Anaptys Announces Rosnilimab Achieved Positive Results in RA Phase 2b Trial and Highest Ever Reported CDAI LDA Response Over 6 Months

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- Achieved statistical significance on primary endpoint at Week 12 on mean change from baseline DAS-28 CRP across all rosnilimab doses vs. placebo
- Achieved statistical significance on key secondary endpoints at Week 12 on ACR20, ACR50 and CDAI LDA
- Demonstrated highest ever reported responses on key secondary endpoints at Week 14 on ACR20, ACR50, ACR70 and CDAI LDA
- 69% of rosnilimab-treated patients achieved CDAI LDA at Week 14 and appear to show sustained CDAI LDA and ACR50 responses and potentially deepening ACR70 responses out to Week 28
- Robust pharmacological activity observed in reduction of PD-1^{high} T cells, increase in total Tregs and reduction of CRP across all doses
- Rosnilimab was safe and well tolerated with similar adverse event rates vs. placebo
- Full Week 28 and additional translational RA data in Q2 2025
- Top-line Week 12 Phase 2 ulcerative colitis data for rosnilimab, now in Q4 2025
- Conference call and webcast to discuss results today at 8:30am ET

SAN DIEGO, Feb. 12, 2025 (GLOBE NEWSWIRE) -- AnaptysBio, Inc. (Nasdaq: ANAB), a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics, today announced statistically significant Week 12 data from the global 424-patient Phase 2b RENOIR trial of investigational rosnilimab, a depleter and agonist of PD-1+ T cells, for moderate-to-severe rheumatoid arthritis (RA). Rosnilimab was safe and well tolerated with similar adverse event rates vs. placebo.

The Phase 2b RENOIR trial is evaluating 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 with a mean baseline disease activity score -- 28 joints (DAS-28) C-Reactive Protein (CRP) score of 5.64 and mean baseline clinical disease activity index (CDAI) score of 37.7 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.

Patients were randomized to receive either 100mg of subcutaneous rosnilimab every four weeks (Q4W), 400mg Q4W, 600mg every two weeks (Q2W), or placebo. The primary endpoint was assessed at Week 12 and secondary endpoints were assessed at both Week 12 and Week 14. Following completion of the Week 14 visit, rosnilimab-treated patients who achieved CDAI low disease activity (LDA) of ≤ 10, continued their assigned treatment through Week 28 in a blinded, all-active treatment period.

Rosnilimab Achieved Primary and Secondary Efficacy Endpoints

The trial achieved its primary endpoint of the mean change from baseline in DAS-28 CRP at Week 12 for all three doses of rosnilimab vs. placebo.

Rosnilimab achieved statistical significance in at least one dose and numerical superiority at all doses, including once monthly administration, on key secondary endpoints of ACR20, ACR50 and CDAI LDA at Week 12, even though higher than typical placebo rates were observed. Also, rosnilimab demonstrated the highest ever reported responses for these key secondary endpoints at Week 14. 69% of rosnilimab-treated patients achieved CDAI LDA at Week 14 and appear to show sustained CDAI LDA and ACR50 responses, as well as potentially deepening ACR70 responses out to Week 28.

Translational blood biomarker data, across all doses, showed similar immunological impact with robust on-target pharmacological activity in rosnilimab-treated patients that was not observed on placebo. Rosnilimab demonstrated rapid and sustained reduction of ~90% PD-1^{high} T cells and ~50% of PD-1+ T cells, and an increase in total Tregs. Together, this resulted in a minimal impact on total T cell counts and favorable T cell composition reflective of healthy immune homeostasis. Additionally, a ~50% reduction in the mean CRP from baseline, an objective measure of inflammation, was observed in rosnilimab-treated patients through the entire trial period that was not observed on placebo.

“We are excited about these trial results and the impact they could have on patients living with RA. Rosnilimab is safe and well

tolerated with the highest ever reported CDAI low disease activity at ~3 months that, to date, is sustained and potentially deepening over 6 months. These findings, further supported by objective translational data, surpass our target product profile in the ~$20 billion U.S. RA market," said Daniel Faga, president and chief executive officer of Anaptys. "In Q2 2025, we will report full six-month data and additional translational data that we expect will further substantiate rosnilimab's impact on restoring healthy immune homeostasis in RA and additional diseases, such as ulcerative colitis (UC). We also look forward to reporting top-line Week 12 Phase 2 data for rosnilimab in UC, now in Q4 2025."

Results for trial endpoints at Week 12 and Week 14 were as follows:

Efficacy Measures			**Rosnilimab** 100mg Q4W	**Rosnilimab** 400mg Q4W	**Rosnilimab** 600mg Q2W	**Placebo**
Overall population (n=424)						
	Primary Endpoint		n=106	n=107	n=105	n=106
	Mean change in DAS28-CRP	*Week 12*	-2.06 *0.0092*	-2.12 *0.0016*	-2.06 *0.0062*	-1.69
		Week 14	-2.52 *<0.0001*	-2.57 *<0.0001*	-2.65 *<0.0001*	-1.39
	Secondary Endpoints		n=106	n=107	n=105	n=106
	CDAI ≤ 10 (LDA)	*Week 12*	46% *0.0224*	50% *0.0053*	38% *0.2982*	31%
		Week 14	69% *<0.0001*	68% *<0.0001*	71% *<0.0001*	23%
	ACR20	*Week 12*	69% *0.0149*	70% *0.0082*	75% *0.0005*	53%
		Week 14	82% *<0.0001*	79% *<0.0001*	81% *<0.0001*	47%
	ACR50	*Week 12*	44% *0.0887*	36% *0.5961*	47% *0.0432*	33%
		Week 14	59% *<0.0001*	59% *<0.0001*	67% *<0.0001*	26%
	ACR70	*Week 12*	22% *0.4903*	22% *0.5090*	22% *0.4734*	18%
		Week 14	42% *<0.0001*	41% *<0.0001*	48% *<0.0001*	10%
b/tsDMARD-naïve (n=250)						
	Secondary Endpoints		n=62	n=62	n=64	n=62
	CDAI ≤ 10 (LDA)	*Week 14*	74% *<0.0001*	65% *<0.0001*	75% *<0.0001*	23%
	ACR20	*Week 14*	81% *<0.0001*	81% *<0.0001*	88% *<0.0001*	48%
	ACR50	*Week 14*	65% *<0.0001*	61% *<0.0001*	73% *<0.0001*	27%
	ACR70	*Week 14*	50% *<0.0001*	45% *<0.0001*	53% *<0.0001*	13%
b/tsDMARD-experienced (n=174)						
	Secondary Endpoints		n=44	n=45	n=41	n=44
	CDAI ≤ 10 (LDA)	*Week 14*	61% *<0.0001*	73% *<0.0001*	63% *<0.0001*	23%
	ACR20	*Week 14*	84% *<0.0001*	76% *<0.0023*	71% *<0.0145*	46%
	ACR50	*Week 14*	52% *<0.0026*	56% *<0.0007*	56% *<0.0008*	23%
	ACR70	*Week 14*	30% *<0.0038*	36% *<0.0004*	39% *<0.0002*	7%

At Week 14, 69% (71% of b/tsDMARD-naïve and 66% of b/tsDMARD-experienced) or 220 of the 318 rosnilimab-treated patients across all doses achieved CDAI LDA and were eligible to remain on continued active therapy through Week 28. As of the Dec. 10, 2024 data cutoff, these patients appear to show sustained CDAI LDA and ACR50 responses and potentially deepening ACR70 responses out to Week 28. This portion of the ongoing trial remains blinded, and complete Week 28 data are anticipated in Q2 2025.

“In RA, there is an urgent need for innovative therapies such as rosnilimab, which have the potential of reducing the debilitating effects of this disease for a longer period of time for a broader range of patients,” said Jonathan Graf, M.D., professor of Medicine, Division of Rheumatology at the University of California, San Francisco and RENOIR investigator. “RA patients have an abnormal population of PD-1^{high} expressing T cells circulating in their bloodstream and joints. I am strongly encouraged by these Phase 2 data, which support the hypothesis that by depleting these PD-1^{high} expressing T cells and agonizing the remaining PD-1+ T cells, rosnilimab offers a fundamentally different approach to treating RA by resetting the immune system, potentially offering more durable relief of symptoms and disease modification.”

Rosnilimab Safe and Well Tolerated with AEs Similar Across Treatment Groups and Placebo

Consistent with prior studies, these rosnilimab Phase 2b data demonstrate a favorable safety and tolerability profile. The data through Week 12 show:

- No malignancies
- No MACE
- No elevation of serious infections vs. placebo
- No anaphylaxis or systemic hypersensitivity associated with rosnilimab
- Low incidence of injection site reactions and similar to placebo

The table below shows safety data for all patients through Week 12:

Adverse Events, n	**Rosnilimab** 100mg Q4W (n=105)	**Rosnilimab** 400mg Q4W (n=107)	**Rosnilimab** 600mg Q2W (n=105)	**Placebo** (n=106)
Patients with any AE, n (%)	**51 (48%)**	**48 (45%)**	**38 (36%)**	**36 (34%)**
Any SAE[1]	1 (1%)	1 (1%)	3 (3%)	1 (1%)
Any Drug-Related SAE	0	0	0	1 (1%)
Severe AE[2]	1 (1%)	0	4 (4%)	2 (2%)
Drug-Related AE	13 (12%)	18 (17%)	17 (16%)	18 (17%)
Infections	24 (23%)	21 (20%)	12 (11%)	14 (13%)
AE Leading to Treatment Discontinuation	1 (1%)	2 (2%)	2 (2%)	1 (1%)
Patients with any AE ≥ 5%, n				
Headache	7 (7%)	6 (6%)	4 (4%)	4 (4%)
Upper respiratory tract infection	7 (7%)	2 (2%)	3 (3%)	1 (1%)

1. SAEs (severe unless otherwise noted): pneumonia – mild (100 mg Q4W); meniscus tear – moderate (400 mg Q4W); anaphylaxis from wasp sting, ureter stone, and cholecystitis/pericardial effusion (600mg Q2W); cellulitis/diarrhea (placebo) 2. Severe AE (excluding SAEs): flu (100mg Q4W); RA flare (600mg Q2W); macular degeneration/retinal hemorrhage (placebo)

As of the Dec. 10, 2024 data cutoff, the safety profile for patients who achieved CDAI LDA through Week 14, and continued active therapy up to Week 28, remains consistent with the reported profile of all rosnilimab-treated patients through Week 12.

"Despite multiple advances in the treatment of patients with RA, a large number remain difficult to treat. Unfortunately, no new drug classes have been approved for RA in the last decade. As we continue to advance our understanding of RA and look to reduce long-term damage to the body’s joints and organs caused by this disease, it is imperative that we develop treatment options with different modes of action, that are not only effective but also safe for long-term use,” said Paul Emery, M.D., Versus Arthritis professor of rheumatology at the University of Leeds and Leeds Biomedical Research Centre, UK. “Rosnilimab’s efficacy data paired with a favorable safety and tolerability profile present a promising new option for people living with RA."

"Today’s data offer new hope for patients living with RA and I am particularly encouraged by the combined efficacy and safety profile in both b/tsDMARD-naïve and -experienced patients. This advance in our understanding of RA would not have been possible without the patients and clinicians who participated in this important trial, and we are sincerely grateful,” added Paul Lizzul, M.D., Ph.D., chief medical officer of Anaptys. “Importantly, these positive clinical and translational data validate our scientific approach to target the PD-1 co-inhibitory receptor on activated immune cells in RA, as well as other heterogeneous, systemic autoimmune and inflammatory diseases, including UC, that would benefit from this novel approach targeting a central node of inflammation.”

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

About the Primary and Secondary Endpoints

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 is the threshold for LDA.

Additionally, secondary endpoint ACR20/50/70 responses are used to measure change in RA disease activity. For example, an ACR50 response requires a patient to have a 50% reduction in the number of swollen and tender joints, and a reduction of 50% 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 Health Assessment Questionnaire (HAQ) score. ACR20 and ACR70 responses require 20% and 70% reductions, respectively, across the measures listed above.

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. Efficacy and safety data from this trial, including translational data, will be presented at future medical meetings.

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, Feb. 12, 2025, at 8:30am ET / 5:30am PT. A live webcast of the call will be available on the Anaptys website at: https://ir.anaptysbio.com/events. A replay of the webcast will be available for at least 30 days following the event.

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. Other antibodies in its portfolio include ANB033, an anti-CD122 antagonist, in a Phase 1 trial and ANB101, a BDCA2 modulator, entering a Phase 1 trial. 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 at Week 28 and Phase 2 clinical trial in ulcerative colitis; and whether current trends in partial 28 Week data will be maintained once complete Week 28 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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