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Strategia Therapeutics Announces Progress in a Phase 1 Clinical Trial of the Anti-cancer Agent “FF-10501-01” for FUJIFILM in Patients with Advanced Hematologic Malignancies

BOSTON—(BUSINESS WIRE) – Strategia Therapeutics, Inc. (Strategia), is announcing progress in a Phase 1 clinical trial of FUJIFILM’s anti-cancer agent, FF-10501-01 in the United States in patients with relapsed or refractory myelodysplastic syndromes (MDS) and acute myeloid leukemia (AML). The emerging results reveal that, in the Phase 1 dose escalation phase thus far (5 dose cohorts), FF-10501-01 has been highly tolerable and has demonstrated promising preliminary efficacy.

These results were published at the 57th American Society of Hematology Meeting by Professor Guillermo Garcia-Manero MD, Principal Investigator, University of Texas MD Anderson Cancer Center.

Strategia is a primary global strategic drug development provider for FUJIFILM Pharmaceuticals U.S.A., Inc. (FPHU) facilitated the preclinical study in hypo-methylating agent (HMA) resistant leukemia cell lines as well as the design and execution of the Phase 1 clinical trial of FF-10501-01 in patients with hematologic malignancies in the United States both conducted at MD Anderson Cancer Center.

In the preclinical study, FF-10501-01 produced potent anti-proliferative and pro-apoptotic effects in AML cell lines through inhibition of de novo guanine nucleotide synthesis, with similar positive effects in HMA-resistant AML cell lines.

In the Phase 1 study, a total of 5 dose cohorts have been enrolled (50 – 400 mg/m² orally twice daily) in 17 patients (13 AML, 4 MDS). Although the trial is still underway, preliminary findings thus far are:

- FF-10501-01 has been well-tolerated to date
- FF-10501-01 produced 2 PRs lasting 2 cycles among 13 patients with relapsed/refractory AML, and 4 patients remain on treatment after 5 -15 cycles
- FF-10501-01 produced 1 bone marrow CR among 4 patients with relapsed/refractory MDS
- PK parameters for FF-10501-01 were linear across the dose range tested
- PD analysis showed potent xanthosine monophosphate suppression in patients receiving \geq 50 mg/m² BID

Additional Phase 1 dose cohorts of 500, 600 and 800 mg/m² BID will be assessed. The Phase 2 portion of the study will open when a recommended Phase 2 dose is determined.

“We are deeply committed to giving our new pharmaceutical R&D platform for FPHU which looks for an innovative and efficient way of globally developing their unique oncology pipelines such as FF-



10501-01.” says Dr. Keizo Koya, CEO of Strategia. “Our special alliance and innovative collaboration with MD Anderson and Fujifilm will translate the highest-quality science into proven clinical success in an efficient and nimble manner for patients in needs.”

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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