AnaptysBio Presents Updated Data from Etokimab Phase 2a Proof-of-Concept Clinical Trial in Severe Eosinophilic Asthma

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- Single dose of etokimab resulted in rapid and sustained lung function improvement and ACQ-5 score reduction through at least Day 64
- Etokimab was well tolerated and no serious adverse events were reported
- Data supports infrequent dosing of etokimab in the treatment of eosinophilic asthma, which is consistent with prior Phase 2a atopic dermatitis trial
- Company plans to initiate a Phase 2b trial in eosinophilic asthma patients in 2019

SAN DIEGO, June 05, 2019 (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 presented updated proof-of-concept data for etokimab, its investigational anti-IL-33 therapeutic antibody, in a single dose Phase 2a clinical trial in adult patients with severe eosinophilic asthma, at the 2019 European Academy of Allergy and Clinical Immunology (EAACI) Congress. The oral presentation, titled “Single-Dose Phase 2a Trial of Etokimab (anti-IL-33) in Severe Eosinophilic Asthma”, was presented by Dr. Marco Londei, AnaptysBio’s Chief Medical Officer, and is available through the publications section of the AnaptysBio website.

Patients in the etokimab arm rapidly improved their Forced Exhaled Volume In One Second (FEV1), which is a measure of lung function, with an eight percent FEV1 improvement over placebo at Day 2, which was sustained through Day 64 with an 11 percent increase over placebo. Asthma Control Questionnaire 5 (ACQ-5) scores, which comprise patient-reported outcomes associated with asthma symptoms, decreased in the etokimab arm by 0.52 over placebo at Day 8 and were sustained to 0.54 over placebo at Day 64, and the etokimab arm achieved the minimal clinically important difference (MCID) of 0.5 below baseline. Blood eosinophil level reduction, which is a biomarker of etokimab’s mechanism, demonstrated 31 percent and 46 percent reductions in the etokimab arm over placebo at Days 2 and 64, respectively. Etokimab was generally well tolerated in all patients and no serious adverse events were reported. These data, taken together with prior Phase 2a atopic dermatitis trial results, suggest that etokimab may enable infrequent dosing across atopic diseases.

“The positive proof-of-concept data generated under this trial are consistent with the genetically-validated rationale for etokimab’s IL-33 inhibitory mechanism in eosinophilic asthma,” said Hamza Suria, president and chief executive officer of AnaptysBio. “We look forward to advancing etokimab in multiple atopic disease indications, including moderate-to-severe atopic dermatitis, chronic rhinosinusitis with nasal polyps and severe eosinophilic asthma.”

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. Patients were permitted to utilize rescue therapy when medically necessary, including in the management of asthma exacerbations. 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, 64, 85, 106 and 127.

Phase 2a Trial Results
Key data and observations indicate the following:

- Baseline parameters of etokimab-dosed patients (n=12) were 545 blood eosinophils per microliter, 2.5 liters FEV1, 65 percent predicted FEV1 and ACQ-5 score of 2.25, while placebo-dosed patients (n=13) had 705 blood eosinophils per microliter, 2.5 liters FEV1, 66 percent predicted FEV1 and ACQ-5 score of 1.88. The average age of patients in the etokimab and placebo arms were 41 and 36, respectively. Nine of 12 (75%) etokimab-dosed patients were male, while nine of 13 (69%) placebo-dosed patients were male.
- No exacerbations or rescue medication usage were reported through Day 64. Post-Day 64, asthma exacerbations were reported in one etokimab-dosed patient and two placebo-dosed patients. Rescue therapy usage, including short-acting beta agonists and oral corticosteroids, were reported in the management of each asthma exacerbation occurrence.
- Patients in the etokimab arm rapidly improved lung function by Day 2, where FEV1 increased by eight percent over placebo. FEV1 increase was sustained at Day 64, where the etokimab arm demonstrated an 11 percent increase over

placebo.

- ACQ-5 scores, which comprise patient reported asthma symptom outcomes, decreased in the etokimab arm by 0.52 over placebo by Day 8 and were sustained to 0.54 over placebo at Day 64. The minimal clinically important difference (MCID) of ACQ-5 is 0.5 relative to baseline, which was achieved in the etokimab arm.
- Blood eosinophils were reduced by 31 percent in the etokimab arm over placebo at Day 2 and sustained to 46 percent over placebo at Day 64. This reduction is consistent with the blood eosinophil changes observed in a prior etokimab Phase 2a trial in moderate-to-severe atopic dermatitis patients.
- Etokimab was generally well-tolerated, and no treatment-emergent adverse events were deemed to be etokimab-related. No serious adverse events were reported during this trial. The most frequent treatment-emergent adverse events reported in the etokimab arm were moderate strep throat in two patients. Placebo-dosed patients reported the most frequent treatment-emergent adverse events as mild vomiting in two patients, mild and moderate asthma exacerbations in two patients and mild cough in two patients.

Parameter	Timepoint	Change Relative to Day 1 Baseline		
		Etokimab (n=12)	Placebo (n=13)	Net
FEV1	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%
	Day 85	9%	7%	2%
	Day 106	11%	11%	0%
	Day 127	13%	8%	5%
ACQ-5 Score	Day 8	-0.62	-0.09	-0.52
	Day 22	-0.48	-0.25	-0.24
	Day 36	-0.6	-0.12	-0.48
	Day 64	-0.67	-0.12	-0.54
	Day 85	-0.67	-0.18	-0.48
	Day 106	-0.72	-0.44	-0.27
	Day 127	-0.77	-0.36	-0.41
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%
	Day 85	-36%	-7%	-29%
	Day 106	-19%	-13%	-6%
	Day 127	-24%	-16%	-8%

Phase 2b Trial

AnaptysBio plans to initiate, during 2019, a multi-dose Phase 2b randomized, double-blinded, placebo-controlled trial in 300-400 moderate-to-severe eosinophilic asthma patients, where multiple dose levels and dosing frequencies will be assessed for key endpoints, including exacerbation reduction, FEV1 and ACQ-5.

About Etokimab

Etokimab, previously referred to as 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, 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. AnaptysBio is currently conducting 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 is also conducting its ECLIPSE trial, a randomized, double-blinded, placebo-controlled Phase 2 trial of etokimab in approximately 100 adult patients with CRSwNP where data is anticipated in the second half of 2019. AnaptysBio also plans to initiate, during 2019, a randomized, double-blinded, placebo-controlled, multi-dose Phase 2b trial of etokimab in 300-400 patients with 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 etokimab,

previously referred to as ANB020, for the treatment of moderate-to-severe atopic dermatitis, eosinophilic asthma, and adult chronic rhinosinusitis with nasal polyps, or CRSwNP; its anti-IL-36R antibody ANB019 for the treatment of rare inflammatory diseases, including generalized pustular psoriasis, or GPP, and palmoplantar pustulosis, or PPP, 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, or 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 (recently acquired by GlaxoSmithKline), including an anti-PD-1 antagonist antibody (dostarlimab, TSR-042), an anti-TIM-3 antagonist antibody (TSR-022) and an anti-LAG-3 antagonist antibody (TSR-033), and an inflammation partnership with Celgene, including an anti-PD-1 checkpoint agonist antibody (CC-90006) currently in clinical development.

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 2b clinical trial of etokimab in eosinophilic asthma; statements regarding potential dosing frequency of etokimab; 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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