AnaptysBio Announces First Quarter 2021 Financial Results and Provides Pipeline Updates

May 4, 2021

- Imsidolimab Phase 3 GPP trial anticipated to commence in mid-2021 following FDA end-of-Phase 2 meeting held during Q2 2021
- JEMPERLI (dostarlimab), our PD-1 antagonist antibody partnered with GlaxoSmithKline (GSK), was approved for endometrial cancer in the US and EU during Q2 2021, earning $30 million in cash milestones and 8-25% royalties, plus Zejula (niraparib) 1% royalty revenue earned starting January 2021
- Expanded imsidolimab clinical development program with initiation of Phase 2 trials in acne and hidradenitis suppurativa, with top-line data readouts anticipated in H1 2022 and H2 2022, respectively
- Top-line data from POPLAR phase 2 clinical trial of imsidolimab monotherapy in palmoplantar pustulosis (PPP), disclosed in Q1 2021, failed to meet primary endpoint
- Ongoing healthy volunteer Phase 1 trial with ANB030, with top-line data anticipated in H2 2021 and initiation of Phase 2 clinical trials in alopecia areata and vitiligo in Q4 2021
- Achievement of first-in-human dosing of ANB032 with healthy volunteer Phase 1 top-line data anticipated in H1 2022

SAN DIEGO, May 04, 2021 (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 first quarter ended March 31, 2021 and provided pipeline updates.

“We look forward to advancing imsidolimab into a Phase 3 trial for GPP following our recent end-of-Phase 2 meeting with the FDA,” said Hamza Suria, president and chief executive officer of AnaptysBio. “AnaptysBio continues to pursue a capital-efficient business model where partnership revenues continue to support advancement of our wholly-owned pipeline poised to generate multiple clinical data catalysts through 2021 and 2022.”

Imsidolimab (Anti-IL-36 Receptor) Program

- We held an end-of-Phase 2 meeting with the FDA during Q2 2021 to review an orphan disease Phase 3 development plan for imsidolimab for the treatment of GPP and anticipate announcing key aspects of our Phase 3 trial design upon its initiation in mid-2021. Our worldwide registry of GPP patients, named RADIANCE, is ongoing, and we expect that this study will improve our understanding of the patient journey and support enrollment of our Phase 3 clinical trial. While initial GPP epidemiology studies suggested at least 3,000 GPP patients in the United States, medical claims analyses conducted by IQVIA indicate approximately 37,000 unique patients were diagnosed with GPP at least once, and approximately 15,000 unique patients were diagnosed with GPP at least twice, by a physician between 2017 and 2019 using the International Classification of Diseases 10th Revision (ICD-10) billing code pertaining to GPP (L40.1).

- We initiated a Phase 2 clinical trial of imsidolimab in hidradenitis suppurativa, named HARP, where 120-patients are randomized equally between two dose levels of imsidolimab and placebo, and top-line data is anticipated in H2 2022. We also commenced an imsidolimab Phase 2 trial in moderate-to-severe acne, named ACORN, where 120-patients are randomized equally between two dose levels of imsidolimab and placebo, and top-line data is anticipated in H1 2022. We continue to anticipate top-line data at the end of 2021 from our EMERGE Phase 2 trial of imsidolimab in EGFR/MEK-mediated skin toxicities and top-line data from our Phase 2 INSPIRE trial in ichthyosis during 2022.

- We announced in Q1 2021 top-line data from our POPLAR phase 2 clinical trial of imsidolimab monotherapy in PPP, which failed to meet the trial’s primary endpoint. While we continue to review secondary endpoints to further understand the activity of imsidolimab in various PPP patient subsets, we do not currently plan to pursue further clinical development of imsidolimab in PPP.

ANB030 (Anti-PD-1 Agonist) Program

- We anticipate top-line data in H2 2021 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.

- We plan to initiate Phase 2 clinical trials of ANB030 in alopecia areata and vitiligo in Q4 2021.

- Preclinical translational data using ANB030 was presented in March 2020 at the Festival of Biologics Meeting.

ANB032 (Anti-BTLA Modulator) Program

- We achieved first-in-human dosing of ANB032, our wholly-owned BTLA modulator antibody, upon initiation of a healthy volunteer Phase 1 trial in the first quarter of 2021, under an Australian Clinical Trial Notification (CTN), and anticipate top-line data from this trial during the first half of 2022.

- We presented preclinical data regarding ANB032 at the 2020 Federation of Clinical Immunology Societies (FOCIS) Virtual Annual Meeting in October 2020.

GSK Partnered Programs

- A BLA for our most advanced partnered program, which is an anti-PD-1 antagonist antibody called JEMPERLI (dostarlimab), was approved by the FDA in April 2021 for the treatment of advanced or recurrent deficient mismatch repair endometrial cancer (dMMREC). This is the first AnaptysBio-generated antibody, of eight currently under clinical development, to obtain FDA approval. We earned a $20.0 million milestone payment as a result of this FDA approval.

- In April 2021 the European Medicines Agency (EMA) granted conditional marketing authorization in the European Union for JEMPERLI for use in women with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) recurrent or advanced endometrial cancer who have progressed on or following prior treatment with a platinum containing regimen, which approval makes JEMPERLI the first anti-PD-1 therapy available for endometrial cancer in Europe. We earned a $10.0 million milestone payment as a result of this approval.

- A second BLA submitted by GSK was accepted by the FDA during the first quarter of 2021 for JEMPERLI in pan-deficient mismatch repair tumors (PdMMRT). We received a $10.0 million cash milestone payment upon the FDA acceptance of GSK's second FDA BLA for JEMPERLI and anticipate an additional $20.0 million cash milestone payment upon FDA approval of this second FDA BLA of JEMPERLI during the second half of 2021. We anticipate an additional $15.0 million and $165.0 million in milestone payments upon achievement of certain JEMPERLI regulatory and commercial milestones, respectively.

- During Q1 2021, we recognized $1.2 million in royalty revenue related to GSK's Zejula product sales, which we estimated based on GSK's historical sales. In October 2020, we amended our GSK collaboration which resulted in increased royalties on global net sales of JEMPERLI to 8-25%, a 1% royalty rate on GSK's global net sales of Zejula and a one-time cash payment of $60.0 million.

First Quarter Financial Results

- Cash, cash equivalents and investments totaled $387.4 million as of March 31, 2021 compared to $411.2 million as of December 31, 2020, for a decrease of $23.8 million. The decrease relates primarily to cash used for operating activities.

- Collaboration revenue was $11.2 million for the three months ended March 31, 2021, $10.0 million related to milestone revenue for the FDA accepted BLA filing of the second dostarlimab indication and $1.2 million related to royalties on GSK's Zejula product sales, compared to $15.0 million of milestone revenue for the three months ended March 31, 2020.

- Research and development expenses were $24.2 million for the three months ended March 31, 2021, compared to $21.0 million for the three months ended March 31, 2020. The increase was due primarily to continued advancement of the Company's clinical programs.

- General and administrative expenses were $5.4 million for the three months ended March 31, 2021, compared to $4.3 million for the three months ended March 31, 2020. The increase was due primarily to personnel-related expenses, including share-based compensation.

- Net loss was $18.2 million for the three months ended March 31, 2021, or a net loss per share of $0.66, compared to a net loss of $8.3 million for the three months ended March 31, 2020, or a net loss per share of $0.30.

Financial Guidance

AnaptysBio expects its net cash burn in 2021 will be close to $100 million. We anticipate that our cash, cash equivalents and anticipated revenues will fund our current operating plan at least into 2024.

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 imsidolimab, its anti-IL-36R antibody, previously referred to as ANB019, for the treatment of dermatological inflammatory diseases, including generalized pustular psoriasis, or GPP, EGFRi skin toxicity, ichthyosis, hidradenitis suppurativa and acne; 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 GSK, including an anti-PD-1 antagonist antibody (JEMPERLI (dostarlimab-gxly)), an anti-TIM-3 antagonist antibody (cobolimab, GSK4069889) 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 trials in EGFRi, ichthyosis, hidradenitis suppurativa and acne, ANB030's Phase 2 clinical trials in alopecia areata and vitiligo, and ANB032's healthy volunteer Phase 1 trial; the timing of announcement of key aspects of imsidolimab's GPP Phase 3 clinical trial design and initiation of the trial; the milestones and royalty payments to be received under the GSK collaboration; and our projected 2021 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)
(unaudited)

	March 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 284,148	$ 250,456
Receivable from collaborative partners	1,247	—
Short-term investments	96,212	143,197
Prepaid expenses and other current assets	5,464	2,908
Restricted cash	60	—
Total current assets	387,131	396,561
Property and equipment, net	1,754	1,783
Long-term investments	7,056	17,546
Other long-term assets	477	602
Restricted cash	—	60
Total assets	$ 396,418	$ 416,552
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,452	$ 4,217
Accrued expenses	11,826	15,262
Other current liabilities	197	342
Total current liabilities	14,475	19,821

Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000 shares authorized and no shares, issued or outstanding at March 31, 2021 and December 31, 2020, respectively	—	—
Common stock, $0.001 par value, 500,000 shares authorized, 27,367 shares and 27,356 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	27	27
Additional paid in capital	664,147	660,665
Accumulated other comprehensive loss	(111)	(4)
Accumulated deficit	(282,120)	(263,957)
Total stockholders' equity	381,943	396,731
Total liabilities and stockholders' equity	$ 396,418	$ 416,552

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

	Three Months Ended March 31,	
	2021	**2020**
Collaboration revenue	$ 11,247	$ 15,000
Operating expenses:		
Research and development	24,185	20,968
General and administrative	5,423	4,285
Total operating expenses	29,608	25,253
Loss from operations	(18,361)	(10,253)
Other income, net:		
Interest income	195	1,897
Other income, net	3	94
Total other income, net	198	1,991
Net loss	(18,163)	(8,262)
Unrealized (loss) income on available for sale securities	(107)	807
Comprehensive loss	$ (18,270)	$ (7,455)
Net loss per common share:		
Basic and diluted	$ (0.66)	$ (0.30)
Weighted-average number of shares outstanding:		
Basic and diluted	27,361	27,264

Source: AnaptysBio, Inc.