AnaptysBio Reports HARP Phase 2 Top-Line Data of Imsidolimab in Moderate-to-Severe Hidradenitis Suppurativa

August 31, 2022

- Imsidolimab (anti-IL-36 receptor antagonist) did not demonstrate improvement over placebo in the primary endpoint and key secondary endpoints
- Imsidolimab was safe and well tolerated with no imsidolimab-related serious or severe adverse events reported
- Company to discontinue imsidolimab clinical development in hidradenitis suppurativa
- Enrollment ongoing in the imsidolimab GEMINI-1 GPP Phase 3 registrational trial with top-line data anticipated Q4 2023 and the company plans to outlicense imsidolimab prior to potential FDA approval
- Company to focus R&D efforts on its novel immune cell modulator pipeline, including its two checkpoint agonists in clinical-stage development, rosnilimab and ANB032

SAN DIEGO, Aug. 31, 2022 (GLOBE NEWSWIRE) -- AnaptysBio, Inc. (Nasdaq: ANAB), a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics, today announced top-line data from its HARP Phase 2 trial for the treatment of moderate-to-severe hidradenitis suppurativa (HS). The trial indicated imsidolimab was safe and well tolerated, however did not demonstrate efficacy over placebo in the trial's primary endpoint and key secondary endpoints. Clinical development of imsidolimab is being discontinued in hidradenitis suppurativa.

"HS is a severely debilitating, painful and chronic skin disease with substantial unmet need. Although the results of this hidradenitis suppurativa trial are disappointing, we are very grateful to the patients, investigators and our employees involved in conducting this trial," said Dr. Paul F. Lizzul, chief medical officer.

Imsidolimab previously demonstrated efficacy and safety in the GALLOP Phase 2 trial in generalized pustular psoriasis (GPP), a systemic, life-threatening inflammatory disease in which imsidolimab has been granted Orphan Disease Designation. Enrollment of the GEMINI-1 GPP Phase 3 registrational trial is ongoing and top-line data is anticipated in Q4 2023. The company plans to outlicense investigational imsidolimab prior to potential FDA approval for the treatment of GPP.

AnaptysBio also continues to advance the development of two wholly-owned immune cell modulators targeting PD-1 and BTLA for autoimmune and inflammatory disease. Top-line data from the AZURE Phase 2 trial of rosnilimab, a PD-1 agonist antibody, in moderate-to-severe alopecia areata is anticipated in the first quarter of 2023, and the company expects to file a U.S. IND for an initial Phase 2 trial of ANB032, a BTLA agonist antibody, in the fourth quarter of 2022.

"The IL-36 pathway plays a key role in the disease pathology of GPP. While we remain optimistic that imsidolimab, an IL-36 receptor antagonist, can meaningfully impact the treatment of patients with GPP, as part of our ongoing strategic portfolio review we have made the decision to complete execution of our Phase 3 program and outlicense imsidolimab prior to potential FDA approval," said Daniel Faga, interim president and chief executive officer of AnaptysBio. "We're well capitalized with over $570 million in cash at the end of Q2, and excited to focus on the R&D of our novel immune cell modulator pipeline, including our two checkpoint agonists in clinical-stage development, rosnilimab and ANB032. We believe their mechanisms of action, acting directly on cell types mediating disease pathology, have the potential to treat a broad range of autoimmune and inflammatory disorders."

HARP P2b Trial Top-line Results

Trial design:

- This double-blind, placebo-controlled Phase 2 trial enrolled 149 patients, at sites located within North America and Europe, with moderate to severe hidradenitis suppurativa. Key inclusion criteria included age between 18 and 75 years, clinically confirmed ongoing moderate-to-severe HS with at least 5 inflammatory nodule and abscess (AN) lesion count, less than 20 draining fistulas and at least Hurley stage 2.
- Patients received subcutaneous monthly doses of imsidolimab 400 mg/200mg (n=50), imsidolimab 200 mg/100mg (n=50), or placebo (n=49) in a 16-week treatment double-blind placebo-controlled period followed by a 16-week extension period. Placebo patients were re-randomized in a 1:1 ratio to imsidolimab 400 mg/200 mg or imsidolimab 200 mg/100 mg in the extension period.
- Mean baseline total inflammatory nodule and abscess (AN) lesion count for the imsidolimab high dose arm, the imsidolimab low dose arm and placebo arm were 14.0, 11.9 and 12.1, respectively. Mean baseline draining fistula count for high dose arm, low dose arm and placebo arms were 4.1, 2.7 and 3.1, respectively.

Safety and tolerability data:

- Imsidolimab was safe and well tolerated with no imsidolimab-related serious or severe adverse events reported.

- The majority of treatment-emergent adverse events (TEAEs), except for COVID-19, were related to underlying HS, were mild to moderate in both imsidolimab arms and resolved without leading to treatment discontinuation and number of TEAEs or TEAE timing did not correlate with dosing.
- The most common TEAEs observed across imsidolimab and placebo dosed patients were COVID-19 (n=10) and Hidradenitis (n=8), which were deemed unrelated to treatment.
- Serious TEAEs were observed in 6.1% (n=3) of placebo patients vs. 4.0 % (n=2) on imsidolimab low dose and 0 in the imsidolimab high dose. Two cases were COVID-19 that occurred in the imsidolimab low dose arm, and all other Serious TEAEs occurred in placebo arm, including right ring finger abscess, abortion spontaneous, and worsening HS.

Patients with:	**Imsidolimab High Dose**	**Imsidolimab Low Dose**	**Placebo**	**Overall**
At least 1 TEAE	38.0% (19)	28.0% (14)	34.7% (17)	33.6% (50)
AE related to treatment	12.0% (6)	10.0% (5)	6.1% (3)	9.4% (14)
AE related to COVID-19	8.0% (4)	6.0% (3)	6.1% (3)	6.7% (10)
AE related to Hidradenitis	2.0% (1)	6.0% (3)	8.2% (4)	5.4% (8)
Serious AE (SAE)	0	4.0% (2)	6.1% (3)	3.4% (5)
SAE related to treatment	0	0	0	0
Severe TEAE	0	2.0% (1)	8.2% (4)	3.4% (5)
Severe TEAE related to treatment	0	0	0	0

Efficacy data:

- The primary endpoint was mean change in AN lesion count from baseline at week 16.
- A secondary endpoint, the Hidradenitis Suppurativa Clinical Response (HiSCR) measure, was also assessed to measure improvement in HS. HiSCR50 is defined as at least 50 percent reduction from baseline AN lesion count and no increase for either abscess or draining fistula count at 16 weeks. HiSCR50 is the endpoint that has been utilized to date for evaluation of HS by regulatory agencies.

Endpoint at Week 16	**Imsidolimab**		**Placebo**	**Difference of Imsidolimab vs Placebo**	
	High Dose	**Low Dose**		**High Dose**	**Low Dose**
Mean AN Count Change from Baseline (SD)	-5.9 (6.05)	-4.1 (4.63)	-5.6 (7.40)	-0.3 (p=0.7841)	1.3 (p=0.2885)
Mean Percent AN Count Change from Baseline (SD)	-44.7 (39.23)	-36.7 (36.59)	-41.2 (43.69)	-4.8 (p=0.5939)	3.5 (p=0.7002)
HiSCR50 (%)	41.0	39.0	35.7	6.0 (p=0.5848)	3.4 (p=0.7522)

About AnaptysBio

AnaptysBio is a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics. We are developing immune cell modulators, including two checkpoint agonists in clinical-stage development, for autoimmune and inflammatory disease: rosnilimab, our anti-PD-1 agonist program in Phase 2 for the treatment of moderate-to-severe alopecia areata; and ANB032, our anti-BTLA agonist program, which is broadly applicable to human inflammatory diseases associated with lymphoid and myeloid immune cell dysregulation. AnaptysBio is also developing imsidolimab, our anti-IL-36R antibody in Phase 3 for the treatment of generalized pustular psoriasis, or GPP. AnaptysBio's antibody pipeline has been developed using our 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).

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 3 trial in GPP and rosnilimab's Phase 2 trial in alopecia areata; timing of an IND filing for ANB032; and our ability to complete, and timing with respect to, any outlicensing transaction with imsidolimab. 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 presentation, 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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