Anaptys Announces New Positive Phase 2b Trial Results for Rosnilimab in Rheumatoid Arthritis at ACR Late-Breaking Oral Presentation

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- New data reinforce rosnilimab's efficacy profile in rheumatoid arthritis (RA) with deepening of clinical responses, including CDAI remission, from Week 12 to Week 28 regardless of prior advanced therapy, including JAKs
- New data confirm durable clinical benefit across multiple higher-order response measures, including CDAI LDA and DAS28 LDA, after Week 28 for at least three months off drug
- Updated safety data through Week 38 demonstrate rosnilimab was well-tolerated with no treatment-related serious adverse events and no malignancies in rosnilimab-treated patients

SAN DIEGO, Oct. 29, 2025 (GLOBE NEWSWIRE) -- AnaptysBio, Inc. (Nasdaq: ANAB), a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics, today announced late-breaking data from the robust, global 424-patient Phase 2b trial of rosnilimab, a selective and potent pathogenic T cell depleter, in rheumatoid arthritis (RA) at the American College of Rheumatology (ACR) Convergence 2025 in Chicago. New study results showed that positive Week 12 data across multiple higher-order response measures continue to deepen into Week 28 regardless of prior treatment. These results were then durable for at least three months off drug. Additionally, rosnilimab was well-tolerated with no treatment-related serious adverse events and no malignancies in rosnilimab-treated patients through end-of-trial follow-up (Week 38).

Paul Emery, M.D., professor of rheumatology at the University of Leeds and Leeds Biomedical Research Centre,U.K., presented data that show:

- As previously reported, at Week 12, statistically significant and clinically meaningful efficacy was achieved on the primary endpoint DAS28-CRP, as well as for ACR20, for all doses, including monthly doses (Q4W);
- At Week 28, CDAI LDA, CDAI remission and ACR50/70 rates continued to improve independent of prior treatments, including anti-TNFα, anti-IL6R or JAK inhibitors;
- Similar effects were seen for patients previously treated with at least two prior biologic or targeted synthetic disease-modifying antirheumatic drug classes (b/tsDMARDs), particularly at the mid (400mg Q4W) and high (600mg Q2W) doses;
- Week 28 responses across multiple clinically meaningful measures, including CDAI LDA, mean CDAI, mean DAS28-CRP and ACR50/70, were durable off drug through at least three months after the last rosnilimab dose;
- Through Week 38, safety data demonstrated rosnilimab was well-tolerated, with no malignancies and no deaths;
- By Week 6, Tph cells were reduced > 90% in the periphery for all doses and the synovium at the two highest doses;
- Highly statistically significant reductions observed in T cell and B cell activation in synovial biopsies, with deeper reductions seen in CDAI LDA responders ($p < 0.0001$).

"Rosnilimab, a novel mechanism of action, demonstrated clinical proof-of-concept for pathogenic T cell depletion with meaningful, durable clinical benefit along with a favorable safety profile in this 38-week, robust Phase 2b RA trial," said Professor Emery. "Importantly, rosnilimab was well-tolerated with few dropouts, no safety trends or signals to date, such as those seen with the JAK inhibitors or other biologics, including no cases of malignancy. The translational data provided strong mechanistic validation, potently reducing Tph cells in blood and synovium by more than 90%. With over half of RA patients cycling through multiple b/tsDMARDs, there remains a high unmet need for a new, safe and durable treatment option."

The presentation is available for download on the Anaptys website here.

About the RENOIR Trial

The Phase 2b RENOIR trial evaluated the efficacy, safety, tolerability, pharmacokinetics and pharmacodynamics of rosnilimab in patients with moderate-to-severe RA on background conventional disease-modifying antirheumatic drugs (cDMARDs) (e.g., methotrexate). The trial enrolled 424 patients across the U.S., Canada and Europe, who were either b/tsDMARD naïve (n=250; 59%) or experienced (n=174; 41%). Patients classified as b/tsDMARD-experienced reported prior utilization of at least one biologic or targeted synthetic therapy, such as TNFα inhibitors, B cell inhibitors, selective costimulatory modulators or JAK inhibitors. Approximately 29% (n=50) of b/tsDMARD-experienced patients were treated with prior JAK inhibitors.

Patients were randomized to receive either 100mg of subcutaneous rosnilimab Q4W, 400mg Q4W, 600mg Q2W, or placebo. The primary and secondary endpoints were assessed at Week 12. Following completion of the Week 14 visit, 220 of the 318 rosnilimab patients (71% of b/tsDMARD-naïve and 66% of b/tsDMARD-experienced) across all doses who achieved a high

threshold of CDAI LDA continued with their assigned treatments through Week 28 in a blinded, all-active treatment period. At that time, participants moved into an off-drug observation period that assessed safety and efficacy for 10-12 weeks, or ~3 months, depending on their treatment assignment and completed the trial by Week 38 (Month 9).

About Rosnilimab

Rosnilimab is a novel therapeutic antibody that directly targets pathogenic T cells, such as activated Tfh/Tph and T effector cells, in the periphery or inflamed tissue. When activated, these T cells proliferate and migrate and secrete inflammatory cytokines that are the drivers of autoimmune and inflammatory diseases.

Rosnilimab is designed to selectively and potently deplete pathogenic T cells in both inflamed tissue and the periphery while sparing nonpathogenic T cells, including naïve T cells, to preserve overall immune function and restore immune homeostasis. This drives specific immunological outcomes, such as a reduction in T cell proliferation, migration and cytokine secretion, and a reduction of plasma cell generation and autoantibody levels.

Rosnilimab is currently under clinical investigation, and its safety and efficacy have not been evaluated by any regulatory authority. Phase 2 top-line data through Week 12 for rosnilimab in ulcerative colitis is anticipated in November/December 2025.

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 pathogenic T cell depleter, completed a Phase 2b trial for the treatment of rheumatoid arthritis and is in a Phase 2 trial for the treatment of ulcerative colitis. The company's pipeline also includes ANB033, a CD122 antagonist, in a Phase 1b trial for celiac disease with plans to expand development into an additional indication. Additionally, ANB101, a BDCA2 modulator, is in a Phase 1a trial. Anaptys has also discovered and out-licensed in financial collaborations multiple therapeutic antibodies, including a PD-1 antagonist (*Jemperli* (dostarlimab-gxly)) to GSK and an IL-36R antagonist (imsidolimab) to Vanda Pharmaceuticals. To learn more, visit www.AnaptysBio.com or follow us on LinkedIn.

Anaptys recently announced the intent to separate its biopharma operations from its substantial royalty assets by year-end 2026, enabling investors to align their investment philosophies and portfolio allocation with the strategic opportunities and financial objectives of each company. Learn more here.

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 top-line Phase 2 clinical trial data in ulcerative colitis; the potential to receive any royalties or milestone payments from the Vanda Pharmaceuticals license agreement; and the potential to receive any additional milestones and royalties from the GSK collaboration. 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.

Contact:
Nick Montemarano
Executive Director, Investor Relations
858.732.0178
investors@anaptysbio.com

Source: AnaptysBio, Inc.