



AnaptysBio- and GSK-Partnered Immuno-Oncology Agent JEMPERLI (dostarlimab-gxly) plus Chemotherapy Approved in the U.S. for dMMR/MSI-H Primary Advanced or Recurrent Endometrial Cancer

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- JEMPERLI is the first immuno-oncology treatment approved in the frontline setting for this patient population in combination with chemotherapy
- U.S. Food and Drug Administration approval represents a potential significant driver of JEMPERLI royalties
- Anticipate top-line data from two GSK Phase 3 studies that include JEMPERLI to read out in 2024: the FIRST study in first-line ovarian cancer (H1 2024) and the COSTAR study in second-line NSCLC (H2 2024)

SAN DIEGO, July 31, 2023 (GLOBE NEWSWIRE) -- AnaptysBio, Inc. (Nasdaq: ANAB), a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics, today announced that GSK has received U.S. Food and Drug Administration (FDA) approval for JEMPERLI (dostarlimab-gxly) plus carboplatin and paclitaxel (chemotherapy) for the treatment of adult patients with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) primary advanced or recurrent endometrial cancer. The supplemental Biologics License Application (sBLA) supporting this new indication received Priority Review and was approved ahead of the Sept. 23, 2023 Prescription Drug User Fee Act action date.

This approval is supported by interim analysis results from Part 1 of GSK's Phase 3 RUBY trial. The dual-primary endpoints in Part 1 are investigator-assessed progression-free survival (PFS) and overall survival (OS). The statistical analysis plan included pre-specified analyses of PFS in the dMMR/MSI-H and intent-to-treat (ITT) populations and OS in the overall population. Part 1 of the RUBY trial continues to assess the dual-primary endpoint of OS in the ITT population.

"We are excited that JEMPERLI plus chemotherapy has been FDA-approved as the first new frontline treatment option in decades for patients with dMMR/MSI-H primary advanced or recurrent endometrial cancer," said Daniel Faga, interim president and chief executive officer of AnaptysBio. "We believe that royalties of JEMPERLI from this approval, as well as its potential in first-line ovarian cancer, in combination with Zejula and in second-line NSCLC, in combination with cobolimab, if GSK's ongoing Phase 3 clinical trials lead to approvals, could over time contribute to our strong capital position as we focus on the development of our immune cell modulator pipeline, including our two checkpoint agonists in clinical-stage development, rosnilimab, a PD-1 agonist, and ANB032, a BTLA agonist."

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.

The sBLA supporting this new indication was reviewed under the FDA Oncology Center of Excellence Project Orbis Framework, which allowed for concurrent submission to and review by US and other international regulatory authorities. As part of Project Orbis, the application remains under review in Australia, Canada, Switzerland, Singapore and the United Kingdom. A marketing authorization application is also under review by the European Medicines Agency.

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 plus carboplatin-paclitaxel followed by dostarlimab versus carboplatin-paclitaxel plus placebo 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 dual-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 mismatch repair proficient (MMRp)/microsatellite stable (MSS) population and OS in the dMMR/MSI-H populations were also performed. RUBY Part 1 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. 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 tumors or metastatic cancers.

In the U.S., JEMPERLI is indicated for adult patients with mismatch repair-deficient (dMMR) recurrent or advanced endometrial cancer, as determined by an 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, and in combination with carboplatin and paclitaxel for the treatment of adult patients with primary advanced or recurrent endometrial cancer that is dMMR, as determined by an FDA-approved test, or microsatellite instability-high (MSI-H). The sBLA supporting this new indication received Breakthrough Therapy designation from the FDA. JEMPERLI is also indicated in the U.S. for patients with dMMR recurrent or advanced solid tumors, as determined by an 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 U.S. 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).

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, currently in a 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 initiation of the company's clinical trials, including rosnilimab's clinical trial in rheumatoid arthritis; whether the company will receive any future royalties from JEMPERLI sales; 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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