FDA Grants Accelerated Approval of JEMPERLI (dostarlimab-gxly) for dMMR Recurrent or Advanced Solid Tumors

August 17, 2021

- Second FDA Approval of PD-1 Antagonist Antibody Under Clinical Development for Solid Tumors in Collaboration with GSK
- JEMPERLI Was Approved For dMMR Endometrial Cancer in the US and Europe in April 2021
- $20MM Milestone Payment Earned by AnaptysBio Upon Second JEMPERLI FDA Approval in Addition to $40MM Already Earned Upon Prior Regulatory Milestones During 2021
- Additional $15MM and $165MM Milestones Due Upon Achievement of JEMPERLI Regulatory and Commercial Milestones, Respectively
- AnaptysBio Due to Receive 8% to 25% Royalty on Global Net Sales of JEMPERLI

SAN DIEGO, Aug. 17, 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 a second indication for GSK's JEMPERLI (dostarlimab-gxly) for the treatment of adult patients with mismatch repair deficient (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.

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. JEMPERLI is the first AnaptysBio-generated antibody to obtain FDA approval, and this is the second indication for JEMPERLI to be approved by the FDA in 2021. This indication is approved under accelerated approval based on tumor 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).

"We are pleased that JEMPERLI has been FDA-approved for a second indication and will be available to a broader cohort of solid tumor patients," said Hamza Suria, president and chief executive officer of AnaptysBio. "AnaptysBio's capital-efficient business model is focused upon advancing our wholly-owned first-in-class antibodies to multiple clinical catalysts over the upcoming 18 months and is supported by milestone and royalty revenues under our GSK collaboration."

AnaptysBio has earned a $20 million milestone payment as a result of this second FDA approval for JEMPERLI in dMMR recurrent or advanced solid tumors. Earlier in 2021, AnaptysBio received a milestone payment of $10 million from GSK for acceptance of the BLA filing with the FDA for this second indication. AnaptysBio also received $20 million and $10 million milestone payments in April 2021 for FDA and European Medicines Agency (EMA) approvals of JEMPERLI for adult patients with a certain type of endometrial cancer, after having received a total of $15 million from GSK during 2020 for the FDA's and EMA's acceptances of these BLA and Marketing Authorisation Application (MAA) filings for JEMPERLI. We anticipate an additional $15 million and $165 million in milestone payments upon achievement of certain JEMPERLI regulatory and commercial milestones, respectively. Royalties due to AnaptysBio for JEMPERLI 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. GSK has recently disclosed peak year annual sales estimates of £1-2 billion for JEMPERLI.[1]

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 JEMPERLI 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.

In the US, prevalence of dMMR across solid tumors has been estimated at 14%. Mismatch repair-deficient status is a biomarker that has been shown to predict response to immune checkpoint blockade with PD-1 therapy. Tumors with this biomarker are most commonly found in endometrial, colorectal and other gastrointestinal cancers, but may also be found in other solid tumors.

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 ™.

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[1] New GSK: new ambitions for patients and shareholders. June 23, 2021.

Please see full Prescribing Information here

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, acne, hidradenitis suppurativa, EGFRi skin toxicity and ichthyosis; rosnilimab, its anti-PD-1 agonist program, previously referred to as ANB030, for the 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. 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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