AnaptysBio Presents Updated ANB020 and ANB019 Clinical Data at the 2018 EAACI Congress

May 29, 2018

- **Blood eosinophil level reduction consistent with clinical efficacy in ANB020 Phase 2a atopic dermatitis trial**
- **ANB020-mediated eosinophil reduction is aligned with genotypic data from prior human IL-33 loss-of-function studies**
- **Favorable safety, pharmacokinetics and pharmacodynamics observed in ANB019 healthy volunteer single and multiple ascending dose Phase 1 trial**

SAN DIEGO, May 29, 2018 (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 that updated data from the company's Phase 2a trial of ANB020, AnaptysBio's wholly-owned anti-IL-33 antibody program, in adult patients with moderate-to-severe atopic dermatitis and the company's Phase 1 trial of ANB019, AnaptysBio's wholly-owned anti-IL-36R antibody program, in healthy volunteers administered with single and multiple ascending doses, were presented today at the 2018 European Academy of Allergy and Clinical Immunology (EAACI) Congress in Munich.

ANB020 Phase 2a Atopic Dermatitis Trial Oral Presentation

An oral presentation, titled "Proof-of-Concept Phase-2a Clinical Trial of ANB020 (Anti-IL-33 Antibody) in the Treatment of Moderate-to-Severe Adult Atopic Dermatitis" was presented by the principal investigator of the ANB020 Phase 2a clinical trial, Dr. Graham Ogg, professor of dermatology at Oxford University in Oxford, England, and is available through the publications section of the AnaptysBio website.

This Phase 2a proof-of-concept trial assessed ANB020 efficacy and safety in 12 moderate-to-severe adult atopic dermatitis patients. The primary efficacy objective of this study was to determine the percentage of patients achieving 50 percent improvement in their Eczema Area Severity Index (EASI) score relative to enrollment baseline (EASI-50) on day 29 post-ANB020 administration. Each patient was dosed with placebo 14 days following enrollment, and subsequently administered a single 300mg intravenous dose of ANB020 one week after placebo.

Key observations presented by Dr. Ogg during the aforementioned presentation included:

- Biomarker data demonstrated that reduction of circulating blood eosinophil was consistent with clinical efficacy measures in this Phase 2a trial, with a maximum reduction of 40 percent at day 29 post-ANB020 administration relative to baseline, which is aligned with genotypic studies that associate lower eosinophil counts with human IL-33 loss-of-function mutations[1]. In addition, clinical efficacy in this Phase 2a trial was consistent with an ex vivo pharmacodynamic assay measuring IL-33 mediated interferon-gamma release, where 98 percent inhibition was observed within 72 hours following ANB020 administration and 86 percent inhibition was sustained at day 57 post-ANB020 administration, which is consistent with the pharmacodynamic activity observed using the same assay in a prior Phase 1 trial of ANB020 in healthy volunteers.
- ANB020 was efficacious in all 12 patients enrolled in this trial with each patient achieving at least EASI-50 on or before day 57 post-ANB020 administration.
- Rapid clinical response was observed by day 15 post-ANB020 administration with nine of 12 patients (75%) achieving EASI-50, of which three patients (25%) also achieved EASI score improvement of 75 percent relative to baseline (EASI-75).
- Day 29 results exceeded the primary efficacy objective of the trial with 10 of 12 patients (83%) achieving EASI-50, of which four patients (33%) also achieved EASI-75.
- Efficacy was sustained through day 140 following single dose administration of ANB020 with five of 12 patients (42%) achieving EASI-50, of which three patients (25%) also achieved EASI-75.
- ANB020 efficacy was not limited by disease severity as ANB020 was similarly efficacious in the seven of 12 enrolled patients treated with systemic immuno-modulators pre-study, which exhibited an average EASI baseline score of 36 upon enrollment, relative to the remaining five of 12 enrolled patients that did not require systemic immuno-modulators pre-study and exhibited an average EASI baseline score of 27. The average baseline EASI score upon enrollment across all 12 patients was 32.
- Other atopic dermatitis efficacy endpoints, including the five-point Investigator's Global Assessment (IGA) scale, the SCORing Atopic Dermatitis (SCORAD) scale, Dermatology Life Quality Index (DLQI) and the five-dimensional pruritus scale, demonstrated rapid and sustained single dose ANB020 efficacy results in a similar manner to the aforementioned EASI results.
- ANB020 was generally well-tolerated by all patients and no drug-related safety signals were observed. The most frequent

adverse events reported were dizziness in 17 percent of patients post-placebo and headache in 25 percent of patients post-ANB020 administration. A single serious adverse event of depression was reported on day 140 post-ANB020 administration, which was consistent with the patient's pre-trial history of depression and was deemed not drug-related.

AnaptysBio has initiated a Phase 2b randomized, double-blinded, placebo-controlled clinical trial in 300 adult patients with moderate-to-severe atopic dermatitis to evaluate various dose levels and dosing frequencies of subcutaneously-administered ANB020, with data expected in 2019.

ANB019 Phase 1 Healthy Volunteer Trial Poster Presentation

A poster presentation, titled "A Phase 1 Study of ANB019, An Anti-IL-36 Receptor Monocloncal Antibody, In Healthy Volunteers", was presented by Dr. Marco Londei, AnaptysBio's chief medical officer, and is also available through the publications section of the AnaptysBio website. 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. Dosing and monitoring has been completed for all subjects in the trial.

ANB019 was well-tolerated by all subjects and no dose-limiting toxicities were observed. The most frequent treatment-emergent adverse events observed in the single ascending dose cohorts were upper respiratory tract infections in 10 of 36 (28%) subjects dosed with ANB019 versus six of 12 (50%) subjects dosed with placebo, and headache in 10 of 36 (28%) subjects dosed with ANB019 versus three of 12 (25%) subjects dosed with placebo. In the multiple ascending dose cohorts, the most frequent treatment-emerging adverse events observed were headache in seven of 18 (39%) subjects dosed with ANB019 versus one of six (17%) subjects dosed with placebo. No serious adverse events were reported among any subjects in the trial.

The *in vivo* half-life of ANB019 was approximately 28 days for both subcutaneous and intravenous routes of administration, with bioavailability of approximately 90 percent. A single dose of ANB019 at certain dose levels was able to completely suppress IL-36 cytokine function for 85 days, as measured by IL-36 cytokine-mediated release of IL-8 using an *ex vivo* pharmacodynamic assay.

The company has initiated a 10-patient, multi-dose, open-label Phase 2 clinical trial of ANB019 in generalized pustular psoriasis (GPP), and anticipates initiating a multi-dose, randomized, placebo-controlled Phase 2 trial of ANB019 in palmo-plantar pustulosis (PPP) during 2018.

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 atopic dermatitis, food allergies and asthma. Following completion of a healthy volunteer Phase 1 trial of ANB020, AnaptysBio has continued clinical development of ANB020 into the aforementioned Phase 2a trial for moderate-to-severe adult atopic dermatitis, a 20-patient placebo-controlled Phase 2a trial in adult peanut allergy patients where top-line data were reported in the first quarter of 2018 and a 24-patient placebo-controlled Phase 2a trial in severe adult eosinophilic asthma patients where top-line data are anticipated in the third quarter 2018. AnaptysBio has initiated a placebo-controlled multi-dose Phase 2b clinical trial of ANB020 in 300 moderate-to-severe adult atopic dermatitis patients where data is anticipated in 2019. AnaptysBio also plans to initiate a multi-dose Phase 2b clinical of ANB020 in moderate-to-severe baseline adult peanut allergy patients.

About ANB019
ANB019 is an antibody that inhibits the function of the interleukin-36-receptor, or IL-36R, which AnaptysBio plans to initially develop as a potential first-in-class therapy for patients suffering from generalized pustular psoriasis (GPP) and palmo-plantar pustulosis (PPP), previously referred to as palmo-plantar pustular psoriasis. AnaptysBio demonstrated favorable safety, pharmacokinetics and pharmacodynamic properties of ANB019 in a Phase 1 clinical trial in healthy volunteers, where 54 subjects were dosed with ANB019 and 18 were dosed with placebo in single and multi-dose cohorts at various subcutaneous and intravenously administered dose levels. AnaptysBio has initiated a 10-patient multi-dose open-label Phase 2 clinical trial of ANB019 in GPP and anticipates initiating a multi-dose, randomized, placebo-controlled Phase 2 trial of ANB019 in PPP during 2018.

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, moderate-to-severe baseline 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 (GPP) and palmoplantar pustulosis (PPP), previously referred to as 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 timing of the release of data from our clinical trials, including ANB020's Phase 2a trial severe adult eosinophilic asthma patients, and Phase 2b clinical trial in moderate-to-severe adult atopic dermatitis patients; our ability to launch a Phase 2b clinical trial of ANB020 in moderate-to-severe adult atopic dermatitis patients and moderate-to-severe baseline adult peanut allergy patients; Phase 2 clinical trials of ANB019 in GPP and PPP and the success of our partnership with TESARO and Celgene. Statements including words such as "plan," "continue," "expect," or "ongoing" and statements in the future tense are forward-looking statements. These forward-looking statements involve risks and uncertainties, as well as assumptions, which, if they do not fully materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. Forward-looking statements are subject to risks and uncertainties that may cause the company's actual activities or results to differ significantly from those expressed 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.

Contact:
Monique Allaire
THRUST Investor Relations
617.895.9511
monique@thrustir.com

Chelcie Lister
THRUST Investor Relations
910.777.3049
Chelcie@thrustir.com

[1] Smith et al. (2017) A rare *IL33* loss-of-function mutation reduces blood eosinophil counts and protects from asthma. PLoS Genet 13(3): e1006659.

AnaptysBio

Source: AnaptysBio, Inc.