FDA Approves JEMPERLI (dostarlimab-gxly) for dMMR Endometrial Cancer

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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 FDA Approval
- $20MM Milestone Payment Earned by AnaptysBio Upon FDA Approval; Additional $45MM and $165MM Milestones Due Upon Dostarlimab Regulatory and Commercial Milestones, Respectively
- AnaptysBio Due to Receive 8% to 25% Royalty on Global Net Sales

SAN DIEGO, April 22, 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 U.S. Food and Drug Administration (FDA) approved GSK's Biologics License Application (BLA) for JEMPERLI (dostarlimab-gxly) for the treatment of 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 prior treatment with a platinum-containing regimen.

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 FDA approval.

"The approval of JEMPERLI is a transformative milestone for AnaptysBio. This event provides important validation for our proprietary SHM antibody discovery platform and provides significant potential future milestone and royalty revenue to support AnaptysBio's growth," said Hamza Suria, president and chief executive officer of AnaptysBio. "While AnaptysBio has partnered certain pipeline assets, our primary value-creation strategy remains focused on advancing wholly-owned, first-in-class therapeutic antibodies from discovery through development, and we look forward to multiple upcoming clinical data readouts from our product pipeline through 2021 and 2022."

Treatment of patients with recurrent or advanced dMMR endometrial cancer, who have progressed on, or are being dosed following, prior treatment with a platinum-based chemotherapy, is the first indication approved by the FDA for JEMPERLI. This indication is approved under accelerated approval based on tumor response rate and durability of response. AnaptysBio has earned a $20.0 million milestone payment as a result of this FDA approval. 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.

The FDA recently 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 $45 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 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 Safety Information for JEMPERLI

Indication

- JEMPERLI is indicated for the treatment of adult patients with mismatch repair deficient (dMMR) recurrent or advanced endometrial cancer (EC), as determined by an FDA-approved test, that has progressed on or following prior treatment with a platinum-containing regimen.
- This indication is approved under accelerated approval based on tumour response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Important Safety Information

Immune-Mediated Adverse Reactions

- Immune-mediated adverse reactions, which can be severe or fatal, can occur in any organ system or tissue and can occur at any time during or after treatment with a PD-1/PD-L1–blocking antibody, including JEMPERLI.
- Monitor closely for signs and symptoms of immune-mediated adverse reactions. Evaluate liver enzymes, creatinine, and thyroid function tests at baseline and periodically during treatment. For suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.
- Based on the severity of the adverse reaction, withhold or permanently discontinue JEMPERLI. In general, if JEMPERLI requires interruption or discontinuation, administer systemic corticosteroids (1 to 2 mg/kg/day prednisone or equivalent) until improvement to ≤Grade 1. Upon improvement to ≤Grade 1, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reaction is not controlled with corticosteroids.

Immune-Mediated Pneumonitis

- JEMPERLI can cause immune-mediated pneumonitis, which can be fatal. The incidence of pneumonitis in patients receiving PD-1/PD-L1 inhibitors, including JEMPERLI, may be increased in patients who have received prior thoracic radiation.
- Immune-mediated pneumonitis occurred in 1.1% (5/444) of patients, including Grade 2 (0.9%) and Grade 3 (0.2%) pneumonitis. Pneumonitis led to discontinuation of JEMPERLI in 0.7% of patients. Systemic corticosteroids were required in all patients with pneumonitis. Pneumonitis resolved in 80% of the 5 patients. Three patients reinitiated JEMPERLI after symptom improvement; of these, 33% had recurrence of pneumonitis.

Immune-Mediated Colitis

- JEMPERLI can cause immune-mediated colitis. Cytomegalovirus infection/reactivation have occurred in patients with corticosteroid-refractory immune-mediated colitis treated with PD-1/PD-L1–blocking antibodies. In cases of corticosteroid-refractory colitis, consider repeating infectious workup to exclude alternative etiologies.
- Immune-mediated colitis occurred in 1.4% (6/444) of patients, including Grade 3 (0.7%) and Grade 2 (0.7%). Colitis did not lead to discontinuation of JEMPERLI in any patients. Systemic corticosteroids were required in 17% (1/6) of patients with colitis. Colitis resolved in 50% of the 6 patients. Of the 2 patients in whom JEMPERLI was withheld for colitis, both reinitiated JEMPERLI.

Immune-Mediated Hepatitis

- JEMPERLI can cause immune-mediated hepatitis, which can be fatal. Immune-mediated Grade 3 hepatitis occurred in 0.2% (1/444) of patients. Systemic corticosteroids were required, and the event resolved.

Immune-Mediated Endocrinopathies

- Adrenal Insufficiency
  - JEMPERLI can cause primary or secondary adrenal insufficiency. For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment per institutional guidelines, including hormone replacement as clinically indicated. Withhold JEMPERLI if not clinically stable. Adrenal insufficiency occurred in 0.9% (4/444) of patients, including Grade 3 (0.5%) and Grade 2 (0.5%). Adrenal insufficiency resulted in discontinuation in 1 (0.2%) patient and resolved in 25% of the 4 patients.
- Hypophysitis
  - JEMPERLI can cause immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field cuts. Hypophysitis can cause hypopituitarism. Initiate hormone replacement as clinically indicated. Withhold JEMPERLI if not clinically stable.
- Thyroid Disorders
  - JEMPERLI can cause immune-mediated thyroid disorders. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement or medical management of hyperthyroidism as clinically indicated. Withhold JEMPERLI if not clinically stable.
  - Thyroiditis occurred in 0.5% (2/444) of patients; both were Grade 2. Neither event of thyroiditis resolved; there were no discontinuations of JEMPERLI due to thyroiditis.
  - Hypothyroidism occurred in 5.6% (25/444) of patients, all of which were Grade 2. Hypothyroidism did not lead to discontinuation of JEMPERLI and resolved in 40% of the 25 patients. Systemic corticosteroids were not required for

any of the 25 patients with hypothyroidism.
    - Hyperthyroidism occurred in 1.8% (8/444) of patients, including Grade 2 (1.6%) and Grade 3 (0.2%). Hyperthyroidism did not lead to discontinuation of JEMPERLI and resolved in 63% of the 8 patients. Systemic corticosteroids were not required for any of the 8 patients with hyperthyroidism.
- Type 1 Diabetes Mellitus, Which Can Present with Diabetic Ketoacidosis
    - JEMPERLI can cause type 1 diabetes mellitus, which can present with diabetic ketoacidosis. Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Withhold or permanently discontinue JEMPERLI depending on severity.

Immune-Mediated Nephritis with Renal Dysfunction

- JEMPERLI can cause immune-mediated nephritis, which can be fatal. Nephritis occurred in 0.5% (2/444) of patients; both were Grade 2. Nephritis did not lead to discontinuation of JEMPERLI and resolved in both patients. Systemic corticosteroids were required in 1 of the 2 patients experiencing nephritis.

Immune-Mediated Dermatologic Adverse Reactions

- JEMPERLI can cause immune-mediated rash or dermatitis. Bullous and exfoliative dermatitis, including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug rash with eosinophilia and systemic symptoms (DRESS), have occurred with PD-1/PD-L1–blocking antibodies. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-bullous/exfoliative rashes. Withhold or permanently discontinue JEMPERLI depending on severity.

Other Immune-Mediated Adverse Reactions

- The following clinically significant immune-mediated adverse reactions occurred in <1% of the 444 patients treated with JEMPERLI or were reported with the use of other PD-1/PD-L1–blocking antibodies. Severe or fatal cases have been reported for some of these adverse reactions.
    - *Nervous System:* Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis, Guillain-Barre syndrome, nerve paresis, autoimmune neuropathy
    - *Cardiac/Vascular:* Myocarditis, pericarditis, vasculitis
    - *Ocular:* Uveitis, iritis, other ocular inflammatory toxicities. Some cases can be associated with retinal detachment. Various grades of visual impairment to include blindness can occur.
    - *Gastrointestinal:* Pancreatitis, including increases in serum amylase and lipase levels, gastritis, duodenitis
    - *Musculoskeletal and Connective Tissue:* Myositis/polymyositis, rhabdomyolysis and associated sequelae including renal failure, arthritis, polymyalgia rheumatica
    - *Endocrine:* Hypoparathyroidism
    - *Other (Hematologic/Immune):* Haemolytic anaemia, aplastic anaemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenia, solid organ transplant rejection

Infusion-Related Reactions

- Severe or life-threatening infusion-related reactions have been reported with PD-1/PD-L1–blocking antibodies. Severe infusion-related reactions (Grade 3) occurred in 0.2% (1/444) of patients receiving JEMPERLI. All patients recovered from the infusion-related reactions.
- Monitor patients for signs and symptoms of infusion-related reactions. Interrupt or slow the rate of infusion or permanently discontinue JEMPERLI based on severity of reaction.

Complications of Allogeneic HSCT after PD-1/PD-L1–Blocking Antibody:

- Fatal and other serious complications can occur in patients who receive allogeneic hematopoietic stem cell transplantation (HSCT) before or after treatment with a PD-1/PD-L1–blocking antibody. 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.

Embryo-Fetal Toxicity and Lactation:

- Based on its mechanism of action, JEMPERLI can cause fetal harm. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with JEMPERLI and for 4 months after their last dose. Because of the potential for serious adverse reactions from JEMPERLI in a breastfed child, advise women not to breastfeed during treatment with JEMPERLI and for 4 months after their last dose.

Common Adverse Reactions

- The most common adverse reactions (Grades 1-4) in ≥10% of 104 dMMR endometrial cancer patients who received JEMPERLI as monotherapy were fatigue (48%), nausea (30%), diarrhoea (26%), anaemia (24%), constipation (20%), vomiting (18%), pruritus (14%), cough (14%), decreased appetite (14%), urinary tract infection (13%), and myalgia (12%).
- JEMPERLI was permanently discontinued due to adverse reactions in 5 (4.8%) patients, including transaminases

increased, sepsis, bronchitis, and pneumonitis. Dosage interruptions due to an adverse reaction occurred in 23% of patients who received JEMPERLI. Adverse reactions that required dosage interruption in ≥1% of patients who received JEMPERLI were anaemia, diarrhoea, increased lipase, and pyrexia.

Please see full Prescribing 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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