AnaptysBio Announces Orphan Drug Designation of Imsidolimab For Treatment of Generalized Pustular Psoriasis

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- Additional Data and Regulatory Strategy Update From Generalized Pustular Psoriasis (GPP) Phase 2 GALLOP Trial Anticipated During H2 2020
- Palmoplantar pustulosis (PPP) Phase 2 POPLAR Trial Top-Line Data Anticipated in H2 2020
- Company Plans To Expand Clinical Development of Imsidolimab To Additional Indications During H2 2020

SAN DIEGO, July 08, 2020 (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 the U.S. Food and Drug Administration (FDA) has granted orphan drug designation for imsidolimab, the company's proprietary anti-interleukin-36 receptor (IL-36R) antibody, for the treatment of patients with GPP.

The FDA's Office of Orphan Drug Products grants orphan status to support development of medicines for underserved patient populations, or rare disorders, that affect fewer than 200,000 people in the U.S. Orphan drug designation may provide certain benefits to AnaptysBio, including market exclusivity upon regulatory approval, if received, exemption of FDA application fees and tax credits for qualified clinical trials.

"Receiving orphan drug designation for the treatment of GPP is an important milestone for our wholly-owned imsidolimab program," said Hamza Suria, president and chief executive officer of AnaptysBio. "We look forward to advancing clinical development of imsidolimab in GPP, PPP and additional clinical indications that may be driven by dysregulated IL-36R signaling."

GPP is a chronic, life-threatening, rare disease with no currently approved therapies. This systemic inflammatory disease is characterized by the development of widespread pustules marked by exacerbations. In severe cases, GPP patients can die from cardio-pulmonary failure, exhaustion and/or infection subsequent to occurrences of pustular flares. Patients with GPP suffer without robust therapeutic options because currently approved psoriasis management therapies have not demonstrated clear efficacy in the treatment of this condition. In addition, these therapies, including high-dose cyclosporine, methotrexate and retinoids, are often tapered or discontinued due to toxicity. Studies have shown that GPP is associated with uncontrolled signaling through the IL-36R, which in some patients can be mediated by genetic mutations. We estimate GPP affects approximately 3,000 patients in the United States.

AnaptysBio is currently advancing clinical development of imsidolimab in two indications and plans to expand into additional unmet medical needs. Treatment of GPP by imsidolimab is being evaluated in the GALLOP Phase 2 trial, where additional clinical data and a regulatory update is anticipated in the second half of 2020. PPP treatment with imsidolimab is being evaluated in the randomized, placebo-controlled POPLAR Phase 2 trial where top-line data is anticipated in the second half of 2020. In addition, AnaptysBio intends to initiate Phase 2 clinical trials with imsidolimab in two additional indications, in which human translational data suggests dysregulated IL-36R signaling, during the second half of 2020.

About AnaptysBio

AnaptysBio is 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. The Company's proprietary anti-inflammatory pipeline includes its anti-IL-33 antibody etokimab, previously referred to as ANB020, for the treatment of chronic rhinosinusitis with nasal polyps, or CRSwNP, and eosinophilic asthma; its anti-IL-36R antibody imsidolimab, previously referred to as ANB019, for the treatment of rare inflammatory diseases, including generalized pustular psoriasis, or GPP, and palmoplantar pustulosis, or PPP; 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 partnership with GlaxoSmithKline, including an anti-PD-1 antagonist antibody (dostarlimab, TSR-042), an anti-TIM-3 antagonist antibody (cobolimab, TSR-022) and an anti-LAG-3 antagonist antibody (encelimab, TSR-033), and an inflammation partnership 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 GPP and PPP, the timing of a regulatory strategy update for GPP and the timing of initiation of clinical trials in additional indications 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 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.

Contact:
Eric Loumeau
AnaptysBio, Inc.
858.732.0179
eloumeau@anaptysbio.com

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