AnaptysBio Announces Portfolio Update Across Best-in-Class Immune Cell Modulating Antibodies

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- Advancing rosnilimab, its PD-1 agonist, into a global Phase 2b trial to treat rheumatoid arthritis with study initiation in Q3 2023
- Advancing ANB032, its BTLA agonist, into a global Phase 2b trial to treat atopic dermatitis with study initiation in Q2 2023
- Advancing rosnilimab into a second Phase 2 trial, in an indication to be announced, with study initiation anticipated by year-end 2023
- Blinded interim review of alopecia areata Phase 2a data demonstrated rosnilimab “proof of mechanism” with robust reductions in peripheral PD-1 high and PD-1+ T cells and suggests administration was generally safe and well tolerated; However, absolute SALT scores were not supportive of the target product profile and further development in alopecia areata will not be pursued
- Ended 2022 with greater than $575 million and approximately 4 years of capital

SAN DIEGO, Jan. 05, 2023 (GLOBE NEWSWIRE) -- AnaptysBio, Inc. (Nasdaq: ANAB), a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics, today announced a portfolio update including initiating development of its wholly owned best-in-class immune cell modulating antibodies in autoimmune and inflammatory diseases with large and significantly underserved patient populations. With cash, cash equivalents and investments greater than $575 million as of December 31, 2022, the company anticipates having approximately 4 years of capital to execute against its non-risk adjusted research and development plan, excluding potential future royalties from its GSK immuno-oncology financial collaboration.

“We have continued to progress our strategic portfolio review and are excited to announce the near-term initiation of two global Phase 2b trials across rosnilimab, our PD-1 agonist, in rheumatoid arthritis and ANB032, our BTLA agonist, in atopic dermatitis. We believe their mechanisms of action, with the potential to restore immune balance by acting directly on cell types mediating disease pathology, have the potential to meaningfully impact large and significantly underserved patient populations,” said Daniel Faga, interim president and chief executive officer of AnaptysBio. “We’re well capitalized to deliver on multiple Phase 2b readouts across our wholly owned checkpoint agonists as well as to advance ANB033, our anti-CD122 antagonist, through clinical proof-of-concept.”

Rosnilimab (PD-1 agonist antibody)

- Rosnilimab, its investigational wholly owned PD-1 agonist, demonstrates best-in-class activity in vitro with superior inhibition of T cell proliferation, reduction in inflammatory cytokine secretion (Th1, Th2, Th17) and depletion of PD-1+ T cells via effector function compared to Lilly PD-1 agonist
- PD-1+ T cells are clinically validated drivers of disease in rheumatoid arthritis (RA)
    - RA patient synovial biopsies have dense T cell infiltrates, with >80% of T cells expressing PD-1 and insufficient PD-L1 expression to down-regulate T cell activity
    - Rosnilimab targets multiple distinct inflammatory mechanisms addressed by approved therapies to treat RA
- Initiation in Q3 2023 of a global Phase 2b trial in moderate-to-severe RA
    - Multi-hundred patient placebo-controlled trial assessing three dose levels of subcutaneously administered rosnilimab for approximately 6 months on well-established endpoints including ACR20/50/70 and DAS28
    - Top-line interim data anticipated by mid-year 2025
- Second global Phase 2 trial, in an indication to be announced, with study initiation anticipated by year-end 2023
- Conducted a blinded interim review of alopecia areata Phase 2a data in December 2022
    - Enrolled 51 patients in a placebo-controlled trial assessing a single 400mg Q4W dosage of subcutaneously administered rosnilimab (randomized 2:1)
    - Study remains blinded with 100% of patients (n=38) through both week 20 dosing period and week 24 primary endpoint and 61% of patients (n=18) through week 32 follow-up period
- Demonstrated rosnilimab “proof of mechanism” with robust reductions in peripheral PD-1+ T cells, including PD-1 high T cell reduction of >80%, across blinded pooled rosnilimab treated and placebo patients, which is consistent with observations in the healthy volunteer Phase 1 trial of >90% in rosnilimab treated patients
- Suggests rosnilimab administration was generally safe and well tolerated

- Severity of Alopecia Tool (SALT) scores were not supportive of achieving the target product profile and further development in alopecia areata will not be pursued
    - While select patients observed changes from baseline SALT scores at week 24, no patients achieved an absolute SALT score <20
    - Interim results suggest that target efficacy was not achieved potentially due to an inadequate tested dose level, limited duration of treatment, and/or complexity of disease biology including the hair growth cycle
    - Unblinded week 32 results, tissue biopsies and additional translational data defining the extent of PD-1 modulation in the periphery and hair follicle will be available in H2 2023

ANB032 (BTLA agonist antibody)

- ANB032, its investigational wholly owned BTLA agonist, demonstrates best-in-class activity in vitro with superior inhibition of T cell proliferation and reduction in inflammatory cytokine secretion (Th1, Th2, Th17) compared to Lilly BTLA agonist
- While Th2 targeted therapies provide benefit to patients with chronic moderate-to-severe atopic dermatitis (AD), there is compelling evidence that AD is broader than a Th2 driven disease, as Th1, Th17 and other cell types, including dendritic cells, may contribute significantly to its pathogenesis
    - ANB032 inhibits inflammatory activity of Th1, Th2 and Th17 and modulates additional cell types such as B cells and dendritic cells, with the potential for broader, deeper and more durable responses than more narrowly targeted interventions
- Initiation in Q2 2023 of a global Phase 2b trial in moderate-to-severe AD
    - IND cleared by the FDA in December 2022
    - 160 patient placebo-controlled trial assessing three dose levels of subcutaneously administered ANB032 (randomized 1:1:1:1) for 12 weeks on well-established endpoints, including EASI75 and IGA 0/1
    - Top-line interim data anticipated by year-end 2024

ANB033 (anti-CD122 antagonist antibody)

- ANB033, its investigational wholly owned anti-CD122 antagonist antibody, targets the common beta subunit shared by the IL-15 and IL-2 receptors
    - IL-15 signaling mediates the survival and maintenance of tissue resident memory T cells (T_{RM})
    - The presence of long-lived and persistent T_{RM} have been shown to drive tissue-specific immune-mediated inflammation
- IND anticipated H1 2024

Legacy clinical-stage cytokine antagonist programs available for outlicensing

- Imsidolimab, its investigational wholly owned anti-IL-36r antagonist antibody, is in Phase 3 trials for generalized pustular psoriasis (GPP)
    - Top-line data from the GEMINI-1 Phase 3 trial anticipated Q4 2023
    - Plan to outlicense imsidolimab prior to potential FDA approval
- Etokimab, its investigational wholly owned anti-IL-33 antagonist antibody, is Phase 2/3-ready for the treatment of respiratory disorders
    - No further internal investment in etokimab is being pursued

GSK immuno-oncology financial collaboration

- Dostarlimab, an anti-PD-1 antagonist antibody, cobolimab, an anti-TIM-3 antagonist antibody, and GSK4074386, an anti-LAG-3 antagonist antibody, were discovered at AnaptysBio and licensed by GSK
- JEMPERLI (dostarlimab-gxly) has the potential for a first-in-class approval in primary advanced or recurrent endometrial cancer after meeting the primary endpoint in the pivotal RUBY Phase 3 trial demonstrating JEMPERLI plus chemotherapy significantly improved PFS versus chemotherapy plus placebo
    - Regulatory submissions anticipated H1 2023
    - GSK expects to publish full results in a medical journal and present at an upcoming scientific meeting
- Dostarlimab plus ZEJULA in the pivotal FIRST Phase 3 trial in 1st line ovarian cancer is ongoing with an interim analysis expected in H2 2023
- Dostarlimab plus cobolimab plus chemotherapy vs. dostarlimab plus chemotherapy is in the pivotal COSTAR Lung Phase 3 trial in advanced non-small cell lung cancer in patients who have progressed on prior anti-PD-(L)1 therapy

About AnaptysBio

AnaptysBio is a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics. It is developing immune cell modulating antibodies, including two checkpoint agonists in clinical-stage development, for autoimmune and inflammatory diseases: rosnilimab, its PD-1 agonist, in a planned Phase 2b trial for the treatment of moderate-to-severe rheumatoid arthritis; and ANB032, its BTLA agonist, in a planned Phase 2b trial for the treatment of moderate-to-severe atopic

dermatitis. Its preclinical immune cell modulator portfolio includes ANB033, an anti-CD122 antagonist antibody for the treatment of autoimmune and inflammatory diseases. AnaptysBio has developed two cytokine antagonists available for outlicensing: imsidolimab, an anti-IL-36r antagonist, in Phase 3 for the treatment of generalized pustular psoriasis, or GPP, and etokimab, an anti-IL-33 antagonist that is Phase 2/3 ready. AnaptysBio has also discovered antibodies licensed to GSK in a financial collaboration for immune-oncology, including an anti-PD-1 antagonist (JEMPERLI (dostarlimab-gxly)), an anti-TIM-3 antagonist (cobolimab, GSK4069889) and an anti-LAG-3 antagonist (GSK4074386).

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 initiation of the company's clinical trials, including rosnilimab's clinical trials in rheumatoid arthritis and in a second indication and ANB032's clinical trial in atopic dermatitis; the timing of the release of data from the company's clinical trials, including imsidolimab's Phase 3 clinical trial in GPP, rosnilimab's Phase 2b clinical trial in rheumatoid arthritis and ANB032's Phase 2b clinical trial in atopic dermatitis; the timing of ANB033's IND filing; statements regarding efficacy, safety and proof of mechanism from blinded data from rosnilimab's clinical trial in alopecia areata; the company's ability to find a licensing partner for imsidolimab or etokimab and the timing of any such transaction; and the company's projected 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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