AnaptysBio Reports Positive Topline Data from Phase 2a Proof-of-Concept Clinical Trial of Etokimab in Severe Eosinophilic Asthma

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- Lung function improvement occurred rapidly following a single dose of etokimab, with an 8 percent increase in FEV1 over placebo at Day 2
- FEV1 improvement was sustained throughout the interim analysis period, with an 11 percent increase over placebo at Day 64
- Blood eosinophil reduction was consistent with lung function improvement, with 31 percent and 46 percent reduction over placebo at Day 2 and Day 64, respectively
- Management to host conference call today at 8:30 a.m. EDT

SAN DIEGO, Sept. 24, 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 positive topline proof-of-concept data for etokimab, its investigational anti-IL-33 therapeutic antibody, in an ongoing single dose Phase 2a clinical trial in adult patients with severe eosinophilic asthma. Patients administered with etokimab rapidly improved their Forced Exhaled Volume In One Second (FEV1), which is a measure of lung function, with an 8 percent FEV1 improvement over placebo at Day 2. FEV1 improvement was sustained through Day 64, with an 11 percent increase over placebo. Blood eosinophil reduction was sustained through the interim analysis period, with a 31 percent reduction at Day 2 and a 46 percent reduction at Day 64 over placebo, which was consistent with FEV1 improvement observed in this trial. Etokimab was generally well tolerated in all patients and no serious adverse events were reported as of this interim analysis.

“Eosinophilic asthma is a debilitating medical condition that results from severe inflammation and airway obstruction,” said Dr. Ian Pavord, professor of Respiratory Medicine at University of Oxford and principal investigator of the Phase 2a trial. “The benefit observed in this trial after a single dose of etokimab demonstrates the potential for IL-33 inhibition in treating severe eosinophilic asthma. I look forward to the continued advancement of etokimab in subsequent clinical trials for patients suffering from this chronic life-long disease.”

Phase 2a Trial Design
This Phase 2a proof-of-concept trial enrolled 25 adult severe eosinophilic asthma patients, who were randomized between a single 300mg intravenous dose of etokimab or placebo upon enrollment (Day 1) at six sites located in the United States and the United Kingdom. Upon screening, which occurred seven to 14 days prior to enrollment, patients were required to have a blood eosinophil count of at least 300 per microliter, confirmed clinical diagnosis of severe asthma according to the Global Initiative for Asthma (GINA) 2016, pre-bronchodilator FEV1 of less than 80 percent of predicted and at least one asthma exacerbation within the past 12 months requiring use of rescue medication. Patients were required to be stably maintained on high-dose inhaled corticosteroids (ICS) and long-acting beta-2-agonists (LABA) for at least three months prior to screening and were required to continue ICS/LABA therapy during the course of this trial. Baseline clinical assessments were conducted for each patient on Day 1 prior to etokimab or placebo dose, and patients completed follow-up clinical assessments on Days 2, 8, 22, 36 and 64 as of this interim analysis. The last follow-up visit for each patient will occur on Day 127 post-dose.

Interim Analysis
Key data and observations as of this interim analysis indicate the following:

- Baseline parameters of etokimab-dosed patients (n=12) were 545 blood eosinophils per microliter, 2.5 liters FEV1 and 65 percent predicted FEV1, while placebo-dosed patients (n=13) had 705 blood eosinophils per microliter, 2.5 liters FEV1 and 66 percent predicted FEV1. Nine of 12 (75%) etokimab-dosed patients were male with an average age of 41, while nine of 13 (69%) placebo-dosed patients were male with an average age of 36.
- Etokimab-dosed patients rapidly improved lung function by Day 2, where FEV1 increased by 8 percent over placebo.
- FEV1 increase was sustained at Day 64, where etokimab-dosed patients demonstrated an 11 percent increase over placebo.
- Blood eosinophil reduction, which is a biomarker illustrative of etokimab’s mechanistic breadth, was observed at 31 percent over placebo at Day 2 and sustained to 46 percent over placebo at Day 64. This reduction correlated with FEV1 improvement and was consistent with the blood eosinophil effects observed in a prior single dose etokimab trial in moderate-to-severe atopic dermatitis patients.
- Etokimab was generally well-tolerated by all patients and no serious adverse events were reported as of this interim analysis. No treatment-emergent adverse events were deemed to be etokimab-related, and the most frequent treatment-emergent adverse events reported were single occurrences of moderate strep throat in two etokimab-dosed patients and single occurrences of mild vomiting in two placebo-dosed patients. No exacerbations or rescue therapy usage has been reported as of the interim analysis.

Parameter	Timepoint	Change Relative to Day 1 Baseline		
		Etokimab (n=12)	Placebo (n=13)	Net
FEV1 Increase (%)	Day 2	12%	4%	8%
	Day 8	9%	5%	4%
	Day 22	16%	8%	8%
	Day 36	14%	8%	6%
	Day 64	15%	4%	11%
Blood Eosinophil Level (%)	Day 2	-22%	9%	-31%
	Day 8	-34%	-15%	-19%
	Day 22	-30%	-10%	-20%
	Day 36	-43%	1%	-44%
	Day 64	-40%	6%	-46%

“We are thrilled to have demonstrated proof-of-concept in this single dose Phase 2a trial and look forward to advancing the development of etokimab for patients suffering from eosinophilic asthma,” said Hamza Suria, president and chief executive officer of AnaptysBio. “Genotypic studies have validated the key role played by IL-33 in asthma, and we believe etokimab’s upstream mechanism has the potential for a broad therapeutic benefit across multiple atopic disorders.”

This Phase 2a trial is currently ongoing and the company plans to report full data from this trial at a medical conference in 2019 following trial completion.

AnaptysBio plans to continue development of etokimab in eosinophilic asthma with a multi-dose Phase 2b randomized, double-blinded, placebo-controlled trial, which is expected to be initiated in 2019.

Conference Call & Webcast Information
The AnaptysBio management team will host a conference call and live webcast on Monday Sept. 24, 2018, at 8:30 a.m. EDT to discuss the information in this press release.

Dial-in: (833) 696-8361 (domestic) or (430) 775-1625 (international)
Conference ID: 5798647

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 Etokimab

Etokimab, previously referred to as ANB020, is an antibody that potently binds and inhibits the activity of interleukin-33 (IL-33), a pro-inflammatory cytokine that multiple studies have indicated is a central mediator of atopic diseases, which AnaptysBio believes is broadly applicable to the treatment of atopic inflammatory disorders, such as moderate-to-severe atopic dermatitis, severe eosinophilic asthma, chronic rhinosinusitis with nasal polyps (CRSwNP) and potentially other allergic conditions. Following completion of a healthy volunteer Phase 1 trial of etokimab, AnaptysBio continued clinical development of etokimab into a Phase 2a trial for moderate-to-severe adult atopic dermatitis and a placebo-controlled Phase 2a trial in severe adult eosinophilic asthma patients. AnaptysBio is enrolling its ATLAS trial, a randomized, double-blinded, placebo-controlled multi-dose Phase 2b clinical trial of etokimab in 300 moderate-to-severe adult atopic dermatitis patients where data is anticipated in the second half of 2019. The company also plans to initiate its ECLIPSE trial, a randomized, double-blinded, placebo-controlled Phase 2 trial of etokimab in approximately 100 adult patients with CRSwNP by the end of 2018 with data anticipated in the second half of 2019. AnaptysBio also plans to initiate a randomized, double-blinded, placebo-controlled, multi-dose Phase 2b trial of etokimab in patients with eosinophilic asthma in 2019.

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 (etokimab, previously referred to as ANB020) for the treatment of moderate-to-severe atopic dermatitis, severe eosinophilic asthma, chronic rhinosinusitis with nasal polyps (CRSwNP); 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 novel anti-inflammatory checkpoint receptor modulator antibodies for treatment of certain autoimmune diseases where immune checkpoint receptors are insufficiently activated. 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 etokimab’s Phase 2b clinical trial in moderate-to-severe adult atopic dermatitis patients and etokimab’s Phase 2 clinical trial in adult patients with CRSwNP; our design of and our ability to launch a Phase 2 clinical trial of etokimab in adults patients with CRSwNP and a Phase 2b clinical trial of etokimab in eosinophilic asthma; and statements by AnaptysBio’s president and chief executive officer. 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.

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