AnaptysBio- and GSK-partnered immuno-oncology agent Jemperli (dostarlimab-gxly) plus chemotherapy demonstrates statistically significant and clinically meaningful improvement in progression-free survival for the treatment of primary advanced or recurrent

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- Results published in *The New England Journal of Medicine* and presented simultaneously at ESMO Virtual Plenary and SGO Annual Meeting
- 72% and 36% reduction in the risk of disease progression or death observed in the dMMR/MSI-H population and overall patient population, respectively
- Clinically meaningful overall survival trend observed at interim analysis
- GSK is planning regulatory submissions for the first half of 2023

SAN DIEGO, March 27, 2023 (GLOBE NEWSWIRE) -- AnaptysBio, Inc. (Nasdaq: ANAB), a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics, today announced that GSK has shared interim results from Part 1 of the RUBY/ENGOT-EN6/GOG3031/NSGO phase 3 trial investigating *Jemperli* (dostarlimab-gxly) plus standard-of-care chemotherapy (carboplatin-paclitaxel) followed by dostarlimab-gxly alone compared to chemotherapy plus placebo followed by placebo in adult patients with primary advanced or recurrent endometrial cancer. These data from GSK's RUBY clinical trial are being shared in a European Society for Medical Oncology (ESMO) Virtual Plenary, presented at the Society of Gynecologic Oncology (SGO) Annual Meeting on Women's Cancer (25-28 March) in Tampa, Florida and published simultaneously in *The New England Journal of Medicine*.

"We continue to be encouraged in the differentiated outcomes delivered by immuno-oncology antibodies discovered at AnaptysBio as GSK advances their development to treat multiple advanced solid tumors. The positive results from the RUBY trial represent a potential breakthrough for patients with primary advanced or recurrent endometrial cancer," said Daniel Faga, interim president and chief executive officer of AnaptysBio. "There is a potential significant royalty opportunity over time to AnaptysBio from *Jemperli* if this indication is approved, as well as from GSK's ongoing Phase 3 trials, including of dostarlimab in first line ovarian cancer and, in combination with cobolimab, a TIM-3 antagonist, in second line NSCLC."

For specific details on the results of Part 1 of the RUBY trial, please reference the GSK stock-exchange announcement here. The safety and tolerability profile of dostarlimab-gxly in combination with carboplatin/paclitaxel in the RUBY phase 3 trial was generally consistent with the known safety profiles of the individual agents.

GSK stated in its press release that its "ambition is for dostarlimab to become the backbone of the Company's ongoing immuno-oncology-based research and development program when used alone and in combination with standard of care and future novel cancer therapies, particularly for patients who currently have limited treatment options. Dostarlimab is being investigated in registrational enabling studies as monotherapy and as part of combination regimens, including in patients with recurrent or primary advanced endometrial cancer, patients with Stage III or IV non-mucinous epithelial ovarian cancer, and patients with other advanced solid tumors or metastatic cancers."

GSK also has advanced, in Q3 2022, both arms of the COSTAR Lung clinical trial to Phase 3, testing both doublet and triplet combinations of dostarlimab-gxly plus chemotherapy, and cobolimab (TIM-3 antagonist) plus dostarlimab-gxly plus chemotherapy in advanced non-small cell lung cancer.

Jemperli was discovered by AnaptysBio and licensed to TESARO, Inc., now a part of the GSK group of companies, under a Collaboration and Exclusive License Agreement signed in March 2014. GSK is responsible for the ongoing development and commercialization of *Jemperli*. AnaptysBio is entitled to receive milestones and tiered royalties of 8% for annual net sales of *Jemperli* below $1 billion and 12% up to 25% of annual net sales above $1 billion. In 2021, AnaptysBio monetized with Sagard Healthcare Royalty Partners certain commercial milestones and royalties for annual net sales of *Jemperli* below $1 billion up to a certain amount of receivables before such receivables revert back to AnaptysBio.

About Endometrial Cancer

Endometrial cancer is found in the inner lining of the uterus, known as the endometrium. Endometrial cancer is the most common gynecologic cancer globally, with approximately 417,000 new cases reported each year worldwide[i], and incidence rates are expected to rise by almost 40% by 2040.[ii][iii] Approximately 15-20% of patients with endometrial cancer will be diagnosed with

advanced disease at the time of diagnosis.[iv]

About RUBY

RUBY is a two-part global, randomized, double-blind, multicenter phase 3 trial of patients with primary advanced or recurrent endometrial cancer. Part 1 is evaluating dostarlimab-gxly plus carboplatin-paclitaxel followed by dostarlimab-gxly versus carboplatin-paclitaxel plus placebo followed by placebo. Part 2 is evaluating dostarlimab-gxly plus carboplatin-paclitaxel followed by dostarlimab-gxly plus niraparib versus placebo plus carboplatin-paclitaxel followed by placebo. The primary endpoints in Part 1 are investigator-assessed PFS based on the Response Evaluation Criteria in Solid Tumors v1.1 and OS. The statistical analysis plan included pre-specified analyses of PFS in the dMMR/MSI-H and ITT populations and OS in the overall population. Pre-specified exploratory analyses of PFS in the MMRp/MSS population and OS in the dMMR/MSI-H populations were also performed. Part 1 RUBY included a broad population, including histologies often excluded from clinical trials and had approximately 10% of patients with carcinosarcoma and 20% with serous carcinoma. In Part 2, the primary endpoint is investigator-assessed PFS. Secondary endpoints in Part 1 and Part 2 include PFS per blinded independent central review, overall response rate, duration of response, disease control rate, patient-reported outcomes, and safety and tolerability.

About *Jemperli* (dostarlimab-gxly)

Jemperli is a programmed death receptor-1 (PD-1)-blocking antibody that binds to the PD-1 receptor and blocks its interaction with the PD-1 ligands PD-L1 and PD-L2.[v]

Jemperli is not approved anywhere in the world for use in combination with standard-of-care chemotherapy (carboplatin-paclitaxel) followed by dostarlimab-gxly for primary advanced or recurrent endometrial cancer. In the US, *Jemperli* is indicated for adult patients with mismatch repair-deficient (dMMR) recurrent or advanced endometrial cancer, as determined by a US FDA-approved test, that has progressed on or following a prior platinum-containing regimen in any setting and are not candidates for curative surgery or radiation. *Jemperli* is also indicated in the US for patients with dMMR recurrent or advanced solid tumors, as determined by a US FDA-approved test, that have progressed on or following prior treatment and who have no satisfactory alternative treatment options. The latter indication is approved in the US under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication in solid tumors may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Please see full Prescribing Information here.

About AnaptysBio

AnaptysBio is a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics. It is developing immune cell modulators, including two checkpoint agonists in clinical-stage development, for autoimmune and inflammatory disease: 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. In addition, AnaptysBio has developed two cytokine antagonists available for out-licensing: 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 for the treatment of respiratory disorders that is Phase 2/3 ready. AnaptysBio has also discovered multiple therapeutic antibodies licensed to GSK in a financial collaboration for immune-oncology, including an anti-PD-1 antagonist antibody (*Jemperli* (dostarlimab-gxly)), an anti-TIM-3 antagonist antibody (cobolimab, GSK4069889) and an anti-LAG-3 antagonist antibody (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 regulatory submissions for *Jemperli* in this indication; and the company's ability to find a licensing partner for imsidolimab or etokimab and the timing of any such transaction. 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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[v] Laken H, Kehry M, Mcneeley P, et al. Identification and characterization of TSR-042, a novel anti-human PD-1 therapeutic antibody. European Journal of Cancer. 2016;69,S102. doi:10.1016/s0959-8049(16)32902-1.

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