AnaptysBio and GlaxoSmithKline Amend Strategic Immuno-Oncology Collaboration

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- Dostarlimab royalties to AnaptysBio increase from 4-8% to 8-25% of global net sales, with first US approval in endometrial cancer anticipated in Q4 2020
- Additional 1% royalty to AnaptysBio on GSK's global net sales of Zejula™ (niraparib) starting January 2021
- GSK to pay one-time cash payment of $60MM to AnaptysBio within 30 days
- GSK obtains freedom to develop and commercialize Zejula™ in combination with third party molecules
- $75MM in dostarlimab FDA BLA and EMA MAA regulatory filing and approval cash milestones anticipated by AnaptysBio in upcoming 18 months

SAN DIEGO, Oct. 26, 2020 (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 AnaptysBio and GlaxoSmithKline (GSK) have amended their immuno-oncology collaboration agreement. The amended agreement provides AnaptysBio with increased royalties on dostarlimab sales under the collaboration, a royalty on GSK's Zejula™ and a one-time cash payment. GSK receives freedom to conduct combination development and commercialization of Zejula™ with third party molecules.

"We are pleased to continue our strategic immuno-oncology collaboration with GSK and look forward to the anticipated first FDA approval of dostarlimab," said Hamza Suria, chief executive officer of AnaptysBio. "The three clinical-stage antibodies under this collaboration were generated by AnaptysBio using our somatic hypermutation technology platform. While our internal focus is the advancement of AnaptysBio's wholly-owned first-in-class anti-inflammatory antibody pipeline, we are pleased to partner with GSK in advancing novel immuno-oncology therapies for patients suffering with cancer."

Originally signed with Tesaro in March 2014, the GSK collaboration is focused on advancing checkpoint receptor antagonist antibodies against PD-1, TIM-3 and LAG-3 in oncology. Dostarlimab is an anti-PD-1 antagonist antibody currently under development by GSK for multiple oncological disorders, including endometrial cancer, non-small cell lung cancer, ovarian cancer, colorectal cancer and mismatch repair deficient solid tumors. Cobolimab, an anti-TIM-3 antagonist antibody, and GSK4069889A, an anti-LAG-3 antagonist antibody, are also under development under this collaboration for various solid tumors. Dostarlimab is being combined with certain antibodies and small molecule agents, including cobolimab, GSK4069889A and Zejula™. First US FDA approval of dostarlimab is anticipated in Q4 2020 for the treatment of endometrial cancer, while MAA review is also underway for the same indication. A second BLA filing for dostarlimab, for the treatment of mismatch repair deficient cancers on a pan-tumor basis, is anticipated in the first half of 2021. Zejula™ is an oral, once-daily poly (ADP-ribose) polymerase (PARP) inhibitor, which has received US approval for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy regardless of biomarker status, and is under development for additional cancer indications.

Under the terms of the amended agreement, GSK has agreed to increase the royalties due to AnaptysBio upon net sales of dostarlimab. Previously, royalties ranged from 4-8%, where the 8% royalty tier was applicable to global net sales above $1 billion. The amended royalty terms range from 8-25%, where AnaptysBio will receive 8% of annual global net sales below $1 billion, and 12-25% of net sales above $1 billion. The $1.1 billion in cash milestone payments due under the collaboration agreement remain unchanged, and AnaptysBio anticipates receiving $75 million in such cash milestones over the next 18 months as dostarlimab obtains FDA and EMA regulatory approval for the first two indications. An additional $165 million in sales milestones is anticipated by AnaptysBio upon achievement of certain dostarlimab annual sales revenues. GSK has also agreed, starting January 1, 2021, to pay AnaptysBio a 1% royalty on all of GSK's global net sales of Zejula™. In addition, GSK has agreed to pay AnaptysBio a one-time cash payment of $60 million within 30 days.

In exchange, AnaptysBio has provided GSK with freedom to conduct development and commercialization of Zejula™ in combination with any third-party molecules.

About AnaptysBio
AnaptysBio is 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. The Company's proprietary anti-inflammatory pipeline includes its anti-IL-36R antibody imsidolimab, previously referred to as ANB019, for the treatment of rare inflammatory diseases, including generalized pustular psoriasis, or GPP, palmoplantar pustulosis, or PPP, EGFRi-mediated skin toxicities and ichthyosis; its anti-IL-33 antibody etokimab, previously referred to as ANB020, for the treatment of chronic rhinosinusitis with nasal polyps, or CRSwNP, and eosinophilic asthma; 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 GlaxoSmithKline, including an anti-PD-1 antagonist antibody (dostarlimab, GSK4057190A), an anti-TIM-3 antagonist antibody (cobolimab, GSK4069889A) 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 royalties, milestone payments and cash payments payable to the company, and the timing or outcome of any regulatory submission or approval of dostarlimab. 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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