Anaptys Announces Phase 2b Trial of ANB032, a BTLA Agonist, Did Not Meet Primary or Secondary Endpoints in Atopic Dermatitis

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- ANB032 was well tolerated across all doses with no safety signals observed
- AD trial and all further investment in ANB032 will be discontinued
- Anticipate top-line Phase 2b data in rheumatoid arthritis in February 2025 for rosnilimab, a PD-1+ T cell depleter and agonist
- Funded beyond additional clinical data catalysts including Phase 2 data in ulcerative colitis for rosnilimab and Phase 1b data for ANB033 and ANB101
- Year-end 2024 cash of approximately $415 million and extending cash runway guidance through year-end 2027, excluding potential GSK milestones and royalties

SAN DIEGO, Dec. 11, 2024 (GLOBE NEWSWIRE) -- AnaptysBio, Inc. (Nasdaq: ANAB), a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics, today announced that investigational ANB032, a BTLA agonist, did not meet the primary and secondary endpoints in any of the doses studied in the global, 201-patient ARISE-AD trial as a monotherapy for moderate-to-severe atopic dermatitis (AD) or eczema. ANB032 was well tolerated with no safety signals observed.

“While ANB032 was safe and well tolerated, we’re disappointed by these efficacy results in AD and will discontinue further investment in this asset. Moving forward, our resources and capital will be focused on the rest of our exciting autoimmune portfolio,” said Daniel Faga, president and chief executive officer of Anaptys. “PD-1 is a co-inhibitory receptor found preferentially on activated T cells. We look forward to sharing for rosnilimab, a depleter and agonist targeting PD-1+ T cells, top-line Phase 2b rheumatoid arthritis data in February 2025 and top-line Phase 2 ulcerative colitis data in Q1 2026, followed by Phase 1b data from our two additional programs.”

The ARISE-AD study evaluated the efficacy, safety, tolerability, pharmacokinetics and pharmacodynamics of ANB032 monotherapy in patients with moderate-to-severe AD. The study enrolled 201 patients with a mean baseline EASI score of 27.3 in the U.S., Canada, Europe, Australia and New Zealand, who were either biologics naïve (n=168) or biologics experienced (n=33), defined as having received treatment with dupilumab or other IL-13 therapies. Patients were randomized to receive for 12 weeks either 100mg of subcutaneous ANB032 every four weeks (Q4W), 400mg every four weeks (Q4W) or 400mg every two weeks (Q2W), or placebo. The primary and secondary endpoints were assessed at Week 14.

Regardless of prior treatment experience, ANB032 did not meet the primary endpoint of the proportion of patients who achieved at least a 75% improvement from baseline in Eczema Area and Severity Index score (EASI-75), or any of the secondary endpoints at Week 14, including EASI-90, mean change in baseline EASI or a 4-point reduction in itch severity as measured by the peak Pruritus Numerical Rating Scale (PNRS) versus placebo.

Absolute response rates on key endpoints in patients treated with ANB032 approached the minimum target product profile with durable off-drug responses; however, higher placebo rates outside of the historical norm, particularly in the U.S., were observed.

ANB032 was well tolerated across all doses with no safety signals observed. Consistent with prior studies, data demonstrate a favorable safety and tolerability profile for ANB032, with one participant across all three active dose arms with a serious adverse event (SAE) of worsening AD and two placebo participants with SAEs. There was no dose relationship or imbalance in AEs and no safety signals observed. The most common (>5%) AEs observed were nasopharyngitis, atopic dermatitis and headache.

“We are sincerely grateful to all of the patients and clinicians who participated in this important trial, without whom we would not be able to continue to learn about how best to treat this debilitating chronic disease,” said Paul Lizzul, M.D., Ph.D., chief medical officer of Anaptys.

About Anaptys

Anaptys is a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics for autoimmune and inflammatory diseases. Its lead program, rosnilimab, a depleter and agonist targeting PD-1+ T cells, in a Phase 2b trial for the treatment of rheumatoid arthritis and in a Phase 2 trial for the treatment of ulcerative colitis. Other antibodies in its portfolio include ANB033, an anti-CD122 antagonist, in a Phase 1 trial and ANB101, a BDCA2 modulator, soon to enter clinical development. Anaptys has also discovered multiple therapeutic antibodies licensed to GSK in a financial collaboration for immuno-oncology, including an anti-PD-1 antagonist (*Jemperli* (dostarlimab-gxly)) and an anti-TIM-3 antagonist (cobolimab, GSK4069889). To learn more, visit www.AnaptysBio.com or follow us on LinkedIn.

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 the Company's clinical trials, including rosnilimab's Phase 2b clinical trial in rheumatoid arthritis and Phase 2 clinical trial in ulcerative colitis; whether rosnilimab will be best-in-class; the potential to receive any additional milestones and royalties from the GSK collaboration; and the Company's estimated year-end cash balance and cash runway. 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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