Anaptys Announces Positive Rosnilimab Data Updated Through Six Months in Robust Phase 2b Trial in RA

June 3, 2025

- Best-in-disease profile with JAK-like efficacy and monthly (Q4W) dosing in both three-month placebo-controlled and six-month blinded treatment period
- Favorable safety and tolerability, particularly when compared to standard of care biologics or JAKs
- Max response rates have not yet been observed; strict continuation criteria at three months in this Phase 2b trial excluded many patients who either achieved or were trending toward LDA and ACR50
- Durable responses for at least two months off drug, with potential for extended dosing intervals (e.g. Q8W) in the maintenance setting
- Conference call and webcast today at 4:15pm ET/1:15pm PT

SAN DIEGO, June 03, 2025 (GLOBE NEWSWIRE) -- AnaptysBio, Inc. (Nasdaq: ANAB), a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics, today announced that investigational rosnilimab, a depleter and agonist targeting PD-1+ T cells, demonstrated a best-in-disease profile in patients with moderate-to-severe rheumatoid arthritis (RA). In the robust, global 424-patient Phase 2b trial, rosnilimab achieved JAK-like efficacy on multiple clinically meaningful measures, including low disease activity (LDA) and remission on the Clinical Disease Activity Index (CDAI), as well as ACR70 response, over a six-month period. Furthermore, responses were then durable for at least two months off drug. Rosnilimab was safe and well tolerated, particularly when compared to standard of care biologics or JAKs.

"This is exciting news for patients living with RA, who cycle through numerous treatment options without achieving a low level of disease activity shown to be correlated with slowing of disease progression. The updated Phase 2b data for rosnilimab confirm a best-in-disease profile through six months that is safe and well tolerated, with JAK-like efficacy and the potential to be administered in a monthly, subcutaneous dose. Additionally, responses after six months of treatment are durable for at least two months off drug, suggesting the potential for extended, every eight-week dosing intervals during maintenance treatment," said Daniel Faga, president and chief executive officer of Anaptys. "These findings, consistent with compelling and objective translational data, surpass our target product profile for rosnilimab in the ~$20 billion U.S. RA market. Our next priority is to complete the ongoing Phase 2 study for rosnilimab in UC, which is on track to report initial data in Q4 2025."

Most rosnilimab patients showed symptomatic and clinical improvement by three months. As previously reported, all three doses of rosnilimab achieved statistically significant reductions in mean change from baseline in DAS-28 CRP, the study's primary endpoint, as well as for ACR20, at Week 12 versus placebo. During the three-month placebo-controlled period in both b/tsDMARD-naïve and b/tsDMARD-experienced patients, rosnilimab demonstrated a rapid onset of ACR20 response, an accepted Phase 3 registrational endpoint, as well as a substantial decrease in objective measures such as C-reactive protein (CRP), that were both comparable to the Phase 2b trial results of upadacitinib.

Rosnilimab demonstrated JAK-like efficacy with deepening of responses through six months on CDAI LDA, CDAI remission and ACR70. Importantly, this is particularly observed in the b/tsDMARD-experienced patients for the 400mg Q4W and 600mg Q2W doses, showing a dose response relative to the 100mg Q4W dose. At baseline, patients had high disease activity with a mean CDAI of 38 and median CDAI of 36. Of the 318 rosnilimab patients in the intent to treat (ITT) population, CDAI of ≤10 (LDA) was achieved by 45% of patients by Week 12 and increased to 69% of patients (220 responders) across all three doses at Week 14, the timepoint required in the trial to be eligible to remain in the all-active treatment period on rosnilimab through Week 28. This sets a ceiling on the number of CDAI LDA responders at Week 28 when using a non-responder imputation (NRI) analysis of the ITT population to calculate rosnilimab response rates.

Max response rates for rosnilimab have not yet been observed as strict criteria at Week 14 prevented patients with meaningful improvement from continuing treatment in the trial. For example, 12 patients achieved CDAI LDA four or six weeks after their last rosnilimab dose at their first follow-up visit (Week 18), but were ineligible to continue in the all-active treatment period and imputed as non-responders at Week 28 in the below NRI analysis. If these 12 responding patients had been eligible to continue treatment, CDAI LDA would have been up to 232 responders (73%) of 318 rosnilimab patients in the ITT across all three doses. Of the remaining patients ineligible to enter the all-active treatment period, ~50% had achieved ACR20 at Week 14 and were trending toward CDAI LDA.

The following data table reports the results at Week 28 (six months) using a conservative NRI analysis of the ITT population of rosnilimab patients randomized in the trial, which counts as responses only patients who entered the all-active treatment period at Week 14 and were in response at Week 28:

Efficacy Measures	**Rosnilimab**	**Rosnilimab**	**Rosnilimab**

	100mg Q4W	400mg Q4W	600mg Q2W
b/tsDMARD-Naïve *(n=188 rosnilimab patients)*	*n=62*	*n=62*	*n=64*
	Week 28(*Δ from Week 12*)		
CDAI ≤ 10 (LDA)	66% *(+18%)*	53% *(+5%)*	72% *(+29%)*
CDAI ≤ 2.8 (Remission)	21% *(+13%)*	18% *(+10%)*	17% *(+12%)*
ACR50	58% *(+10%)*	52% *(+10%)*	69% *(+17%)*
ACR70	53% *(+27%)*	37% *(+9%)*	55% *(+32%)*
b/tsDMARD-Experienced *(n=130 rosnilimab patients)*	*n=44*	*n=45*	*n=41*
	Week 28(*Δ from Week 12*)		
CDAI ≤ 10 (LDA)	34% *(-9%)*	56% *(+5%)*	49% *(+20%)*
CDAI ≤ 2.8 (Remission)	14% *(+7%)*	16% *(+7%)*	15% *(+3%)*
ACR50	27% *(-12%)*	44% *(+15%)*	42% *(+3%)*
ACR70	23% *(+7%)*	36% *(+20%)*	29% *(+9%)*

NRI analysis on ITT population (n =318 total rosnilimab patients; 188 b/tsDMARD-naïve, 130 b/tsDMARD-experienced); Values rounded to the nearest whole number

CDAI LDA responders at Week 28 had durable responses for at least two months off drug, supporting the potential for maintenance dosing with extended dosing intervals (e.g. Q8W). As of the March 11, 2025 data cutoff date, 83% were still in LDA at Week 34 across all doses. Of the remaining 17% of patients who did not sustain CDAI LDA at Week 34, most remained near the cutoff of CDAI=10, with a median CDAI of 13.

Importantly, rosnilimab demonstrated clinically meaningful improvements that deepened through Week 28 across multiple validated patient-reported outcomes, including the pain visual analog scale (VAS) and the health assessment questionnaire, or HAQ-Disability Index (DI), a self-reporting tool to measure function and disability. The Pain VAS scale ranges from zero to 100, where scores of 20 indicate mild pain and above 60 indicate severe pain. The rosnilimab patients who entered the all-active treatment period improved on the Pain VAS from a mean baseline of ~65 to ~15, a ~50-point change where the minimal clinically important difference (MCID) is a ~10-point change from baseline. HAQ-DI scores range from zero to three, where scores of one to two indicate moderate to severe disability. The rosnilimab patients who entered the all-active treatment period with a score of ~1.6 reported a 0.9-point reduction in the HAQ-DI to ~0.7, where the MCID is a 0.22-point change from baseline.

Clinical outcomes were further substantiated by compelling and objective translational data. An ~50% reduction in the mean CRP from baseline, an objective measure of inflammation, was observed through Week 28 in rosnilimab patients who entered the all-active period. Additionally, translational blood and synovial biopsy biomarker data showed differentiated and consistent immunological impact with robust, on-target pharmacological activity in rosnilimab patients that was not observed on placebo. In blood, rosnilimab demonstrated rapid, deep and sustained reductions of ~90% in PD-1^{high} T cells and ~50% in PD-1+ T cells, and an increase in total Tregs. Together, this resulted in stable total T cell counts and favorable T cell composition reflective of healthy immune homeostasis. Additionally, synovial biopsies of the most impacted joint taken at baseline and after six weeks showed a deep reduction of ~90% in PD-1+ T cells at the 400mg Q4W and 600mg Q2W doses, showing a dose response relative to the 100mg Q4W dose. Gene expression studies of the synovium demonstrated significant decreases of T cell activation and B cell activation pathways in rosnilimab patients. Similarly, highly significant decreases in additional downstream pathways including those relevant to TNF and IL-6 within the synovium were observed.

"RA is a chronic disease that often begins in early adulthood, making it critical to effectively control disease activity over a patient's entire lifetime and prevent damage to joints and other organs, reduce pain and improve quality of life. Witnessing rosnilimab, with its novel mode of action, dramatically reduce RA disease activity through six months in most patients, whether having failed multiple classes of b/tsDMARD therapies or b/tsDMARD-naïve, is truly exciting for patients living with this disease and the field of RA treatment," said Jonathan Graf, M.D., professor of Medicine, Division of Rheumatology at the University of California, San Francisco and RENOIR investigator. "Additionally, impressive translational data provide further evidence that by targeting specific PD-1 expressing cells, rosnilimab has a substantial impact downstream on multiple known pathways that drive RA pathogenesis, with the potential to restore immune homeostasis necessary to achieve meaningful, long-lasting disease remission. Developing innovative and safe treatment options with novel modes of action for long-term use is crucial to meet the urgent needs of today's patients with lifelong disease."

Rosnilimab Was Well Tolerated with No Safety Signals

Consistent with prior studies, a favorable safety and tolerability profile across all rosnilimab doses was observed with no treatment-related serious adverse events (SAEs), malignancies, anaphylaxis or systemic hypersensitivity, and a low incidence of injection site reactions. Most adverse events (AEs) were mild to moderate in severity. Less than 2% of patients in the entire trial discontinued rosnilimab due to an AE, including only one patient after three months for a moderate headache treated with over-the-counter pain medication. Non-treatment related SAEs observed were consistent with known RA patient history and comorbidities.

"This was a robust and well-controlled Phase 2b study with more than 300 patients treated with rosnilimab for up to six months. To date, rosnilimab has shown a safe and well tolerated profile with almost all patients choosing to stay on therapy through the end of the study. Rosnilimab has not demonstrated any concerning safety trends or signals, such as those seen with the JAK inhibitors

and most other biologics," said Paul Emery, M.D., Versus Arthritis professor of rheumatology at the University of Leeds and Leeds Biomedical Research Centre, UK. "This is remarkable, given these patients have a two-to-threefold increased risk of comorbidities such as infections, cardiac events and malignancies, before accounting for the impact of background DMARDs, mostly methotrexate."

The table below shows safety data for trial participants on an exposure adjusted incidence rate (per 100 patient years) from Week 0 through Week 28. Placebo data provided for 12 weeks of treatment, only.

Participants with Adverse Events	**Placebo** (n=106)	**Rosnilimab** 100mg Q4W (n=105)	**Rosnilimab** 400mg Q4W (n=107)	**Rosnilimab** 600mg Q2W (n=105)
Any AE, n (per 100 PY)	**39 (125.6)**	**73 (260.9)**	**66 (206.5)**	**52 (149.1)**
Any SAE[1]	1 (2.4)	2 (3.8)	2 (3.7)	4 (7.7)
Any Drug-Related SAE	1 (2.4)	0 (0)	0 (0)	0 (0)
Severe AE[2]	2 (4.8)	4 (7.5)	1 (1.9)	4 (7.8)
Drug-Related AE	18 (48.8)	17 (36.1)	28 (62.0)	19 (41.7)
AE Leading to Treatment Discontinuation	1 (2.4)	1 (1.9)	3 (5.6)	2 (3.8)
Infections	16 (41.5)	41 (98.7)	39 (89.4)	31 (67.6)
Serious	1 (2.4)	1 (1.9)	1 (1.9)	1 (1.9)
Opportunistic[3]	2 (4.8)	1 (1.9)	1 (1.8)	1 (1.9)
Patients with any AE>5%, n (per 100 PY)				
Headache	4 (9.7)	10 (19.9)	10 (19.4)	5 (9.8)
Upper respiratory tract infection	2 (4.8)	14 (27.8)	7 (13.4)	10 (19.6)
Nasopharyngitis	4 (9.6)	9 (17.5)	8 (15.4)	1 (1.9)
Elevated ALT (alanine aminotransferase)[4]	1 (2.4)	8 (15.5)	5 (9.5)	4 (7.8)

1. SAEs (severe unless otherwise noted): RSV – moderate (600mg Q2W); anaphylaxis from wasp sting (600mg Q2W); ureter stone (600mg Q2W); cholecystitis / pericardial effusion (600mg Q2W); meniscus tear – moderate (400mg Q4W); diverticulitis – moderate (400mg Q4W); embolic ischemic stroke (100mg Q4W); pneumonia – mild (100mg Q4W); cellulitis/diarrhea (placebo)
2. Severe AEs (excluding SAEs): RA flare (600mg Q2W); blood creatine phosphokinase increase (400mg Q4W); endometriosis (100mg Q4W); alanine aminotransferase increased/aspartate aminotransferase increase (100mg Q4W); flu/headache (100mg Q4W); macular degeneration/retinal hemorrhage (placebo)
3. Values shown are for herpes zoster, the only opportunistic infection reported, and were all moderate
4. No patient met the predefined protocol liver function test stopping criteria. Only one ALT elevation was severe, which resolved without interruption of therapy, none were serious, all had an outcome of recovered/resolved or recovering/resolving

"At Anaptys, we are dedicated to developing novel treatments for patients living with inflammatory diseases. Beyond achieving necessary symptomatic improvements and reductions, we strive to advance treatment toward the clinical resolution of disease by restoring immune homeostasis. Today's updated positive data reinforce our targeted goals with the added potential for convenient monthly dosing through six months and beyond, on top of maintaining sustainable and durable outcomes," said Paul Lizzul, M.D., Ph.D., M.P.H., MBA, chief medical officer of Anaptys. "We extend our sincere gratitude to all the patients and investigators who participated in this trial and contributed to these clinically meaningful and significant findings that will help advance the field for all patients living with RA, as well as patients with other autoimmune or inflammatory diseases."

Anaptys Investor Call

Anaptys management will host an investor call and live webcast, with an accompanying slide presentation, to review results of the data from the Phase 2b RA trial, today, June 3, 2025, at 4:15pm ET/1:15pm PT. A live webcast of the call will be available on the Anaptys website at: https://ir.anaptysbio.com/presentations-and-events. A replay of the webcast will be available for at least 30 days following the event.

About the Phase P2b RENOIR Trial and the Primary and Secondary Endpoints

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 biologic or targeted synthetic DMARD (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 the 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).

The primary endpoint of mean change in DAS28-CRP at Week 12 is calculated based on differential weighting of individual measures, including the patient's general health, CRP and a count of 28 swollen and tender joints, with a score ranging from 0 to 9.4.

Secondary endpoints include the CDAI score, a composite assessment used to measure the severity of RA based on the sum of four assessment tools; the number of swollen and tender joints, the patient's global disease activity index, and the physician's global disease activity index. The score ranges from 0 to 76, with a score ≤10 defined as the threshold for LDA. CDAI remission score is ≤2.8. Additionally, ACR20/50/70 responses are used to measure change in RA disease activity. For example, an ACR70 response requires a patient to have a 70% reduction in the number of swollen and tender joints, and a reduction of 70% in three of the following five parameters: physician global assessment of disease, patient global assessment of disease, patient assessment of pain, CRP or erythrocyte sedimentation rate, and degree of disability in HAQ score.

Further details about the trial are available on: Trial Details | ClinicalTrials.gov.

About Rosnilimab

Rosnilimab is a novel therapeutic antibody that directly targets PD-1, a co-inhibitory receptor preferentially expressed on the surface of activated T cells, which broadly impacts the pathogenic drivers of inflammatory diseases such as RA and UC. Rosnilimab is a targeted therapy designed to deplete PD-1^{high} T cells and agonize the remaining PD-1+ T cells to restore the immune system back to a state of homeostasis. This is anticipated to result in specific immunological outcomes in both inflamed tissue and the periphery, such as reduction in T cell proliferation, migration and cytokine secretion, and 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.

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, is in a Phase 2b trial for the treatment of rheumatoid arthritis and in a Phase 2 trial for the treatment of ulcerative colitis. The company's pipeline also includes ANB033, a CD122 antagonist, and ANB101, a BDCA2 modulator, in Phase 1 trials. Anaptys has also discovered multiple therapeutic antibodies licensed to GSK in a financial collaboration for immuno-oncology, including a PD-1 antagonist (*Jemperli* (dostarlimab-gxly)) and a 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 at Week 38 and Phase 2 clinical trial in ulcerative colitis; and whether current trends will be maintained once complete Week 38 data becomes available. 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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