



AnaptysBio Announces Second Quarter 2018 Financial Results and Provides Pipeline Updates

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- *Top-line Phase 2a Data from Etokimab (ANB020) in Eosinophilic Asthma Expected in Third Quarter of 2018*
- *Etokimab Clinical Development Program Expanded to Include Chronic Rhinosinusitis with Nasal Polyps*
- *Commercial Considerations Led to Deprioritization of Further AnaptysBio-Sponsored Clinical Development of Etokimab in Peanut Allergy*
- *Five Top-line Clinical Efficacy Readouts from Wholly-Owned Pipeline Anticipated by End of 2019*

SAN DIEGO, Aug. 07, 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 reported operating results for the second quarter ended June 30, 2018 and provided pipeline updates.

"We made significant advances during the second quarter of 2018 in the clinical development of our first-in-class wholly-owned antibody therapeutics for patients with severe inflammatory conditions," said Hamza Suria, president and chief executive officer of AnaptysBio. "We are excited to advance the clinical development of etokimab in large atopic disease markets, including our ongoing Phase 2b ATLAS trial in moderate-to-severe atopic dermatitis, our ongoing Phase 2a trial in severe eosinophilic asthma and our upcoming Phase 2 ECLIPSE trial in adult chronic rhinosinusitis with nasal polyps. Development of ANB019 in orphan diseases has been initiated with our Phase 2 GALLOP trial in generalized pustular psoriasis and upcoming Phase 2 POPLAR trial in palmoplantar pustulosis. We look forward to the five clinical efficacy readouts anticipated from our etokimab and ANB019 programs by the end of 2019, starting with our upcoming etokimab Phase 2a top-line data in eosinophilic asthma during the third quarter of 2018, as key milestones in our mission to bring novel treatments to patients with severe inflammatory diseases."

Etokimab (ANB020 Anti-IL-33 Program)

- In July 2018, etokimab (pronounced ee-toh-key-mab) was adopted as the nonproprietary name by the United States Adopted Names (USAN) Council, in consultation with the World Health Organization (WHO) International Nonproprietary Names Expert Committee, for AnaptysBio's anti-IL-33 antibody drug candidate previously referred to as ANB020.
- In May 2018, updated data from the company's Phase 2a trial of etokimab, AnaptysBio's wholly-owned anti-IL-33 antibody program, in adult patients with moderate-to-severe atopic dermatitis were presented at the European Academy of Allergy and Clinical Immunology (EAACI) Congress 2018 in Munich by the principal investigator of the trial, Dr. Graham Ogg, professor of dermatology at Oxford University in Oxford, England. 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 after a single dose of etokimab relative to baseline, which is aligned with genotypic studies that associate lower eosinophil counts with human IL-33 loss-of-function mutations. In addition, clinical efficacy data in this Phase 2a trial were consistent with an *ex vivo* pharmacodynamic assay measuring IL-33 mediated interferon-gamma release, where 98 percent inhibition was observed within 72 hours following etokimab 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 etokimab in healthy volunteers.
 - A single dose of etokimab resulted in achievement of EASI-50 by all 12 patients enrolled in this trial on or before day 57 post-etokimab administration. Rapid clinical response was observed by day 15 post-etokimab administration and 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. EASI-50 results were sustained through day 140 following single dose administration of etokimab, five of 12 patients (42%) achieved EASI-50, of which three patients (25%) also achieved EASI-75. 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 etokimab efficacy results in a similar manner to the aforementioned EASI results.
 - Etokimab 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-etokimab administration. A single serious adverse event of depression was reported on day 140 post-etokimab administration, which was consistent with the patient's pre-trial history of depression and was deemed not drug-related.
- The company is enrolling a Phase 2b randomized, double-blinded, placebo-controlled, multi-dose study in 300 adult patients with moderate-to-severe atopic dermatitis, also referred to as the ATLAS clinical trial, to assess different dose levels and dosing

frequencies of subcutaneously-administered etokimab for a 16-week treatment period followed by an eight-week follow-up period, with data expected in the second half of 2019. Sixty patients are being randomized into each of the five arms in the ATLAS trial where dosing will occur as follows: (i) initial 600mg loading dose followed by 300mg monthly doses of etokimab, (ii) initial 300mg loading dose followed by 150mg monthly doses of etokimab, (iii) initial 300mg loading dose followed by 150mg doses of etokimab every eight weeks, (iv) monthly 20mg doses of etokimab and (v) monthly doses of placebo.

- AnaptysBio expects to report top-line efficacy and safety data, including improvement in Forced Expiratory Volume in One Second (FEV1), from its ongoing double-blinded, placebo-controlled severe eosinophilic asthma trial Phase 2a trial, where approximately 24 adult severe eosinophilic asthma patients are treated with a 300mg intravenous single dose of etokimab versus placebo, each in combination with inhaled corticosteroids and long-acting beta agonists as background therapy, in the third quarter of 2018.
- The Company has expanded development of etokimab into adult chronic rhinosinusitis with nasal polyps (CRSwNP), which is a debilitating atopic disorder associated with elevated IL-33 pathway signaling, affecting approximately 1.3 million adults in the U.S., and AnaptysBio estimates approximately 400,000 of these patients are inadequately controlled with standard-of-care. The Company plans to initiate a randomized, placebo-controlled Phase 2 trial, also referred to as the ECLIPSE trial, in approximately 100 adult CRSwNP patients treated with two different multi-dosing frequencies of subcutaneously-administered etokimab or placebo, each in combination with mometasone furoate nasal spray as background therapy, for a treatment period of 16 weeks followed by an eight-week follow-up period. The Company plans to initiate the ECLIPSE trial by the end of 2018, and anticipates top-line data will be available in the second half of 2019.
- As a result of market assessment regarding the adoption of the peanut oral food challenge in future commercial usage of etokimab in peanut allergy patients, AnaptysBio has decided to deprioritize further company-sponsored clinical development of etokimab in moderate-to-severe baseline adult peanut allergy patients. At this time, AnaptysBio does not intend to utilize its clinical development resources to pursue a Phase 2b clinical trial of etokimab in peanut allergy, however the Company may pursue potential investigator-sponsored trials related to this indication.

ANB019 (Anti-IL-36 Receptor Program)

- Data from the company's Phase 1 healthy volunteer trial of ANB019, its wholly-owned anti-interleukin-36 receptor, or IL-36R therapeutic antibody, were presented during May in a poster session at the EAACI Congress 2018 in Munich. 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. 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 favorable safety, pharmacokinetics and pharmacodynamic properties of ANB019 demonstrated by this Phase 1 trial support advancement of ANB019 into Phase 2 studies for GPP and PPP.
- AnaptysBio has initiated a 10-patient open-label Phase 2 trial of ANB019 in GPP, also known as the GALLOP trial and top-line data are anticipated by early 2019. Patients are dosed with a 750mg intravenous loading dose of ANB019 upon enrollment, followed by 100mg subcutaneously-administered monthly doses of ANB019 for a treatment period of up to 16 weeks post enrollment and followed an eight-week follow-up period. The company plans to initiate a placebo-controlled 50-patient multi-dose Phase 2 trial in PPP, also known as the POPLAR trial, where top line data is anticipated in the second half of 2019.

Second Quarter Financial Results

- Cash, cash equivalents and investments totaled \$300.6 million as of June 30, 2018 compared to \$324.3 million as of December 31, 2017, for a decrease of \$23.7 million. The decrease primarily relates to operating cash outflow for clinical and manufacturing related expenses, as well as personnel costs.
- Research and development expenses were \$10.6 million for the three months ended June 30, 2018, as compared to \$7.2 million for the three months ended June 30, 2017. The increase was primarily due to continued advancement of the Company's ANB020 and ANB019 clinical programs and additional personnel-related expenses, including share based compensation, as well as the recognition of lower research and development tax incentives during the three months ended June 30, 2018.
- General and administrative expenses were \$3.8 million for the three months ended June 30, 2018, as compared to \$2.4 million for the three months ended June 30, 2017. The increase was primarily attributable to additional personnel-related expenses, including share based compensation, to support the Company's growth.

Financial Guidance

AnaptysBio expects that its cash, cash equivalents and investments will fund its current operating plan through the end of 2019.

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 we believe is broadly applicable to the treatment of atopic inflammatory disorders, such as moderate-to-severe adult atopic dermatitis, severe adult eosinophilic asthma, adult CRSwNP and potentially other allergic conditions. Following completion of a healthy volunteer Phase 1 trial of etokimab, AnaptysBio has continued clinical development of etokimab into a Phase 2a trial for moderate-to-severe adult atopic dermatitis 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 is enrolling its ATLAS trial, a 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. AnaptysBio also plans to initiate its ECLIPSE trial, a randomized, 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.

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 palmoplantar pustulosis (PPP). AnaptysBio conducted a Phase 1 clinical trial in healthy volunteers, where 54 subjects are dosed with ANB019 and 18 are dosed with placebo in single and multi-dose cohorts at various subcutaneous and intravenously administered dose levels. In May 2018, AnaptysBio presented data from this Phase 1 clinical trial, which demonstrated favorable safety, pharmacokinetics and pharmacodynamic properties that support advancement of ANB019 into Phase 2 studies. AnaptysBio is enrolling its GALLOP trial, a Phase 2 study of ANB019 in GPP where data is anticipated in early 2019, and plans to initiate its POPLAR trial, a Phase 2 study in PPP in 2018 where data is anticipated in the second half of 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 adult atopic dermatitis, severe adult eosinophilic asthma, adult chronic rhinosinusitis with nasal polyps; 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 palmoplantar pustular psoriasis; and novel anti-inflammatory checkpoint receptor modulator antibodies for 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 etokimab's Phase 2a trial in severe adult eosinophilic asthma patients, and Phase 2b clinical trial in moderate-to-severe adult atopic dermatitis patients and ANB019's Phase 2 in GPP and PPP, our ability to launch a Phase 2b clinical trial of etokimab in moderate-to-severe adult atopic dermatitis patients, Phase 2 trial in adult chronic rhinosinusitis with nasal polyps patients and Phase 2 clinical trial of etokimab in adults patients with chronic rhinosinusitis with nasal polyps; 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.

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ANAPTYSBIO, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except par value data)

| | <u>June 30, 2018</u> | <u>December 31, 2017</u> |
|---|--------------------------|------------------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 57,057 | \$ 81,189 |
| Australian tax incentive receivable | 152 | 1,601 |
| Short-term investments | 210,852 | 167,218 |
| Prepaid expenses and other current assets | 3,758 | 2,688 |
| Total current assets | <u>271,819</u> | <u>252,696</u> |
| Property and equipment, net | 1,086 | 665 |
| Long-term investments | 32,730 | 75,897 |
| Other long-term assets | 322 | 46 |
| Restricted cash | 60 | 60 |
| Total assets | <u>\$ 306,017</u> | <u>\$ 329,364</u> |
| LIABILITIES, PREFERRED STOCK AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 4,426 | \$ 2,323 |
| Accrued expenses | 4,837 | 4,875 |
| Notes payable, current portion | 7,500 | 6,875 |
| Other current liabilities | 27 | 17 |
| Total current liabilities | <u>16,790</u> | <u>14,090</u> |
| Notes payable, net of current portion | 4,120 | 7,553 |
| Deferred rent | 128 | 140 |
| Preferred stock, \$0.001 par value, 10,000 shares authorized and no shares, issued or outstanding at June 30, 2018 and December 31, 2017, respectively | — | — |
| Common stock, \$0.001 par value, 500,000 shares authorized, 24,029 shares and 23,791 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively | 24 | 24 |
| Additional paid in capital | 399,370 | 393,017 |
| Accumulated other comprehensive loss | (677) | (426) |
| Accumulated deficit | (113,738) | (85,034) |
| Total stockholders' equity | <u>284,979</u> | <u>307,581</u> |
| Total liabilities, preferred stock and stockholders' equity | <u>\$ 306,017</u> | <u>\$ 329,364</u> |

ANAPTYSBIO, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except per share data)
(unaudited)

| | <u>Three Months Ended June 30,</u> | | <u>Six Months Ended June 30,</u> | |
|-----------------------|--|-------------|--------------------------------------|-------------|
| | <u>2018</u> | <u>2017</u> | <u>2018</u> | <u>2017</u> |
| Collaboration revenue | \$ — | \$ 7,000 | \$ — | \$ 7,000 |

| | | | | |
|--|--------------------|-------------------|--------------------|--------------------|
| Operating expenses: | | | | |
| Research and development | 10,583 | 7,205 | 22,393 | 15,140 |
| General and administrative | 3,832 | 2,350 | 7,779 | 4,403 |
| Total operating expenses | <u>14,415</u> | <u>9,555</u> | <u>30,172</u> | <u>19,543</u> |
| Loss from operations | <u>(14,415)</u> | <u>(2,555)</u> | <u>(30,172)</u> | <u>(12,543)</u> |
| Other income (expense), net | | | | |
| Interest expense | (436) | (439) | (887) | (867) |
| Change in fair value of liability for preferred stock warrants | — | — | — | (1,366) |
| Interest income | 1,297 | 281 | 2,482 | 404 |
| Other income (expense), net | (64) | 29 | (127) | 253 |
| Total other income (expense), net | <u>797</u> | <u>(129)</u> | <u>1,468</u> | <u>(1,576)</u> |
| Net loss | (13,618) | (2,684) | (28,704) | (14,119) |
| Unrealized income (loss) on available for sale securities | 124 | (46) | (250) | (59) |
| Other comprehensive income (loss) | <u>124</u> | <u>(46)</u> | <u>(250)</u> | <u>(59)</u> |
| Comprehensive loss | <u>\$ (13,494)</u> | <u>\$ (2,730)</u> | <u>\$ (28,954)</u> | <u>\$ (14,178)</u> |
| Net loss per common share: | | | | |
| Basic and diluted | <u>\$ (0.57)</u> | <u>\$ (0.13)</u> | <u>\$ (1.20)</u> | <u>\$ (0.79)</u> |
| Weighted-average number of shares outstanding: | | | | |
| Basic and diluted | <u>23,932</u> | <u>20,271</u> | <u>23,867</u> | <u>17,797</u> |



Source: AnaptysBio, Inc.