Astex Pharmaceuticals and MD Anderson Announce Strategic Collaboration to Accelerate Clinical Evaluation of Therapies for Patients with Leukemia

Pleasanton, CA, and Houston, TX – September 8th, 2020. -- Astex Pharmaceuticals, Inc., a wholly owned subsidiary of Otsuka Pharmaceutical Co. Ltd., based in Tokyo, Japan, and The University of Texas MD Anderson Cancer Center today announces a strategic collaboration agreement aimed at accelerating the clinical evaluation of Astex's pipeline of products for patients with certain types of leukemia, including myelodysplastic syndromes (MDS), chronic myelomonocytic leukemia (CMML) and acute myeloid leukemia (AML). The collaboration will combine MD Anderson's clinical trials infrastructure and expertise with Astex's clinical pipeline products.

The initial focus will be on evaluating Astex's oral decitabine and cedazuridine hypomethylating agent (INQOVI®) in combinations with other therapies. INQOVI recently was approved by the US FDA and by Health Canada for the treatment of intermediate- and high-risk MDS and CMML.

"MD Anderson is dedicated to providing the best treatment options to our patients, and there is tremendous interest in evaluating how a new generation of oral targeted therapies might work in combination to treat those with leukemia," said Guillermo Garcia-Manero, M.D., Professor and Chief of Section of Myelodysplastic Syndromes, Department of Leukemia at MD Anderson. "This collaboration with Astex will allow us to expand those studies with the ultimate goal of providing patients with oral drug combinations that have the potential of improving clinical outcomes."

Under the collaboration agreement, MD Anderson and Astex will design new clinical studies to be conducted at MD Anderson. Astex will provide funding, test compounds and other support. The collaboration will be overseen by a joint steering committee.

"MD Anderson has been a collaborator with Astex on multiple clinical studies for our pipeline products," said Mohammad Azab, president & chief medical officer of Astex. "We are delighted to be entering into this new collaboration and look forward to continuing to advance this important area of clinical research."

About INQOVI (See https://www.inqovi.com)

INQOVI is indicated for treatment of adult patients with myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Myelosuppression: Fatal and serious myelosuppression can occur with INQOVI. Based on laboratory values, new or worsening thrombocytopenia occurred in 82% of patients, with Grade 3 or 4 occurring in 76%. Neutropenia occurred in 73% of patients, with Grade 3 or 4 occurring in 71%. Anemia occurred in 71% of patients, with Grade 3 or 4 occurring in 55%. Febrile neutropenia occurred in 33% of patients, with Grade 3 or 4 occurring in 32%.

Fatal and serious infectious complications can occur with INQOVI. Pneumonia occurred in 21% of patients, with Grade 3 or 4 occurring in 15%. Sepsis occurred in 14% of patients, with Grade 3 or 4 occurring in 11%. Fatal pneumonia occurred in 1% of patients, fatal sepsis in 1%, and fatal septic shock in 1%.

Obtain complete blood cell counts prior to initiation of INQOVI, prior to each cycle, and as clinically indicated to monitor response and toxicity. Administer growth factors, and anti-infective therapies for treatment or prophylaxis as appropriate. Delay the next cycle and resume at the same or reduced dose as recommended.

Embryo-Fetal Toxicity: INQOVI can cause fetal harm. Advise pregnant women of the potential risk to a fetus. Advise patients to use effective contraception during treatment with INQOVI and for 6 months (females) or 3 months (males) after last dose.

ADVERSE REACTIONS

Serious adverse reactions in > 5% of patients included febrile neutropenia (30%), pneumonia (14%), and sepsis (13%). Fatal adverse reactions included sepsis (1%), septic shock (1%), pneumonia (1%), respiratory failure (1%), and one case each of cerebral hemorrhage and sudden death.

The most common adverse reactions (≥ 20%) were fatigue, constipation, hemorrhage, myalgia, mucositis, arthralgia, nausea, dyspnea, diarrhea, rash, dizziness, febrile neutropenia, edema, headache, cough, decreased appetite, upper respiratory tract infection, pneumonia, and transaminase increased. The most common Grade 3 or 4 laboratory abnormalities (≥50%) were leukocytes decreased, platelet count decreased, neutrophil count decreased, and hemoglobin decreased.

USE IN SPECIFIC POPULATIONS

Lactation: Because of the potential for serious adverse reactions in the breastfed child, advise women not to breastfeed during treatment with INQOVI and for at least 2 weeks after the last dose.

Renal Impairment: No dosage modification of INQOVI is recommended for patients with mild or moderate renal impairment (creatinine clearance [CLcr] of 30 to 89 mL/min based on Cockcroft-Gault). Due to the potential for increased adverse reactions, monitor patients with moderate renal impairment (CLcr 30 to 59 mL/min) frequently for adverse reactions. INQOVI has not been studied in patients with severe renal impairment (CLcr 15 to 29 mL/min) or end-stage renal disease (ESRD: CLcr <15 mL/min).

Please see the Full Prescribing Information at:

https://www.inqovi.com/pi

INQOVI is being commercialized by Taiho Oncology, Inc. and Taiho Pharma Canada, Inc. in the U.S. and Canada respectively. Taiho and Astex are members of the Otsuka group of companies

About MD Anderson

The University of Texas MD Anderson Cancer Center in Houston ranks as one of the world's most respected centers focused on cancer patient care, research, education and prevention. The institution's sole mission is to end cancer for patients and their families around the world. MD Anderson is one of only 51 comprehensive cancer centers designated by the National Cancer Institute (NCI). MD Anderson is ranked No.1 for cancer care in U.S. News & World Report's "Best Hospitals" survey. It has ranked as one of the nation's top two hospitals for cancer care since the survey began in 1990 and has ranked first 16 times in the last 19 years. MD Anderson receives a cancer center support grant from the NCI of the National Institutes of Health (P30 CA016672).

About Astex Pharmaceuticals, Otsuka Pharmaceutical and Taiho Oncology

Astex Pharmaceuticals, Inc. is a leader in innovative drug discovery and development, committed to the fight against cancer. Astex is developing a proprietary pipeline of novel therapies and has multiple partnered products in development under collaborations with leading pharmaceutical companies. Astex is a wholly owned subsidiary of Otsuka Pharmaceutical Co. Ltd., based in Tokyo, Japan.

Otsuka Pharmaceutical Co., Ltd. is a global healthcare company with the corporate philosophy: "Otsuka–people creating new products for better health worldwide." Otsuka researches, develops, manufactures and markets innovative and original products, with a focus on pharmaceutical products for the treatment of diseases and nutraceutical products for the maintenance of everyday health.

Taiho Oncology, Inc., is a subsidiary of Taiho Pharmaceutical Co., Ltd. and an indirect subsidiary of Otsuka Holdings Co., Ltd. Taiho has established a world-class clinical development organization that works urgently to develop innovative cancer treatments and has built a commercial business in the U.S. Taiho has an oral oncology pipeline consisting of both novel antimetabolic agents and selectively targeted agents.

For more information about Astex Pharmaceuticals, Inc. please visit: https://www.astx.com

For more information about Otsuka Pharmaceutical, please visit: https://www.otsuka.co.jp/en/

For more information about Taiho Pharmaceutical, please visit: https://www.taihooncology.com/

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