AnaptysBio- and GSK-partnered immuno-oncology agent JEMPERLI (dostarlimab-gxly) meets primary endpoint in Phase 3 RUBY trial in primary advanced or recurrent endometrial cancer

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- **Pivotal Phase 3 (Part 1) trial demonstrates JEMPERLI plus chemotherapy significantly improved PFS versus chemotherapy plus placebo in patients with primary advanced or recurrent endometrial cancer**
- **First-in-class pivotal data in endometrial cancer, if approved, to be a potential significant driver of JEMPERLI royalties to AnaptysBio**

SAN DIEGO, Dec. 02, 2022 (GLOBE NEWSWIRE) -- AnaptysBio, Inc. (Nasdaq: ANAB), a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics, today announced that GSK's RUBY/ENGOT-EN6/GOG3031/NSGO Phase 3 trial of JEMPERLI (dostarlimab) plus standard of care chemotherapy compared to chemotherapy plus placebo in patients with primary advanced or recurrent endometrial cancer, met its primary endpoint of investigator-assessed progression-free survival (PFS). The JEMPERLI regimen showed a statistically significant and clinically meaningful benefit in the prespecified mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) patient subgroup and in the overall population. A clinically relevant benefit in PFS was also observed in the mismatch repair proficient (MMRp)/microsatellite stable (MSS) patient subgroup.

While the overall survival (OS) data were immature at the time of this analysis, a favorable trend was observed in the overall population, including both the dMMR/MSI-H and MMRp/MSS subgroups.

The safety and tolerability profile of dostarlimab plus chemotherapy was consistent with clinical trials of similar regimens.

Regulatory submissions based on the trial results are anticipated in the first half of 2023. GSK expects to publish full results from the RUBY trial in a medical journal and present at an upcoming scientific meeting.

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 net sales of JEMPERLI below $1 billion and 12% up to 25% of net sales above $1 billion. In 2021, AnaptysBio monetized with Sagard Healthcare Royalty Partners certain commercial milestones and royalties for net sales of JEMPERLI below $1 billion up to a certain amount of receivables before such receivables revert back to AnaptysBio.

"We are encouraged to see AnaptysBio-discovered molecules continue to deliver differentiated outcomes for patients in indications with substantial unmet need. We are grateful to our partners at GSK for enabling broad development of JEMPERLI and to the patients in the RUBY and other JEMPERLI trials for their participation," said Daniel Faga, interim president and chief executive officer of AnaptysBio. "We believe that potential first-in-class approvals for JEMPERLI in endometrial cancer and other indications could over time materially contribute to our strong capital position as we focus on the R&D of our immune cell modulator pipeline. This includes our two checkpoint agonists in clinical-stage development, rosnilimab, a PD-1 agonist, and ANB032, a BTLA agonist, which act directly on cell types mediating disease pathology and have the potential to treat a broad range of autoimmune and inflammatory disorders."

About RUBY

RUBY is a two-part global, randomised, double-blind, multicentre study of patients with primary advanced or recurrent endometrial cancer. Part 1 is evaluating dostarlimab plus carboplatin-paclitaxel followed by dostarlimab versus placebo plus carboplatin-paclitaxel followed by placebo. Part 2 is evaluating dostarlimab plus carboplatin-paclitaxel followed by dostarlimab plus niraparib versus placebo plus carboplatin-paclitaxel followed by placebo. The primary endpoints are progression-free survival (PFS), per RECIST v1.1 by investigator assessment, and overall survival in Part 1, and PFS in Part 2. Secondary endpoints include PFS per blinded independent central review (BICR), overall response rate, duration of response, disease control rate, patient-reported outcomes, and safety and tolerability. RUBY is part of an international collaboration of European Network of Gynaecological Oncological Trial groups (ENGOT) and the GOG Foundation.

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. JEMPERLI is being investigated in registrational enabling studies, as monotherapy and as part of combination regimens, including in women with recurrent or primary advanced endometrial cancer, women with stage III or IV non-mucinous epithelial ovarian cancer, and in patients with other advanced solid tumours or metastatic cancers.

JEMPERLI is indicated in the US for adult patients with dMMR recurrent or advanced endometrial cancer, as determined by an FDA-approved test, that have progressed on or following prior treatment with a platinum-containing regimen. JEMPERLI is also indicated in the US for dMMR recurrent or advanced solid tumours, as determined by an FDA-approved test, that have progressed on or following prior treatment and who have no satisfactory alternative treatment options. These indications are approved in the US under accelerated approval based on tumour response rate and durability of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). In the EU, JEMPERLI received conditional approval for adult patients with dMMR/MSI-H recurrent or advanced endometrial cancer who have progressed on or following prior treatment with a platinum-containing regimen.

About AnaptysBio

AnaptysBio is a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics. We are developing immune cell modulators, including two checkpoint agonists in clinical-stage development, for autoimmune and inflammatory disease: rosnilimab, our anti-PD-1 agonist program in Phase 2 for the treatment of moderate-to-severe alopecia areata; and ANB032, our anti-BTLA agonist program. AnaptysBio is also developing imsidolimab, our anti-IL-36R antibody in Phase 3 for the treatment of generalized pustular psoriasis, or GPP. Our preclinical and research portfolio includes ANB033, an anti-CD122 antagonist antibody for the treatment of inflammatory diseases. AnaptysBio has also developed antibodies in an immuno-oncology collaboration with GSK, 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).

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