Strategia Therapeutics Initiates a Phase 1/2a Clinical Trial of the Anti-cancer Agent E6201 in Patients with Advanced Hematologic Malignancies

BOSTON—(BUSINESS WIRE) – Strategia Therapeutics, Inc. (Strategia) – from the company’s former name, Boston Strategics. Corp. – has begun a Phase 1/2a clinical trial of anti-cancer agent E6201 in patients with advanced hematologic malignancies, including relapsed or refractory acute myeloid leukemia (AML), high-risk myelodysplastic syndromes (MDS) and chronic myelomonocytic leukemia (CMML). The trial is being carried out at the University of Texas M.D. Anderson Cancer Center with Gautam Borthakur, M.D., as the Principal Investigator.

There are approximately 19,000 new cases of AML in the U.S. each year, with over 10,000 deaths; the number of patients estimated to be living with AML is 40,000. Patients relapsed or refractory to currently available therapy have limited options. MDS is a type of hematological malignancy, in which the disorder of blood-forming “hematopoietic stem cells” causes inefficient production of blood cells triggering cytopenia. It is also a refractory disease for some patients with poor prognosis, progressing to acute myeloid leukemia. The U.S. incidence of MDS is 14,000 cases per year, most of them in the senior age group.

E6201, discovered by Eisai Co., Ltd., is a dual-inhibitor of FMS-like tyrosine kinase 3 (FLT-3) and mitogen-activated protein (enzyme) kinase (MEK). Activation of FLT3 is observed in patients with AML carrying either internal tandem duplication (ITD) or point (D835) mutations in the FLT3 gene, and E6201 has demonstrated activity against both mutations. The Ras/Raf signaling pathway signals through the downstream signal transducers MEK1 and extracellular signal-related kinases (ERK) and activation of this pathway is seen in AML cells of patients failing FLT3 inhibitor therapy. Preclinical studies conducted by Dr. Borthakur indicate inhibition of both pathways is important to durable responses.

The University of Texas MD Anderson Cancer Center is one of the world’s top general cancer centers with over 10,000 patients enrolled in therapeutic clinical trials each year and approximately 20,000 employees. Strategia is able to utilize the world’s top-level clinical testing functions available at the MD Anderson Cancer Center under a Strategic Alliance Agreement to carry out Phase 1 and early Phase 2 clinical trials to gain safety and preliminary proof of activity in cancer patients at an early stage. “This drug may be important for patients with advanced hematologic malignancies who have failed conventional therapeutics, including single-agent FLT3 inhibitors”, said Gautam Borthakur, M.B.B.S., Associate Professor of Leukemia at M.D. Anderson Cancer Center. By inhibition of both the FLT3 and MEK pathways we hope to provide more durable clinical benefit than through inhibition of one pathway alone. This study will build on our preclinical evidence, and further this important clinical research at our institution.”
“This is the first proprietary drug under full development by Strategia. Both FLT3 and MEK are important new targets for the treatment of advanced hematologic malignancies. Inhibition of both pathways known to be involved in the progression of FLT3 positive AML is an important next step in new targeted therapeutics for the treatment of this disease”, said Dr. Linda Paradiso, Head of Drug Development for Strategia. “We have in-licensed E6201 from Eisai Co., Ltd. and they have been an excellent collaborative partner. Both companies are fully committed to deliver breakthrough therapies using innovative approaches to achieve industry benchmark-beating timelines, quality, and financial investments for important novel anti-cancer agents”.

About Strategia Therapeutics, Inc. (Strategia)

Strategia is an innovative pharmaceutical R&D company with experience in developing, managing and optimizing global drug development programs. Its mission is to create a new model for collaborative drug development by bringing together small, global expert teams, each of which has expertise specific to a single drug. By focusing its efforts in this way, Strategia rapidly and successfully moves each project forward to completion while keeping internal infrastructure small and streamlined.

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