# AnaptysBio Reports Top-Line Data from Interim Analysis of ECLIPSE Phase 2 Clinical Trial of Etokimab in Chronic Rhinosinusitis with Nasal Polyps

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- Etokimab q4w and q8w treatment arms failed to achieve NPS and SNOT-22 statistical significance over placebo at this week 8 interim analysis
- Secondary analyses demonstrated NPS and blood eosinophil level improvement in both asthma and non-asthma comorbid patients versus placebo in each etokimab-dosed arm, while ACQ-5 scores were improved in the asthmatic subset
- Blood eosinophil reduction achieved statistical significance over baseline in both etokimab treatment arms
- Etokimab was generally well-tolerated and demonstrated an acceptable safety profile
- Company intends to assess path forward for its etokimab program after reviewing week 16 primary endpoint data by year-end 2020

SAN DIEGO, Aug. 10, 2020 (GLOBE NEWSWIRE) -- AnaptysBio, Inc. (Nasdaq: ANAB), a clinical-stage biotechnology company developing first-in-class antibody product candidates focused on emerging immune control mechanisms applicable to inflammation and immune-oncology indications, today reported top-line data from a week 8 interim analysis of the Company's ongoing ECLIPSE Phase 2 clinical trial of etokimab, an anti-interleukin-33 (IL-33) monoclonal antibody, in patients with chronic rhinosinusitis with nasal polyps (CRSwNP).

Patients dosed with etokimab every four (q4w) or eight weeks (q8w) failed to achieve statistically significant improvement in their bilateral nasal polyps score (NPS), an endoscopic measure of nasal occlusion, and in their sino-nasal outcome test (SNOT-22), a patient reported quality-of-life assessment, versus placebo at the week 8 timepoint. Both endpoints demonstrated statistically significant improvement over baseline levels of NPS and SNOT-22. Blood eosinophil levels, which are a biomarker of etokimab's mechanism, demonstrated statistically significant reduction relative to baseline in both etokimab treatment arms. The Company intends to determine next steps for the etokimab program after reviewing week 16 primary endpoint by year-end 2020.

"We are disappointed that etokimab did not demonstrate significance over placebo in either treatment arm in this week 8 interim analysis," said Hamza Suria, president and chief executive officer of AnaptysBio. "We plan to re-assess the etokimab program following review of the complete week 16 data from the ECLIPSE trial later this year."

**ECLIPSE Trial Design**
This Phase 2 trial enrolled 105 adult chronic rhinosinusitis with nasal polyps patients, who were randomized between three 16-week dosing arms: (i) 300mg subcutaneous (SC) loading dose followed by q4w 150mg SC, (ii) 300mg SC loading dose followed by q8w 150mg SC and (iii) placebo, in each case concomitant with 400 micrograms daily of mometasone furoate nasal spray. Patients were enrolled, at approximately 25 sites across the United States, with a confirmed diagnosis of CRSwNP, a minimum NPS score of 4 with at least a score of 1 in each nostril and minimum SNOT-22 score of 16 after completion of at least 8 weeks of prior therapy washout. Each arm was stratified for asthma comorbidity. This interim analysis was conducted to assess key endpoints through week 8 of treatment. The co-primary endpoints for this trial are NPS and SNOT-22 change relative to baseline at week 16. Patients will be followed for an 8-week monitoring period subsequent to the 16-week treatment period. Missing data values were imputed using a mixed-effect model with repeated measures (MMRM) approach.

| Endpoint | Parameter | Etokimab q4w (n=35) | Etokimab q8w (n=35) | Placebo (n=35) |
|---|---|---|---|---|
| NPS | Baseline | 5.4 | 5.2 | 5.7 |
| | Week 8 | -10% | -11% | -4% |
| | p-value vs placebo | 0.3348 | 0.3042 | N/A |
| | p-value vs baseline | 0.0286 | 0.0243 | 0.4288 |
| SNOT-22 | Baseline | 51.4 | 53.9 | 56.9 |
| | Week 8 | -23% | -23% | -19% |
| | p-value vs placebo | 0.9927 | 0.9275 | N/A |
| | p-value vs baseline | <0.0001 | <0.0001 | <0.001 |
| Blood Eosinophil Level (cells/microliter) | Baseline | 440 | 350 | 430 |
| | Week 8 | -23% | -23% | 7% |
| | p-value vs baseline | 0.004 | <0.001 | 0.358 |

**Table 1. Key Interim Analysis Endpoints**

**Interim Analysis Results**
NPS, SNOT-22 and blood eosinophil endpoints assessed in this interim analysis are outlined in Table 1. Least-squares mean reduction in NPS versus placebo did not achieve statistical significance in the etokimab q4w arm (p-value of 0.3348) or the q8w arm (p-value of 0.3042), and least-squares mean SNOT-22 change versus placebo also did not achieve significance vs placebo in either etokimab treatment arm (p-values of 0.9927 and 0.9275 for the q4w and q8w arms, respectively). Least-squares mean NPS change relative to baseline was statistically significant in the etokimab q4w arm (p-value of 0.0286) and the q8w arm (p-value of 0.0243), and least-squares mean SNOT-22 change relative to baseline was also significant in both etokimab arms (p-values of <0.0001 for each arm). Blood eosinophil level reduction achieved statistical significance over baseline in the etokimab q4w arm (p-value of 0.004) and q8w arm (p-value of <0.001).

Secondary analyses assessed the differential effects of etokimab treatment upon enrolled CRSwNP patients with or without comorbid asthma. Sixty-three percent of the etokimab q4w arm, 69% of the etokimab q8w arm and 69% of the placebo arm were diagnosed with asthma. Baseline FEV1 and percent predicted FEV1 for the asthma subset in the etokimab q4w arm was 2.95 liters and 84%, 2.97 liters and 87% for the etokimab q8w arm and 3.06 liters and 87% for the placebo arm, suggesting mild asthma severity in the comorbid patients. NPS and blood eosinophils levels were reduced in both the asthma and non-asthma subsets of each etokimab treatment arm versus placebo, while SNOT-22 was only reduced over placebo in the non-asthma subset vs placebo in each etokimab arm. ACQ-5 scores were reduced in the asthma subset of both etokimab treatment arms vs placebo while FEV1 levels remained relatively unchanged.

Additional secondary endpoint analyses were conducted upon the eosinophilic asthma subset persistent in approximately 40% of each etokimab treatment arm and 51% of the placebo arm. NPS, ACQ-5 and eosinophil levels were reduced below placebo in each etokimab arm, while FEV1 and SNOT-22 were reduced versus placebo in the etokimab q8w arm only.

Safety assessment indicated that etokimab was generally well-tolerated. Most adverse events observed were mild and no dose trends or unexpected safety signals were observed. Three serious adverse events were observed in the etokimab q4w arm (urinary tract infection, kidney stone and pneumonia aspiration), each of which were deemed to be treatment unrelated.

AnaptysBio intends to assess next steps for its etokimab program after reviewing complete data from this trial, including week 16 primary endpoint data, anticipated by year-end 2020. The Company has postponed initiation of its planned etokimab Phase 2b eosinophilic asthma trial.

**About AnaptysBio**
AnaptysBio is a clinical-stage biotechnology company developing first-in-class antibody product candidates focused on emerging immune control mechanisms applicable to inflammation and immuno-oncology indications. The Company's proprietary anti-inflammatory pipeline includes its anti-IL-33 antibody etokimab, previously referred to as ANB020, for the treatment of chronic rhinosinusitis with nasal polyps, or CRSwNP, and eosinophilic asthma; its anti-IL-36R antibody imsidolimab, previously referred to as ANB019, for the treatment of rare inflammatory diseases, including generalized pustular psoriasis, or GPP, and palmoplantar pustulosis, or PPP; its anti-PD-1 agonist program, ANB030, for treatment of certain autoimmune diseases where immune checkpoint receptors are insufficiently activated; and its BTLA modulator program, ANB032, which is broadly applicable to human inflammatory diseases associated with lymphoid and myeloid immune cell dysregulation. 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 collaboration with GlaxoSmithKline, including an anti-PD-1 antagonist antibody (dostarlimab, GSK4057190A), an anti-TIM-3 antagonist antibody (cobolimab, GSK4069889A) and an anti-LAG-3 antagonist antibody (GSK4074386), and an inflammation collaboration with Bristol-Myers Squibb, 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 week 16 data for the ECLIPSE Phase 2 clinical trial in chronic rhinosinusitis with nasal polyps. 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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