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Aurigene announces initiation of CA-170 phase 2 trial

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Aurigene Discovery Technologies Limited, a wholly owned subsidiary of Dr. Reddy's Laboratories Ltd. and a specialized biotechnology company engaged in discovery and early clinical development of novel and best-in-class therapies to treat cancer and inflammatory diseases, announced plans to initiate a Phase 2 trial of CA-170, a PDL1-VISTA inhibitor to be conducted at sites in India.

This was announced following the presentation of preliminary data from the initial 34 patients with cancer treated in the dose escalation stage of the Phase 1 trial of CA-170 at the European Society for Medical Oncology (ESMO) 2017 Congress by Aurigene's collaborator and licensee of CA-170, Curis, Inc., a biotechnology company focused on the development and commercialization of innovative and effective therapeutics for the treatment of cancer. The trial has been conducted in the U.S., South Korea and Spain. The Phase 2 trial is the result of the initial safety data and preliminary evidence of clinical benefit observed in the trial.

CA-170 is an oral small molecule targeting the immune checkpoints PDL1 and VISTA. Data presented at the ESMO 2017 conference represent the initial 34 patients treated to date in the dose escalation Phase 1 trial. 30 patients were naïve to prior immunotherapy treatment, while four patients had experienced prior treatment with approved anti-checkpoint antibodies. No dose limiting toxicities were observed at doses ranging from 50 mg to 800 mg once daily dosing examined thus far. CA-170 demonstrated good oral bioavailability and plasma drug levels were shown to increase in a near-linear manner with increasing doses.

Evidence of immune modulation, including an increase in activated CD8+ T cells, was observed in patient blood and tumor biopsy samples examined following treatment. Of the 21 patients evaluable for disease assessment, 13 patients experienced disease stabilization. Four immunotherapy treatment-naïve patients treated with CA-170 experienced shrinkage of their tumors. Six patients remained on drug treatment beyond three months, including all four patients with tumor shrinkages. In addition, seven of the 34 patients remain on study and are continuing with treatment.

“These results are consistent with the observations made in the preclinical setting and further affirm CA-170’s mechanism of action as an oral small molecule checkpoint inhibitor. Based on these initial clinical results, we are excited for the opportunity to expand testing of CA-170, possibly in earlier lines of treatment and in a greater number of immunotherapy treatment-naïve cancer patients,” commented Mr. CSN Murthy, Chief Executive Officer of Aurigene. “Together with Curis, we have designed a Phase 2 trial, treating selected populations of patients of interest in the CA-170 program to be treated at major cancer centers in India. Aurigene’s decision to sponsor and fund this trial is further affirmation of our commitment to CA-170 and a reflection of the successful collaboration we have with Curis in multiple development programs. Aurigene has the commercial rights to the program in India and Russia in addition to milestones, royalties other commercial supply rights globally.”

“We are pleased with these early results. Evidence of tumor shrinkage and multiple patients remaining on drug treatment for extended periods, along with signals for biomarkers of immune modulation in patient blood and tumor samples, tells us the program continues to move in the right direction. We plan to continue with the dose escalation and continued analysis of patient biopsy samples in the Phase 1 trial,” said Ali Fattaey, Ph.D., President and Chief Executive Officer of Curis. “We expect to provide additional updates at upcoming conferences including the Society for Immunotherapy of Cancer (SITC) annual meeting in November.”

“The ability for cancer patients to administer a potential checkpoint inhibitor on their own as a once daily oral drug is a significant and unique opportunity in our field,” added Adil Daud, M.D., investigator in the CA-170 Phase 1 trial and director of Melanoma Clinical Research at the UCSF Helen Diller Family Comprehensive Cancer Center. “These initial clinical results are encouraging and merit continued development.”