AnaptysBio Announces Third Quarter 2020 Financial Results and Provides Pipeline Updates

November 4, 2020

- Positive topline data from GALLOP Phase 2 clinical trial of imsidolimab in moderate to severe Generalized Pustular Psoriasis (GPP) announced in October 2020
- FDA end-of-Phase 2 meeting anticipated in Q4 2020 to outline registration path of imsidolimab for the treatment of GPP, in accordance with the orphan drug designation obtained in July 2020
- POPLAR Phase 2 clinical trial of imsidolimab monotherapy in palmoplantar pustulosis (PPP) fully enrolled and topline data anticipated in Q1 2021
- Expansion of imsidolimab program into two new clinical indications, EGFRi-mediated skin toxicities and ichthyosis, with Phase 2 trials to be initiated in Q4 2020
- US BLA approval for dostarlimab, our PD-1 antagonist antibody partnered with GlaxoSmithKline (GSK), anticipated for endometrial cancer in Q4 2020, resulting in payment of $20 million of the $75 million in FDA BLA and EMA MAA regulatory milestone payments anticipated in upcoming 18 months
- Amended strategic immuno-oncology collaboration with GlaxoSmithKline to increase dostarlimab royalties, add Zejula™ royalty effective January 2021 and receive additional $60 million cash in Q4 2020

SAN DIEGO, Nov. 04, 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 immuno-oncology indications, today reported operating results for the third quarter ended September 30, 2020 and provided pipeline updates.

“We are excited with the recent interim results from our GALLOP trial and look forward to engaging with regulatory authorities to progress imsidolimab into registration trials for the treatment of GPP,” said Hamza Suria, president and chief executive officer of AnaptysBio. “Under our amended immuno-oncology collaboration with GSK, we look forward to the anticipated first FDA approval of dostarlimab and its advancement for patients suffering with various oncological disorders.”

Imsidolimab (Anti-IL-36 Receptor) Program

- In July, we announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation for imsidolimab, our proprietary anti-interleukin-36 receptor (IL-36R) antibody, for the treatment of patients with GPP. Treatment of GPP by imsidolimab is being evaluated in the GALLOP Phase 2 trial.
- Patients demonstrated rapid onset, overall safety and promising efficacy upon imsidolimab monotherapy in a Day 29 interim analysis of our GALLOP Phase 2 GPP trial. Six of 8 patients achieved the primary endpoint of disease improvement upon Day 29, while erythema with skin pustules, which clinically defines GPP, decreased by 94% on Day 29 relative to baseline.
- An end-of-Phase 2 meeting, based upon data available from the 8 patients enrolled in the GALLOP trial, is anticipated in Q4 2020.
- We are also conducting a randomized, placebo-controlled, multi-dose Phase 2 trial in approximately 50 patients with palmoplantar pustulosis, or PPP, also known as the POPLAR trial, which is now fully enrolled with topline data anticipated in Q1 2021.
- We anticipate expanding the imsidolimab program in two new indications, EGFR-mediated skin toxicities and ichthyosis, based upon human translational data that suggests each of these conditions are mediated by dysregulated signaling through the IL-36 pathway. Initiation of Phase 2 trials for each of these indications is anticipated in Q4 2020.
- Worldwide registry of GPP and PPP patients, named RADIANCE, to be initiated in Q1 2021, to improve understanding of the patient journey and support enrollment of future trials.

ANB030 (Anti-PD-1 Agonist) Program

- We anticipate topline data from our ongoing Phase 1 healthy volunteer clinical trial of ANB030, our wholly-owned PD-1 agonist antibody, designed to assess the safety, pharmacokinetics and pharmacodynamics of ANB030 in single and multiple ascending dose cohorts in mid-2021. Preclinical translational data using ANB030 was presented in March 2020 at the Festival of Biologics Meeting.

ANB032 (Anti-BTLA Modulator) Program

- We anticipate filing an investigational new drug application (IND) for ANB032, our wholly-owned BTLA modulator antibody, in Q4 2020. We presented preclinical data regarding ANB032 at the 2020 Federation of Clinical Immunology Societies (FOCIS) Virtual Annual Meeting in October 2020.

Etokimab (ANB020 Anti-IL-33) Program

- In an interim analysis at week 8 of the ongoing ECLIPSE Phase 2 trial of etokimab in chronic rhinosinusitis with nasal polyps, 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 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. We intend to decide on a path forward for the etokimab program after reviewing week 16 primary endpoint data by year-end 2020.

Dostarlimab (Anti-PD-1 Antagonist) Program Partnered with GSK

- In October 2020, we amended our immuno-oncology collaboration with GSK resulting in increased financial consideration to AnaptysBio. Royalties due to AnaptysBio for dostarlimab were increased to 8-25% of global net sales, where AnaptysBio will receive 8% of annual global net sales below $1 billion, and 12-25% of net sales above $1 billion. The $1.1 billion in cash milestone payments due under the collaboration agreement remain unchanged, and AnaptysBio anticipates receiving $75 million in such cash milestones over the next 18 months as dostarlimab obtains FDA and EMA regulatory approval for the first two indications. An additional $165 million in sales milestones is anticipated by AnaptysBio upon achievement of certain dostarlimab annual sales revenues. GSK has also agreed, starting January 1, 2021, to pay AnaptysBio a 1% royalty on all of GSK's global net sales of Zejula™. In addition, GSK has agreed to pay AnaptysBio a one-time cash payment of $60 million within 30 days. In exchange, AnaptysBio has provided GSK with freedom to conduct development and commercialization of Zejula™ in combination with third-party molecules and settled the ongoing legal dispute between AnaptysBio and GSK.

Third Quarter Financial Results

Cash, cash equivalents and investments totaled $374.5 million as of September 30, 2020 compared to $428.5 million as of December 31, 2019, for a decrease of $54.0 million. The decrease relates primarily to cash used for operating activities.

Collaboration revenue was zero and $15.0 million for the three and nine months ended September,30 2020, which related to milestone payments for successful BLA and MAA filings for dostarlimab by GSK, compared to zero and $5 million for the three and nine months ended September 30, 2019.

Research and development expenses were $19.5 million and $58.5 million for the three and nine months ended September 30, 2020, compared to $29.9 million and $77.9 million for the three and nine months ended September 30, 2019. The decrease was due primarily to reduced outside services for manufacturing and clinical expenses based on the timing of projects.

General and administrative expenses were $4.8 million and $13.8 million for the three and nine months ended September 30, 2020, compared to $3.8 million and $12.3 million for the three and nine months ended September 30, 2019. The increase was due primarily to increased legal and insurance expenses.

Net loss was $23.8 million and $53.6 million for the three and nine months ended September 30, 2020, or a net loss per share of $0.87 and $1.96, compared to a net loss of $31.0 million and $77.1 million for the three and nine months ended September 30, 2019, or a net loss per share of $1.15 and $2.85.

Financial Guidance
AnaptysBio expects its net cash burn in 2020 will be close to breakeven assuming the $20 million milestone payment upon first FDA approval of dostarlimab is received by year-end. We anticipate that our cash, cash equivalents and anticipated revenues will fund our current operating plan at least into 2023.

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-36R antibody imsidolimab, previously referred to as ANB019, for the treatment of rare inflammatory diseases, including generalized pustular psoriasis, or GPP, palmoplantar pustulosis, or PPP, EGFRi and ichthyosis; its anti-PD-1 agonist program, ANB030, for treatment of certain autoimmune diseases where immune checkpoint receptors are insufficiently activated; its BTLA modulator program, ANB032, which is broadly applicable to human inflammatory diseases

associated with lymphoid and myeloid immune cell dysregulation; and 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. 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 imsidolimab's Phase 2 clinical trial in PPP; the timing of initiation of imsidolimab's Phase 2 clinical trials in EGFRi and ichthyosis; and etokimab's week 16 data for the ECLIPSE Phase 2 clinical trial in chronic rhinosinusitis with nasal polyps; the timing of an end-of-Phase 2 meeting with the FDA for GPP; the timing of an IND filing for ANB032; the milestones and royalty payments to be received under the GSK collaboration; and our projected 2020 cash burn and cash runway. 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)

	September 30, 2020	December 31, 2019
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 209,154	$ 171,017
Short-term investments	129,192	203,210
Prepaid expenses and other current assets	7,468	3,506
Total current assets	345,814	377,733
Property and equipment, net	1,585	1,618
Long-term investments	36,177	54,305
Other long-term assets	1,114	1,481
Restricted cash	60	60
Total assets	$ 384,750	$ 435,197
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,484	$ 16,237
Accrued expenses	18,139	11,052
Notes payable, current portion	—	1,375
Other current liabilities	851	871
Total current liabilities	24,474	29,535
Other long-term liabilities	33	654

Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000 shares authorized and no shares, issued or outstanding at September 30, 2020 and December 31, 2019, respectively	—	—
Common stock, $0.001 par value, 500,000 shares authorized, 27,346 shares and 27,255 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	27	27
Additional paid-in capital	657,560	648,669
Accumulated other comprehensive income	259	338
Accumulated deficit	(297,603)	(244,026)
Total stockholders' equity	360,243	405,008
Total liabilities and stockholders' equity	$ 384,750	$ 435,197

AnaptysBio, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Collaboration revenue	$ —	$ —	$ 15,000	$ 5,000
Operating expenses:				
Research and development	19,542	29,931	58,458	77,912
General and administrative	4,794	3,814	13,766	12,262
Total operating expenses	24,336	33,745	72,224	90,174
Loss from operations	(24,336)	(33,745)	(57,224)	(85,174)
Other income (expense), net:				
Interest expense	—	(240)	—	(841)
Interest income	625	2,757	3,583	8,702
Other (expense) income, net	(56)	144	64	110
Total other income (expense), net	569	2,661	3,647	7,971
Loss before income taxes	(23,767)	(31,084)	(53,577)	(77,203)
Provision for income taxes	—	51	—	130
Net loss	(23,767)	(31,033)	(53,577)	(77,073)
Other comprehensive (loss) income:				
Unrealized (loss) income on available for sale securities, net of tax of $0, ($25), $0 and $189, respectively	(494)	(94)	(79)	703
Comprehensive loss	$ (24,261)	$ (31,127)	$ (53,656)	$ (76,370)
Net loss per common share:				
Basic and diluted	$ (0.87)	$ (1.15)	$ (1.96)	$ (2.85)
Weighted-average number of shares outstanding:				
Basic and diluted	27,316	27,058	27,286	27,022

Source: AnaptysBio, Inc.