AnaptysBio Announces British Journal of Dermatology Publication of Imsidolimab (IL-36R) Previously Reported Phase 2 GALLOP Data in Generalized Pustular Psoriasis (GPP)

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- Rapid and sustained efficacy demonstrated in GPP patients after only a single dose, achieving primary endpoint at Week 4
- Flare control sustained on monthly subcutaneous doses through Week 16
- Imsidolimab was generally safe and well tolerated with low overall ADA incidence
- Top-line GEMINI-1 Phase 3 trial data expected in Q4 2023

SAN DIEGO, May 02, 2023 (GLOBE NEWSWIRE) -- AnaptysBio, Inc. (Nasdaq: ANAB), a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics, today announced the publication of data from the open-label, single-arm Phase 2 GALLOP study evaluating the efficacy, tolerability and safety of imsidolimab, its investigational anti-interleukin-36 receptor (IL-36R) IgG4 antibody for the treatment of generalized pustular psoriasis (GPP), in the *British Journal of Dermatology*. Patients with GPP who received a single dose of imsidolimab demonstrated a rapid and sustained improvement of symptoms and pustular eruptions of GPP flare within days after initiating treatment.

A potentially debilitating and life-threatening systemic inflammatory skin disease, GPP affects an estimated 15,000 to 37,000 individuals in the U.S. It is characterized by intermittent and/or recurrent episodes, or flares, of widespread pustular eruptions that can be accompanied by fever, nausea, pain, anorexia and general malaise.

“We remain excited and quite pleased with the dramatic effects demonstrated by imsidolimab’s Phase 2 efficacy and safety data and the potential benefit to patients suffering with life threatening inflammatory GPP,” said Paul F. Lizzul, chief medical officer of AnaptysBio. “We look forward to sharing the top-line data on the efficacy, safety and tolerability of a single dose IV infusion of imsidolimab in moderate-to-severe GPP patients from the ongoing GEMINI-1 Phase 3 trial in Q4 2023, whereafter we plan to out license the program prior to a potential FDA approval.”

In the Phase 2 GALLOP study, a total of eight adult patients with GPP flare were enrolled and received a 750mg IV dose of imsidolimab and six patients were evaluable at both Day 29 and Day 113 and who also completed the study. Clinical responses were observed as early as Day 3, most rapidly for pustulation relative to other visible manifestations of GPP, with continued and consistent improvement across multiple efficacy assessments at Day 8, Day 29, and through Day 113. Of the six patients evaluable on Day 29, all achieved the primary endpoint of clinical response on the clinical global impression scale (CGI). Additionally, the GPP Physician Global Assessment (GPPPGA) scale was implemented by protocol amendment during the trial and was assessed in four of the eight enrolled patients, where zero (clear) or one (almost clear) response was achieved in 50% (two) patients at Week 4. Six of eight patients received a monthly 100mg subcutaneous dose of imsidolimab beginning at Week 4 and continued through Week 12. At Week 16, 75% (three of four) of evaluable patients were responders (clear or almost clear) on the GPPPGA scale.

Imsidolimab was generally well-tolerated. Most treatment-emergent adverse events (TEAEs) were mild to moderate in severity. No patients discontinued the study due to a non-serious TEAE. Two patients experienced serious adverse events (SAEs) that recovered without sequelae. Through Week 16, anti-drug antibodies were detected in one patient, which occurred at Week 12 and did not impact imsidolimab pharmacokinetics, safety or efficacy.

Initial top-line Phase 2 study results were presented at European Academy of Dermatology and Venerology (EADV) Congress in October 2021.

GEMINI Phase 3 Studies

AnaptysBio is conducting two GPP Phase 3 trials for imsidolimab. The first, called GEMINI-1, will enroll approximately 45 moderate-to-severe GPP patients, each experiencing an active flare at baseline, who will be randomized equally to receive either a single dose of 750mg IV imsidolimab, 300mg IV imsidolimab or placebo. The primary endpoint of the Phase 3 program is the proportion of patients achieving clear or almost clear skin as determined by a GPPPGA score of zero or one at Week 4. Top-line data from an interim analysis of GEMINI-1 is anticipated in the fourth quarter of 2023.

Patients completing the GEMINI-1 trial can subsequently roll over into GEMINI-2, the second Phase 3 trial for imsidolimab in GPP, and will receive monthly doses of 200mg subcutaneous imsidolimab or placebo. The objective of GEMINI-2 is to assess the efficacy, durability of effect, recurrence of flare, and safety of imsidolimab during up to three years of monthly dosing.

The U.S. Food and Drug Administration granted Orphan Drug Designation to imsidolimab for the treatment of GPP in July 2020.

AnaptysBio announced in August 2022 that it intends to complete execution of the GEMINI Phase 3 GPP program and out license imsidolimab prior to potential FDA approval.

About AnaptysBio

AnaptysBio is a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics. It is developing immune cell modulators, including two checkpoint agonists in clinical-stage development, for autoimmune and inflammatory disease: rosnilimab, its PD-1 agonist, in a planned Phase 2b trial for the treatment of moderate-to-severe rheumatoid arthritis; and ANB032, its BTLA agonist, in a planned Phase 2b trial for the treatment of moderate-to-severe atopic dermatitis. Its preclinical immune cell modulator portfolio includes ANB033, an anti-CD122 antagonist antibody for the treatment of autoimmune and inflammatory diseases. In addition, AnaptysBio has developed two cytokine antagonists available for out-licensing: imsidolimab, an anti-IL-36R antagonist, in Phase 3 for the treatment of generalized pustular psoriasis, or GPP, and etokimab, an anti-IL-33 antagonist for the treatment of respiratory disorders that is Phase 2/3 ready. AnaptysBio has also discovered multiple therapeutic antibodies licensed to GSK in a financial collaboration for immune-oncology, 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).

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 imsidolimab's Phase 3 clinical trial in GPP; and the company's ability to find a licensing partner for imsidolimab or etokimab and the timing of any such transaction. 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 its 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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