Anaptys Announces Positive Top-Line GEMINI-2 Phase 3 Clinical Trial Results of Imsidolimab (IL-36R) in Generalized Pustular Psoriasis (GPP)

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- All eight patients from GEMINI-1 who responded to a single intravenous (IV) imsidolimab dose and were subsequently re-randomized to monthly subcutaneous (SC) maintenance dosing of imsidolimab in GEMINI-2 through at least 24 weeks maintained clear to almost clear skin and none experienced a flare
- Of the remaining eight responding patients from GEMINI-1 re-randomized to placebo in GEMINI-2, 25% maintained clear to almost clear skin and 63% of these patients experienced a flare
- Safety and tolerability in GEMINI-2 patients was consistent with reported profile from GEMINI-1
- Plan to submit a comprehensive data abstract for GEMINI-1 and GEMINI-2 to a H2 2024 medical meeting
- Intend to out-license imsidolimab in 2024

SAN DIEGO, May 09, 2024 (GLOBE NEWSWIRE) -- AnaptysBio, Inc. (Nasdaq: ANAB), a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics, today announced positive top-line results from its global GEMINI-1 and GEMINI-2 Phase 3 trials evaluating the safety and efficacy of investigational imsidolimab (IL-36R mAb) in patients with generalized pustular psoriasis (GPP), a severe orphan disease that is potentially life-threatening if left untreated.

In the 45-patient GEMINI-1 Phase 3 trial, patients were randomized 1:1:1 to receive a single infusion of 750mg intravenous (IV) imsidolimab, 300mg IV imsidolimab or placebo at Day 0. Of the patients who received a single dose of 750mg IV imsidolimab, 53% achieved a GPP Physician Global Assessment (GPPPGA) score of 0/1 (clear or almost clear skin) at Week 4 (primary endpoint), compared to 13% of the patients on placebo (p=0.0131). Of the patients who received a single dose of 300mg IV imsidolimab, 53% achieved GPPPGA 0/1 at Week 4.

Sixteen GPPPGA 0/1 responder patients from GEMINI-1 were subsequently re-randomized to monthly maintenance dosing of either 200mg subcutaneous (SC) imsidolimab or placebo in the GEMINI-2 Phase 3 trial. Patients were followed for at least 24 weeks and up to a maximum of 92 weeks. Of the eight responding patients from GEMINI-1 who were re-randomized to monthly 200mg SC imsidolimab maintenance therapy, 100% maintained a GPPPGA score of 0/1 and none of them experienced a flare. Of the remaining eight responding patients from GEMINI-1 who were re-randomized to placebo, 25% maintained a GPPPGA score of 0/1 and 63% experienced a flare.

“The success of the GEMINI-1 and GEMINI-2 Phase 3 trials highlights Anaptys’ ability to internally discover and develop differentiated antibodies that deliver meaningful outcomes for patients,” said Daniel Faga, president and chief executive officer of Anaptys. “The results of these modestly sized studies reinforce that only one single IV dose of imsidolimab was required to achieve rapid clearance of GPP through four weeks and maintained in patients receiving a monthly SC maintenance dose. We remain intent on out-licensing imsidolimab to bring this therapy to patients living with this highly morbid condition.”

Imsidolimab Well Tolerated Through End of Study

Data from both trials demonstrate a consistent, favorable safety and tolerability profile with no treatment-related serious adverse events (SAEs) or SAEs leading to discontinuation reported in imsidolimab-treated patients.

Additionally, the data show:

- Low incidence and no elevation of infections versus placebo
- No cases reported of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) or Guillain-Barre syndrome (GBS)
- No infusion reactions reported
- Overall incidence of anti-drug antibodies (ADA) was low and, when detected, determined to be non-neutralizing

Next Steps with GEMINI-1 and GEMINI-2 Trials

Anaptys plans to submit a comprehensive data abstract for GEMINI-1 and GEMINI-2 results to a H2 2024 medical meeting.

With all patients having passed 24 weeks and the furthest patient being treated through 92 weeks, the company is concluding the GEMINI-2 trial. The company plans to out-license imsidolimab in 2024, and a potential future filing of a biologics license

application (BLA) with the U.S. Food and Drug Administration (FDA) will be contingent on an out-licensing transaction.

“We’re immensely grateful to all the study investigators, study staff and trial participants who helped evaluate this potential new treatment option for GPP,” said Paul Lizzul, M.D., Ph.D., chief medical officer of Anaptys. “We’re pleased that we have generated clinically meaningful data to support a potential future regulatory submission.”

GEMINI-1 and GEMINI-2 Trial Designs

Anaptys’ first Phase 3 GEMINI-1 clinical trial was a four week, double-blind, placebo-controlled, randomized study to evaluate the efficacy and safety of imsidolimab in patients with GPP, irrespective of mutational status. A total of 45 patients, 15 patients per arm, were enrolled across diverse global regions ranging from the U.S., EU, MENA, and Asia. Patients were randomized 1:1:1 to receive a single infusion of 750mg IV imsidolimab, 300mg IV imsidolimab or placebo at Day 0.

The objective of the GEMINI-2 trial was to assess the safety and efficacy of imsidolimab for maintenance of response, and the prevention of GPP flares with monthly SC dosing. A total of 42 patients were subsequently re-randomized into GEMINI-2. The 16 GPPPGA 0/1 responder patients from GEMINI-1 were re-randomized 1:1 to receive either monthly SC maintenance therapy of 200mg imsidolimab or placebo.

About imsidolimab and GPP

Imsidolimab is a fully humanized IgG4 antibody that inhibits the function of the interleukin-36-receptor, or IL-36R, that is being developed for the treatment of GPP.

GPP is a rare, chronic, systemic autoinflammatory disease that is potentially life-threatening if left untreated.

During a GPP flare, individuals experience the sudden eruption of painful pustules. These pustules appear over large areas of the skin, accompanied by redness, severe itchiness, and dry, cracked or scaly skin. People with GPP may also experience more general symptoms such as fever, headache, extreme tiredness or a burning sensation on the skin.

About Anaptys

Anaptys is a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics. It is developing immune cell modulators, including two checkpoint agonists for autoimmune and inflammatory disease: ANB032, its BTLA agonist, in a Phase 2b trial for the treatment of atopic dermatitis and rosnilimab, its PD-1 agonist, in a Phase 2b trial for the treatment of rheumatoid arthritis and in a Phase 2 trial for the treatment of ulcerative colitis. Its preclinical immune cell modulator portfolio includes ANB033, an anti-CD122 antagonist antibody, and ANB101, a BDCA2 modulator antibody, for the treatment of autoimmune and inflammatory diseases. In addition, Anaptys has developed two cytokine antagonists available for out-licensing: imsidolimab, an anti-IL-36R antagonist that has completed Phase 3 trials for the treatment of generalized pustular psoriasis, and etokimab, an anti-IL-33 antagonist that is Phase 2/3 ready. Anaptys has also discovered multiple therapeutic antibodies licensed to GSK in a financial collaboration for immuno-oncology, including an anti-PD-1 antagonist antibody (*Jemperli* (dostarlimab-gxly)) and an anti-TIM-3 antagonist antibody (cobolimab, GSK4069889). To learn more, visit www.AnaptysBio.com or follow us on LinkedIn and X.

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 a presentation of Phase 3 clinical data at a medical conference; whether imsidolimab will be approved by regulatory authorities; 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,” “intend,” “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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