AnaptysBio Reports Imsidolimab POPLAR Phase 2 Clinical Trial in Moderate-to-Severe Palmoplantar Pustulosis (PPP) Did Not Meet Primary Endpoint

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- Imsidolimab treatment did not demonstrate statistically significant improvement over placebo in PPPASI change from baseline at week 16 primary endpoint
- Imsidolimab was generally well tolerated and no serious or severe adverse events were reported in the drug arm of the trial
- AnaptysBio does not currently plan to conduct further clinical development in PPP
- Advancement of imsidolimab to continue across 5 other distinct indications, including anticipated advancement into Phase 3 trial in generalized pustular psoriasis (GPP) in mid-2021

SAN DIEGO, March 08, 2021 (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 palmoplantar pustulosis (PPP), also known as the POPLAR trial, failed to meet its primary endpoint.

While further clinical development in PPP is not currently anticipated, AnaptysBio will continue development of imsidolimab in five other immuno-dermatological indications, including GPP, EGFRi-mediated skin toxicity, ichthyosis, hidradenitis suppurativa and acne. Initiation of a Phase 3 clinical trial in GPP is anticipated during mid-2021 following completion of protocol alignment with the FDA.

“While the top-line results are disappointing, I would like to sincerely thank everyone involved in the POPLAR trial, including the patients, the investigators, their staff and our employees,” said Hamza Suria, president and chief executive officer of AnaptysBio. “Imsidolimab is currently being advanced in 5 other immuno-dermatology indications and we look forward to multiple additional clinical readouts during 2021 and 2022.”

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

- Mean baseline Palmoplantar Pustular Psoriasis Area Severity Index (PPPASI) scores were 16 for the 30 patients enrolled in the imsidolimab arm and 19 for the 29 patients enrolled in the placebo arm, with an overall average of 18. Mean baseline Palmoplantar Pustulosis Investigator Global Assessment (PPPIGA) was 3.1 for each arm. Patients were on average 50 years of age and 78% were female.
- The primary endpoint of least-squares mean difference (LSMD) PPPASI improvement at week 16 (Day 113) was 6.1 for imsidolimab-treated patients and 6.3 for placebo-treated patients relative to their respective baselines, which has a p-value of 0.93 for the difference between the groups. Twenty-four patients completed the week 16 primary endpoint analysis in each arm of the trial.

LSMD PPPASI Relative to Baseline	Imsidolimab	Placebo	Difference	p-value
Week 4 (Day 29)	-3.1	-3.1	0.0	0.99
Week 8 (Day 59)	-4.6	-3.7	-0.9	0.62
Week 12 (Day 85)	-5.6	-3.4	-2.2	0.25
Week 16 (Day 113, primary endpoint)	-6.1	-6.3	0.2	0.93

- Imsidolimab-treated patients had a mean PPPASI change from baseline of 5.78 or 38% improvement, while placebo-treated patients improved by 6.78 or 33% improvement, each relative to baseline. Percent PPPASI improvement versus baseline was numerically greater for imsidolimab-treated patients relative to placebo-treated patients at each study timepoint (Days 3, 8, 15, 22, 29, 43, 57, 71, 85 and 113), ranging from approximately 3% to 19%.
- Nine (38%) patients achieved fifty percent PPPASI improvement (PPPASI50) and 4 (17%) patients achieved seventy five percent PPPASI improvement (PPPASI75) in the imsidolimab arm at week 16, while 12 (50%) and 3 (13%) achieved these responder thresholds in the placebo arm, respectively.
- Five (21%) imsidolimab-treated patients achieved a PPPIGA score of zero (clear) or 1 (almost clear) at week 16 relative to

3 (13%) placebo-dosed patients.

Percent Improvement Relative To Baseline at Week 16	Imsidolimab	Placebo
Mean PPPASI	38%	33%
PPPASI50	38%	50%
PPPASI75	17%	13%
PPPIGA 0/1	21%	13%

- Imsidolimab was generally well-tolerated with a similar frequency of adverse events between treatment groups, and no severe or serious adverse events were observed in the imsidolimab arm. One severe and one serious adverse event was reported in the placebo-treated arm. The most common adverse events observed in the imsidolimab and placebo arms were three and four cases of mild nasopharyngitis, respectively, that were each deemed treatment unrelated.

POPLAR Phase 2 Trial Design
Fifty-nine PPP patients were enrolled in this trial at 36 sites located within North America and Europe. Patients were washed out of prior PPP therapy and no concomitant therapy was permitted during the trial. Key inclusion criteria included age between 18 and 75 years, clinically confirmed ongoing moderate-to-severe PPP disease with minimum PPPIGA score of at least 3 (moderate), disease history of at least 3 months, and active pustules on palms and/or soles upon enrollment. Patients were treated with a 200mg subcutaneous induction dose of imsidolimab at Day 1, followed by monthly 100mg subcutaneous doses on Days 29, 57 and 85. The primary endpoint of this trial was mean change in PPPASI at week 16 relative to baseline and the estimator for between-group comparison was LSMD. Baseline clinical assessments were conducted for each patient on Day 1 prior to imsidolimab dosing. Missing data was modeled using mixed model for repeated measures (MMRM) methodology.

About Imsidolimab
Imsidolimab, previously known as ANB019, is an antibody that inhibits the function of the interleukin-36-receptor, or IL-36R, which AnaptysBio plans to initially develop as a potential first-in-class therapy for patients suffering from generalized pustular psoriasis, or GPP, EGFR-mediated skin toxicity, ichthyosis, hidradenitis suppurativa and acne.

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-36R antibody imsidolimab, previously referred to as ANB019, for the treatment of rare inflammatory diseases, including generalized pustular psoriasis, or GPP, EGFRi skin toxicity, ichthyosis, hidradenitis suppurativa and acne; 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 collaboration with GlaxoSmithKline, including an anti-PD-1 antagonist antibody (dostarlimab GSK4057190A), an anti-TIM-3 antagonist antibody (cobolimab, GSK4069889A) 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 trials in EGFRi and ichthyosis; the timing of initiation of imsidolimab's Phase 2 clinical trials in hidradenitis suppurativa and acne; and the timing of initiation of imsidolimab's Phase 3 clinical trial in GPP. 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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