AnaptysBio Reports Positive Topline Proof-of-Concept Data from Phase 2a Clinical Trial of ANB020 in Atopic Dermatitis

October 10, 2017

- 83 Percent of Patients Achieved EASI-50 at Day 29 Following a Single Dose of ANB020
- EASI-50 was Observed Early and Persisted Through Day 57
- Management to Host Conference Call Today at 8:30 a.m. EDT

SAN DIEGO, Oct. 10, 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 proof-of-concept data for ANB020, its investigational anti-IL-33 therapeutic antibody, in an ongoing Phase 2a clinical trial in adult patients with moderate-to-severe atopic dermatitis. After a single dose of ANB020, 75 percent of patients achieved an Eczema Area Severity Index (EASI) score improvement of 50 percent relative to enrollment baseline (EASI-50) at day 15, 83 percent of patients achieved EASI-50 at day 29 and 75 percent of patients achieved EASI-50 at day 57. All 12 patients achieved EASI-50 at one or more timepoints through Day 57 post-ANB020 administration. ANB020 was generally well tolerated in all patients as of this interim analysis.

“Moderate-to-severe atopic dermatitis is a serious disease associated with chronic skin inflammation and debilitating pruritus, with a clear unmet medical need,” said Dr. Graham Ogg, professor of dermatology at University of Oxford and primary investigator of the Phase 2a study. “The rapid and sustained benefit observed in patients after a single dose of ANB020 is an encouraging interim result from this trial. I look forward to the continued development of ANB020 as a potential future therapeutic option for patients suffering from this disease.”

Phase 2a Trial Design
The Phase 2a proof-of-concept trial enrolled 12 moderate-to-severe adult atopic dermatitis patients, who were initially administered a single intravenous dose of placebo within 14 days of enrollment, followed by a single intravenous 300mg dose of ANB020 one week subsequent to placebo. Clinical response was assessed by the improvement of each patient’s EASI score, a tool used to measure the extent and severity of atopic dermatitis, at key time points following ANB020 administration relative to their enrollment baseline. Pruritus, also known as itchiness, as measured by the 5-D pruritus scale score, was also assessed for each patient. Exploratory mechanistic biomarkers included granulocyte infiltration and cytokine levels in localized skin lesions measured five days after placebo administration and five days after ANB020 administration.

Interim Analysis
An interim analysis conducted after all 12 patients had reached day 57 following ANB020 single administration, indicates the following:

- The average baseline EASI score upon enrollment was 32. The average EASI score reduction and pruritus score reduction at seven days post-placebo administration was four percent and 10 percent, respectively. All 12 patients were inadequately controlled by topical corticosteroids and seven were treated with systemic non-biologic anti-inflammatory therapy prior to the screening washout period of this trial.
- Rapid clinical response was observed at day 15 post-ANB020 administration with nine of 12 patients (75 percent) achieving EASI-50, of which three patients (25 percent) also achieved EASI score improvement of 75 percent relative to baseline (EASI-75). The average EASI score reduction at day 15 was 58 percent and the average pruritus reduction was 28 percent relative to baseline.
- At day 29 post-ANB020 administration, 10 of 12 patients (83 percent) achieved EASI-50, of which four patients (33 percent) also achieved EASI-75. The average EASI score reduction at this time point was 61 percent and the average pruritus reduction was 32 percent relative to baseline.
- Sustained clinical response was observed at day 57 post-ANB020 administration, with nine of 12 patients (75 percent) achieving EASI-50, of which five patients (42 percent) also achieved EASI-75. Average EASI reduction was 62 percent and the average pruritus reduction was 21 percent relative to baseline.
- Exploratory biomarker assessment indicated reduction of granulocyte infiltration into localized skin lesions by an average of 30 percent amongst all patients and 60 percent among the 10 patients achieving EASI-50 at 29 days post-ANB020 administration, while exploratory cytokine biomarker levels were below detection limit and therefore inconclusive.
- ANB020 was generally well-tolerated by all patients and no severe adverse events have been reported to date. The most frequent treatment-emergent adverse events reported were mild dizziness in two patients subsequent to placebo dosing, and mild headache in two patients post-ANB020 administration.

“We are very encouraged by the efficacy results to date in this Phase 2a study, which exemplify our strategic focus on developing first-in-class anti-inflammatory antibody therapeutics to help patients suffering from debilitating inflammatory diseases,” said Hamza

Suria, president and chief executive officer of AnaptysBio. “We look forward to further advancing the development of ANB020 for the treatment of patients with atopic diseases.”

The Phase 2a study is currently ongoing and EASI scores will be assessed for each patient up to 140 days post-ANB020 treatment. The company plans to report full data from this trial at a medical conference following study completion.

During the first half of 2018, AnaptysBio plans to initiate a Phase 2b randomized, double-blinded, placebo-controlled study in 200-300 adult patients with moderate-to-severe atopic dermatitis to evaluate multi-dose subcutaneous administration of ANB020, with data expected in 2019.

AnaptysBio also continues to advance its ongoing ANB020 Phase 2a studies in adults with severe peanut allergy with topline data expected in the fourth quarter of 2017, and adults with severe eosinophilic asthma with topline data expected in the first half of 2018.

Conference Call & Webcast Information
The AnaptysBio management team will host a conference call and live webcast with slides with the investment community today, Tuesday, October 10, 2017, at 8:30 a.m. EDT to discuss the information in this press release.

When: October 10, 2017, 8:30 a.m. EDT
Dial-in: (833) 696-8361 (domestic) or (430) 775-1625 (international)
Conference ID: 93436997

The live webcast and accompanying slides can be accessed under the investor relations section of AnaptysBio’s website at www.anaptysbio.com. A replay of the conference call will be archived under the investor relations section of the AnaptysBio website for 30 days shortly after the call.

About ANB020
ANB020 is an antibody that potently binds and inhibits the activity of interleukin-33, or IL-33, a pro-inflammatory cytokine that multiple studies have indicated is a central mediator of atopic diseases, including asthma, food allergies and atopic dermatitis. Following completion of a healthy volunteer Phase 1 trial of ANB020, AnaptysBio is continuing clinical development of ANB020 into Phase 2a studies for moderate-to-severe adult atopic dermatitis, severe adult peanut allergy and severe adult eosinophilic asthma.

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 and 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 data from AnaptysBio’s clinical trials, including ANB020’s Phase 2a clinical trials for the treatment of moderate-to-severe adult atopic dermatitis, severe peanut allergy and severe adult eosinophilic asthma and planned Phase 2b clinical trial of ANB020 for the treatment of moderate-to-severe adult atopic dermatitis, AnaptysBio’s ability to launch a Phase 2b clinical trial of ANB020 for the treatment of moderate-to-severe adult atopic dermatitis and the anticipated timing thereof, the potential of ANB020 as an effective future therapeutic option for patients with moderate-to-severe adult atopic dermatitis and AnaptysBio’s ability to further advance the development of ANB020 for the treatment of patients with atopic 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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