AnaptysBio and GSK-partnered immuno-oncology agents JEMPERLI (dostarlimab-gxly) and cobolimab show positive progress in two separate non-small cell lung cancer trials

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- **Positive headline results from PERLA, a head-to head Phase 2 trial of JEMPERLI vs. Keytruda in patients with metastatic non-squamous non-small cell lung cancer**
- **COSTAR, a Phase 2 trial of JEMPERLI plus cobolimab, an anti-TIM-3 antagonist antibody licensed to TESARO, Inc. (GSK) as part of the same collaboration agreement as JEMPERLI, achieved pre-specified efficacy and safety criteria**
- **Combination of JEMPERLI plus cobolimab to advance to Phase 3 for the treatment of advanced non-small cell lung cancer where AnaptysBio expects to receive a $5 million milestone from GSK during Q4 2022 on dosing of the first patient with cobolimab**

SAN DIEGO, Oct. 05, 2022 (GLOBE NEWSWIRE) -- AnaptysBio, Inc. (Nasdaq: ANAB), a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics, today announced that GSK's study PERLA, a head-to-head trial of JEMPERLI vs. Keytruda in patients with metastatic non-squamous non-small cell lung cancer, met its primary endpoint of objective response rate (ORR) of dostarlimab plus chemotherapy versus pembrolizumab plus chemotherapy as assessed by blinded independent central review per RECIST v1.1.

GSK expects to present full results from the PERLA trial, including the primary endpoint of ORR and the key secondary endpoint of progression-free survival, with results by programmed death ligand-1 (PD-L1) expression subgroups, at an upcoming scientific meeting.

AnaptysBio also announced today that GSK is advancing both arms of the COSTAR Lung clinical trial from Phase 2 to Phase 3, testing both doublet and triplet combinations of dostarlimab plus chemotherapy, and cobolimab plus dostarlimab plus chemotherapy in advanced non-small cell lung cancer. This decision follows the recommendation of the trial's Independent Data Monitoring Committee, reflecting the achievement of pre-specified efficacy and safety criteria per the COSTAR protocol.

The COSTAR Lung Phase 3 trial is a randomized, open label 3-arm trial comparing cobolimab plus dostarlimab plus docetaxel to dostarlimab plus docetaxel to docetaxel alone in patients with advanced NSCLC who have progressed on prior anti-PD-(L)1 therapy and chemotherapy. AnaptysBio expects to receive a $5 million milestone payment from GSK upon dosing of the first patient with cobolimab in the Phase 3 portion of COSTAR.

JEMPERLI and cobolimab were discovered at 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 research, development, commercialization and manufacturing of each of these monoclonal antibody therapies under the agreement.

"We are encouraged to see immuno-oncology molecules discovered at Anaptys delivering differentiated outcomes and advancing on multiple fronts by GSK," said Daniel Faga, interim president and chief executive officer of AnaptysBio. "We intend to leverage our strong capital position, which has been supported in part from the partial monetization of potential future royalty streams from this immuno-oncology portfolio, as we focus on the R&D of our novel immune cell modulator pipeline. This includes our two checkpoint agonists in clinical-stage development, rosnilimab, a PD-1 agonist, and ANB032, a BTLA-agonist, which act directly on cell types mediating disease pathology and have the potential to treat a broad range of autoimmune and inflammatory disorders."

About PERLA
The PERLA phase 2 trial is a global, randomized, double-blind trial of 243 patients evaluating the efficacy and safety of dostarlimab plus chemotherapy compared to pembrolizumab plus chemotherapy in patients with metastatic non-squamous NSCLC without a known sensitizing epidermal growth factor receptor, anaplastic lymphoma kinase, or receptor tyrosine kinase-1 mutation, V600E mutation of the BRAF gene or other genomic mutation for which an approved targeted therapy is available. Patients were randomized 1:1 to receive either dostarlimab 500 mg intravenous (IV) or pembrolizumab 200 mg IV every three weeks in combination with chemotherapy. Patients were stratified by PD-L1 expression (TPS <1% versus 1%–49% versus ≥50%) and smoking status (never vs former/current). The primary endpoint was objective response rate of dostarlimab plus chemotherapy versus pembrolizumab plus chemotherapy assessed by blinded independent central review per RECIST v1.1. Secondary endpoints include overall survival, investigator-assessed progression-free survival per RECIST v1.1, and safety.

About COSTAR Lung
The COSTAR Lung trial (NCT04655976) is a phase 2/3 global, randomized, open-label trial of 750 patients. The study evaluates

the efficacy and safety of cobolimab plus dostarlimab plus docetaxel and dostarlimab plus docetaxel compared to docetaxel in patients with advanced non-squamous and squamous NSCLC whose disease had progressed on prior therapy with an anti-PD-(L)1 agent and a platinum doublet-based chemotherapy given in combination or in sequence. The study does not include patients with a known sensitizing epidermal growth factor receptor, anaplastic lymphoma kinase, or receptor tyrosine kinase-1 mutation, for which an approved targeted therapy is available. Patients are randomized 2:2:1 to receive either cobolimab 300 mg plus dostarlimab 500mg plus docetaxel 75 mg/m2 intravenous (IV) every three weeks (Q3W) or dostarlimab 500mg plus docetaxel 75 mg/m2 IV Q3W or docetaxel 75 mg/m2 IV Q3W. Patients are stratified by prior line of therapy (1 vs 2), PD-L1 expression (TPS ≥50% versus <50%) and histology (non-squamous vs squamous). The primary endpoint at interim analysis 1 (IA1) was objective response rate between arms as assessed by blinded independent central review per RECIST v1.1 and evaluated by an independent data monitoring committee (IDMC). The primary endpoint at final analysis is overall survival.

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.vii 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. JEMPERLI is not approved anywhere in the world in combination with chemotherapy in first-line patients with metastatic non-squamous NSCLC or in combination with other agents to treat patients with advanced NSCLC who have progressed on prior anti-PD-L1 therapy and chemotherapy.

About Cobolimab
Cobolimab is an investigational monoclonal antibody against the inhibitory receptor, T-cell immunoglobulin and mucin domain-containing protein 3 (TIM-3), with potential immune checkpoint inhibitory and antineoplastic activities.

About AnaptysBio
AnaptysBio is a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics. We are developing immune cell modulators, including two checkpoint agonists in clinical-stage development, for autoimmune and inflammatory disease: rosnilimab, our anti-PD-1 agonist program in Phase 2 for the treatment of moderate-to-severe alopecia areata; and ANB032, our anti-BTLA agonist program, which is broadly applicable to human inflammatory diseases associated with lymphoid and myeloid immune cell dysregulation. AnaptysBio is also developing imsidolimab, our anti-IL-36R antibody in Phase 3 for the treatment of generalized pustular psoriasis, or GPP. AnaptysBio's antibody pipeline has been developed using our 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).

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