European Commission Approves JEMPERLI (dostarlimab), the First Anti-PD-1 Therapy Approved for Recurrent or Advanced dMMR/MSI-H Endometrial Cancer in Europe

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- PD-1 Antagonist Antibody Under Clinical Development for Solid Tumors in Collaboration with GlaxoSmithKline (GSK)
- First AnaptysBio-Generated Antibody, of 8 Currently Under Clinical Development, to Obtain Regulatory Approval in Europe
- $10MM Milestone Payment Earned by AnaptysBio Upon EC Approval; Additional $35MM and $165MM Milestones Due Upon Dostarlimab Regulatory and Commercial Milestones, Respectively
- AnaptysBio Due to Receive 8% to 25% Royalty on Global Net Sales of Dostarlimab

SAN DIEGO, April 23, 2021 (GLOBE NEWSWIRE) -- AnaptysBio, Inc. (Nasdaq: ANAB), a clinical-stage biotechnology company developing first-in-class antibody product candidates focused on emerging immune control mechanisms applicable to inflammation and immuno-oncology indications, today announced that the European Commission has granted conditional marketing authorization for JEMPERLI (dostarlimab) for use in women with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) recurrent or advanced endometrial cancer who have progressed on or following prior treatment with a platinum containing regimen. The approval makes dostarlimab the first anti-PD-1 therapy available for endometrial cancer in Europe.

JEMPERLI was generated by AnaptysBio using its proprietary somatic hypermutation (SHM) antibody platform and subsequently developed by TESARO, Inc., now a part of GSK, under a collaboration agreement. Eight AnaptysBio-generated therapeutic antibodies have advanced into clinical development to date, and JEMPERLI is the first AnaptysBio-generated antibody to obtain regulatory approval.

“We are delighted that JEMPERLI is the first AnaptysBio-generated antibody to be approved in Europe and look forward to meaningful potential future milestone and royalty revenue from our collaboration with GSK,” said Hamza Suria, president and chief executive officer of AnaptysBio. “These revenues will continue to support AnaptysBio’s primary value-creation strategy, which is focused on advancing wholly-owned first-in-class therapeutic antibodies through multiple upcoming clinical catalysts in 2021 and 2022.”

JEMPERLI is indicated as a monotherapy for treatment of adult patients with recurrent or advanced dMMR/MSI-H endometrial cancer, who have progressed on, or are being dosed following, prior treatment with a platinum-containing regimen, and is the first indication approved by the European Commission for JEMPERLI. AnaptysBio has earned a $10.0 million milestone payment as a result of this approval. Earlier this month, AnaptysBio earned a $20.0 million milestone payment as a result of approval by the U.S. Food and Drug Administration for JEMPERLI in endometrial cancer. In 2020, AnaptysBio received milestone payments of $10.0 million and $5.0 million for the FDA’s and EMA’s acceptances of the BLA and Marketing Authorisation Application (MAA) filings for JEMPERLI, respectively.

Earlier this year, FDA accepted a subsequent BLA filing for JEMPERLI for the treatment of adult patients with dMMR recurrent or advanced solid tumors who have progressed on or following prior treatment. AnaptysBio recently received a $10.0 million payment from GSK as a result of this milestone. Payments totaling an additional $35 million will be due to AnaptysBio upon the achievement of future regulatory milestones for JEMPERLI in the United States and Europe. Furthermore, $165 million in sales milestones are due to AnaptysBio upon achievement of certain annual JEMPERLI net sales revenues. Royalties due to AnaptysBio for dostarlimab range from 8% to 25% of global net sales, where AnaptysBio will receive 8% of annual global net sales below $1 billion, and 12-25% of net sales above $1 billion. JEMPERLI is also being developed by GSK for the treatment of other tumor types and treatment settings, including currently ongoing phase III trials in recurrent or primary advanced endometrial cancer in combination with chemotherapy standard of care (RUBY) and the phase III FIRST study of platinum-based therapy with dostarlimab and niraparib versus standard of care platinum-based therapy as first-line treatment of stage III or IV non-mucinous epithelial ovarian cancer.

In addition, JEMPERLI is being evaluated as monotherapy and in combination therapy across multiple tumor types and other cancers, including platinum-resistant ovarian cancer, non-small cell lung cancer, multiple myeloma and melanoma.

GSK continues to develop additional antibodies partnered with AnaptysBio, including cobolimab, an AnaptysBio-generated anti-TIM-3 antagonist antibody, and GSK4074386, an anti-LAG-3 antagonist antibody. Under the terms of the collaboration, AnaptysBio is due to receive development and regulatory milestone payments for each of the first two indications for each of these antibodies. AnaptysBio can potentially receive a total of $1.1 billion in aggregate milestone payments under this collaboration. In addition, AnaptysBio will receive royalties ranging from 4% to 8% on global net sales of cobolimab and GSK4074386 and 1% of GSK’s global net sales of ZEJULA ™.

Important Information for JEMPERLI in the EU

Indication
JEMPERLI is indicated as monotherapy for the treatment of adult patients with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) recurrent or advanced endometrial cancer (EC) that has progressed on or following prior treatment with a platinum-containing regimen.

Immune-Mediated Adverse Reactions
Immune-related adverse reactions, which may be severe or fatal, can occur in patients treated with antibodies blocking the programmed cell death protein-1 / programmed death-ligand 1 (PD-1/PD-L1) pathway, including JEMPERLI. While immune-related adverse reactions usually occur during treatment with PD-1/PD-L1 blocking antibodies, symptoms can also manifest after discontinuation of treatment. Immune-related adverse reactions may occur in any organ or tissue and may affect more than one body system simultaneously. Important immune-related adverse reactions listed in this section are not inclusive of all possible severe and fatal immune-related reactions.

Early identification and management of immune-related adverse reactions are essential to ensure safe use of PD-1/PD-L1 blocking antibodies. Patients should be monitored for symptoms and signs of immune-related adverse reactions. Clinical chemistries, including liver tests and thyroid function tests, should be evaluated at baseline and periodically during treatment. For suspected immune-related adverse reactions, adequate evaluation including specialty consultation should be ensured.

Based on the severity of the adverse reaction, treatment with JEMPERLI should be withheld or permanently discontinued and corticosteroids (1 to 2 mg/kg/day prednisone or equivalent) or other appropriate therapy administered. Upon improvement to Grade ≤1, corticosteroid taper should be initiated and continued for 1 month or longer. Based on limited data from clinical studies in patients whose immune-related adverse reactions could not be controlled with corticosteroid use, administration of other systemic immunosuppressants can be considered. Hormone replacement therapy for endocrinopathies should be instituted as warranted.

Treatment with JEMPERLI should be permanently discontinued for any Grade 3 immune-related adverse reaction that recurs and for any Grade 4 immune-related adverse reaction toxicity, except for endocrinopathies that are controlled with replacement hormones and unless otherwise specified in the Summary of Product Characteristics (SmPC).

Immune-Related Pneumonitis
Pneumonitis has been reported in patients receiving JEMPERLI. Patients should be monitored for signs and symptoms of pneumonitis. Suspected pneumonitis should be confirmed with radiographic imaging and other causes excluded. Patients should be managed with JEMPERLI treatment modifications and corticosteroids.

Immune-related pneumonitis occurred in 7 (1.4%) of 515 patients, including Grade 2 (1.2%) and Grade 3 (0.2%) pneumonitis. Pneumonitis led to discontinuation of JEMPERLI in 3 (0.6%) patients. Systemic corticosteroids (prednisone ≥ 40 mg per day or equivalent) were required in all 7 patients experiencing pneumonitis. Pneumonitis resolved in 6 (85.7%) patients.

Immune-Related Colitis
JEMPERLI can cause immune-related colitis. Patients should be monitored for signs and symptoms of colitis and managed with treatment modifications, anti-diarrhoeal agents and corticosteroids.

Colitis occurred in 8 (1.6%) patients, including Grade 2 (1.0%) and Grade 3 (0.6%) colitis. Colitis did not lead to discontinuation of JEMPERLI in any patients. Systemic corticosteroids (prednisone ≥ 40 mg per day or equivalent) were required in 2 (28.6%) patients. Colitis resolved in 6 (75.0%) patients experiencing colitis.

Immune-Related Hepatitis
JEMPERLI can cause immune-related hepatitis. Patients should be monitored for changes in liver function periodically as indicated, based on clinical evaluation and managed with JEMPERLI treatment modifications and corticosteroids.

Hepatitis occurred in 1 (0.2%) patient, which was Grade 3. Systemic corticosteroids (prednisone ≥ 40 mg per day or equivalent) were required. Hepatitis did not lead to discontinuation of JEMPERLI and resolved.

Immune-Mediated Endocrinopathies

Hypothyroidism occurred in 37 (7.2%) patients, all of which were Grade 2. Hypothyroidism did not lead to discontinuation of JEMPERLI and resolved in 13 (35.1%) patients.

Hyperthyroidism occurred in 10 (1.9%) patients, including Grade 2 (1.7%) and Grade 3 (0.2%). Hyperthyroidism did not lead to discontinuation of JEMPERLI and resolved in 8 (80%) patients.

Thyroiditis occurred in 2 (0.4%) patients; both were Grade 2. Neither event of thyroiditis resolved; there were no discontinuations of JEMPERLI due to thyroiditis.

Adrenal insufficiency occurred in 7 (1.4%) patients, including Grade 2 (0.8%), and Grade 3 (0.6%). Adrenal insufficiency resulted in discontinuation of JEMPERLI in 1 (0.2%) patient and resolved in 2 (28.6%) patients.

Immune-Mediated Nephritis
Nephritis, including tubulointerstitial nephritis, occurred in 3 (0.6%) patients; all were Grade 2. Systemic corticosteroids (prednisone ≥ 40 mg per day or equivalent) were required in 2 (66.7%) patients experiencing nephritis. Nephritis led to discontinuation of JEMPERLI in 1 (0.2%) patient and resolved in 2 of 3 (66.7%) patients.

Immune-Related Rash
Immune-related rash occurred in 17 (3.3%) patients, including Grade 3 in 6 (1.2%) patients receiving JEMPERLI. The median time to onset of rash was 41 days (range 2 days to 407 days). Systemic corticosteroids (prednisone ≥ 40 mg per day or equivalent) were required in 5 (29%) patients experiencing rash. Rash did not lead to discontinuation of JEMPERLI and resolved in 13 (76.5%) patients.

Immune-Related Arthralgia
Immune-related arthralgia occurred in 21 (4.1%) patients. Grade 3 immune-related arthralgia was reported in 3 (0.6%) patients receiving JEMPERLI. The median time to onset of arthralgia was 87 days (range 1 day to 783 days). Systemic corticosteroids (prednisone ≥ 40 mg per day or equivalent) were required in 2 (9.5%) patients experiencing arthralgia. Arthralgia did not lead to discontinuation of JEMPERLI and resolved in 8 (38%) patients experiencing arthralgia.

Other Immune-Related Adverse Reactions
Given the mechanism of action of JEMPERLI other potential immune-related adverse reactions may occur, including potentially serious events [e.g. myositis, myocarditis, encephalitis, demyelinating neuropathy (including Guillain Barré syndrome), sarcoidosis].

Clinically significant immune-related adverse reactions reported in less than 1% of patients treated with JEMPERLI as monotherapy in clinical studies include autoimmune haemolytic anaemia, pancreatitis, iridocyclitis, uveitis and diabetic ketoacidosis. Patients should be monitored for signs and symptoms of immune-related adverse reactions and managed as described in the SmPC.

Solid organ transplant rejection has been reported in the post-marketing setting in patients treated with PD-1 inhibitors. Treatment with JEMPERLI may increase the risk of rejection in solid organ transplant recipients. The benefit of treatment with JEMPERLI versus the risk of possible organ rejection should be considered in these patients.

Fatal and other serious complications can occur in patients who receive allogeneic haematopoietic stem cell transplantation (HSCT) before or after being treated with a PD-1/PD-L1–blocking antibody. Transplant-related complications include hyperacute graft-versus-host disease (GvHD), acute GvHD, chronic GvHD, hepatic veno-occlusive disease after reduced intensity conditioning, and steroid-requiring febrile syndrome (without an identified infectious cause). These complications may occur despite intervening therapy between PD-1/PD-L1 blockade and allogeneic HSCT. Follow patients closely for evidence of transplant-related complications and intervene promptly. Consider the benefit versus risks of treatment with a PD-1/PD-L1–blocking antibody prior to or after an allogeneic HSCT.

Infusion-Related Reactions
Infusion-related reactions including hypersensitivity occurred in 7 (1.4%) patients, including Grade 2 (1.2%) and Grade 3 (0.2%) infusion-related reactions. All patients recovered from the infusion-related reaction.

Immunogenicity
Anti-drug antibodies (ADA) were tested in 315 patients who received JEMPERLI and the incidence of JEMPERLI treatment-emergent ADAs was 2.5%. Neutralising antibodies were detected in 1.3% of patients. In the patients who developed anti-JEMPERLI antibodies, there was no evidence of altered efficacy or safety of JEMPERLI.

Elderly population
Of the 515 patients treated with JEMPERLI monotherapy, 50.7% were under 65 years, 37.9% were 65-75 years, and 11.5% were 75 years or older. No overall differences in safety were reported between elderly (≥ 65 years) and younger patients (< 65 years).

Pregnancy, Lactation and Fertility
JEMPERLI is not recommended during pregnancy and in women of childbearing potential not using contraception. JEMPERLI should not be used during breast-feeding and breast-feeding should be avoided for at least 4 months after the last dose of JEMPERLI. Fertility studies have not been conducted with JEMPERLI.

COMMON ADVERSE REACTIONS
JEMPERLI is most commonly associated with immune-related adverse reactions. Most of these, including severe reactions, resolved following initiation of appropriate medical therapy or withdrawal of JEMPERLI.

In patients with advanced or recurrent solid tumours (N = 515), the most common adverse reactions (> 10%) were anaemia (25.6%), nausea (25.0%), diarrhoea (22.5%), vomiting (18.4%), arthralgia (13.8%), pruritus (11.5%), rash (11.1%), pyrexia (10.5%) and hypothyroidism (10.1%). JEMPERLI was permanently discontinued due to adverse reactions in 17 (3.3%) patients; most of them were immune-related events. Adverse reactions were serious in 8.7% of patients; most serious adverse reactions were immune-related adverse reactions.

Refer to the JEMPERLI Prescribing Information for a full list of adverse events and the complete important safety information.

About AnaptysBio

AnaptysBio is a clinical-stage biotechnology company developing first-in-class antibody product candidates focused on unmet medical needs in inflammation. The Company's proprietary anti-inflammatory pipeline includes imsidolimab, its anti-IL-36R antibody, previously referred to as ANB019, for the treatment of dermatological inflammatory diseases, including generalized pustular psoriasis, or GPP, EGFRi skin toxicity, ichthyosis, hidradenitis suppurativa and acne; its anti-PD-1 agonist program, ANB030, for treatment of certain autoimmune diseases where immune checkpoint receptors are insufficiently activated; and its BTLA modulator program, ANB032, which is broadly applicable to human inflammatory diseases associated with lymphoid and myeloid immune cell dysregulation. AnaptysBio's antibody pipeline has been developed using its proprietary somatic hypermutation, or SHM platform, which uses in vitro SHM for antibody discovery and is designed to replicate key features of the human immune system to overcome the limitations of competing antibody discovery technologies. AnaptysBio has also developed multiple therapeutic antibodies in an immuno-oncology collaboration with GSK, including an anti-PD-1 antagonist antibody (JEMPERLI (dostarlimab-gxly) GSK4057190), an anti-TIM-3 antagonist antibody (cobolimab, GSK4069889) and an anti-LAG-3 antagonist antibody (GSK4074386), and an inflammation collaboration with Bristol-Myers Squibb, including an anti-PD-1 checkpoint agonist antibody (CC-90006) currently in clinical development.

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 milestones and royalty payments to be received under the GSK partnership and the timing of the release of data from our clinical trials. 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 our 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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