustular psoriasis, and AnaptysBio's ability to further advance the development of ANB019 for the treatment of patients with these diseases. Statements including words such as "plan," "continue," "expect," or "ongoing" and statements in the future tense are forward-looking statements. Forward-looking statements are subject to risks and uncertainties that may cause the company's actual activities or results to differ materially from those expressed or implied in any forward-looking statement, including risks and uncertainties related to the company's ability to advance its product candidates, obtain regulatory approval of and ultimately commercialize its product candidates, the timing and results of preclinical and clinical trials, the company's ability to fund development activities and achieve development goals, the company's ability to protect intellectual property and other risks and uncertainties described under the heading "Risk Factors" in documents the company files from time to time with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of this press release, and the company undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.

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