AnaptysBio Reports Imsidolimab ACORN Phase 2 Clinical Trial Data in Moderate-to-Severe Acne

March 14, 2022

- Imsidolimab (anti-IL-36R Ab) treatment did not demonstrate improvement over placebo in top-line primary or secondary endpoints
- AnaptysBio to discontinue imsidolimab clinical development in acne
- Imsidolimab was generally safe, well tolerated and no imsidolimab-related serious or severe adverse events were reported
- Enrollment ongoing in imsidolimab GEMINI-1 GPP Phase 3 trial and top-line data from HARP Phase 2 trial in moderate-to-severe hidradenitis suppurativa anticipated in H2 2022
- Rosnilimab (anti-PD-1 agonist Ab) AZURE Phase 2 moderate-to-severe alopecia areata enrollment ongoing and ANB032 (anti-BTLA modulator Ab) Phase 1 healthy volunteer top-line data anticipated in Q2 2022
- Continue to operate in a capital-efficient manner with approximately $615 million in cash at end 2021 and anticipated 2022 net cash burn of $90 to $100 million

SAN DIEGO, March 14, 2022 (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 announced that top-line data from its Phase 2 clinical trial of imsidolimab for the treatment of moderate-to-severe acne, also known as the ACORN trial, did not demonstrate efficacy over placebo on primary or secondary endpoints.

AnaptysBio continues to advance three wholly-owned pipeline programs through clinical development. While clinical development is being discontinued in acne, imsidolimab demonstrated efficacy and safety in the GALLOP Phase 2 trial in generalized pustular psoriasis (GPP) and enrollment of the GEMINI-1 GPP Phase 3 trial is ongoing and top-line data from the imsidolimab HARP Phase 2 trial in moderate-to-severe hidradenitis suppurativa is anticipated during the second half of 2022. Beyond imsidolimab, enrollment is ongoing in the AZURE Phase 2 trial of rosnilimab, a PD-1 agonist antibody, in moderate-to-severe alopecia areata and healthy volunteer Phase 1 top-line data for ANB032, a BTLA modulator antibody, is anticipated in the second quarter of 2022.

“Although the results of this ACORN trial are disappointing, I would like to thank all of the patients, investigators, staff and our employees involved in conducting this trial,” said Hamza Suria, AnaptysBio’s president and chief executive officer. “We look forward to further advancement of imsidolimab for the treatment of GPP and hidradenitis suppurativa. AnaptysBio continues to utilize its strong cash position in a capital-efficient manner to advance three wholly-owned clinical-stage programs with $90 to $100 million anticipated net cash burn in 2022.”

ACORN Trial Data
Top-line data from the ACORN trial are as follows:

- Mean baseline facial inflammatory lesion counts for the imsidolimab high dose arm, the imsidolimab low dose arm and placebo arm were 30, 29 and 27, respectively. Each arm had an average baseline facial investigator global assessment (IGA) score of 3.1. Patients were on average 20 years of age and 65% were female.
- Imsidolimab was generally safe, well tolerated and no treatment-related severe or serious adverse events were observed (Table 1). Treatment-emergent adverse events (TEAEs) in both imsidolimab arms resolved without leading to treatment discontinuation and TEAE timing did not correlate with dosing. The most common TEAEs observed across imsidolimab and placebo dosed patients were COVID diagnoses and upper respiratory tract infections (URTI), which were deemed unrelated to treatment. Three patients were diagnosed with treatment-unrelated COVID and three patients reported treatment-unrelated URTIs in the imsidolimab high dose arm, while one instance of each were reported in the imsidolimab low dose arm. The placebo arm reported five patients with COVID diagnoses, of which one also reported a URTI, which were all treatment-unrelated. Severe TEAEs included one patient with treatment-unrelated URTI in the imsidolimab high dose arm, one patient with treatment-unrelated oropharyngeal pain and associated fatigue in the imsidolimab low dose arm and one patient in the placebo arm with treatment-unrelated severe COVID diagnosis. Fallopian tube cyst and associated pelvic pain were reported as treatment-unrelated serious TEAEs in one imsidolimab high dose patient. One placebo-dosed patient discontinued treatment due to proteinuria.

Number of Patients Reporting	Imsidolimab High Dose Arm	Imsidolimab Low Dose Arm	Placebo
At least one TEAE	44%	23%	27%
Severe TEAE	1	1	1

Treatment-related severe TEAE	0	0	0
Serious TEAE	1	0	0
Treatment-related serious TEAE	0	0	0
TEAE leading to treatment discontinuation	0	0	1

Table 1. Summary of reported treatment-emergent adverse events (TEAEs).

- The primary endpoint of facial inflammatory lesion count change from baseline at week 12 was -6.8 (-27%) for the imsidolimab high dose arm, -7.4 (-21%) for the imsidolimab low dose arm and -9.6 (-38%) for the placebo arm (Table 2). Facial IGA of clear (zero) or almost clear (1) with at least a 2-point decrease from baseline, a secondary endpoint, was achieved at week 12 by 12% of patients in the imsidolimab high dose arm, 0% of the patients in the imsidolimab low dose arm and 14% of patients in the placebo arm.

Facial Inflammatory Lesion Count Percent Change From Baseline	Imsidolimab High Dose Arm	Imsidolimab Low Dose Arm	Placebo
Week 2	-7%	-2%	-14%
Week 4	-3%	-14%	-29%
Week 8	-22%	-20%	-28%
Week 12	-27%	-21%	-38%

Table 2. Percent change from baseline of facial inflammatory lesion count at multiple timepoints.

ACORN Phase 2 Trial Design

One hundred and twenty-three moderate-to-severe acne patients were enrolled in this trial at 15 sites located within the USA. Patients were washed out of prior therapy and no concomitant therapy was permitted during the trial. Key inclusion criteria included age between 12 and 45 years, clinically confirmed ongoing moderate-to-severe acne with minimum facial IGA score of at least 3 (moderate), at least 20 inflammatory facial lesions and no more than 5 nodules present upon enrollment. Patients in the imsidolimab high dose arm were treated with a 400mg subcutaneous induction dose at Day 1, followed by monthly 200mg subcutaneous doses at weeks 4 and 8, while the imsidolimab low dose arm was treated with a 200mg subcutaneous induction dose and monthly 100mg subcutaneous doses. The primary endpoint of this trial was mean change in facial inflammatory lesion count at week 12 relative to baseline. Baseline clinical assessments were conducted for each patient at screening and on Day 1 prior to imsidolimab dosing. Missing data was modeled using mixed model for repeated measures (MMRM) methodology.

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, and moderate-to-severe hidradenitis suppurativa; rosnilimab, its anti-PD-1 agonist program, previously referred to as ANB030, for the treatment of moderate-to-severe alopecia areata; 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) GSK4057190), 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 trial in hidradenitis suppurativa, rosnilimab's Phase 2 clinical trial in alopecia areata, and ANB032's healthy volunteer Phase 1 trial; and our projected 2022 cash burn. 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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