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FORMA Therapeutics' Olutasidenib Demonstrates Positive Phase 1b/2 Results, Including Blood-Brain Barrier Penetration And Stable Disease In Patients With IDH1-Mutated Glioma

– Data Presented at the 2019 Society for NeuroOncology Annual Meeting –

WATERTOWN, Mass. – November 21, 2019 – FORMA Therapeutics Inc., a clinical stage biopharmaceutical company focused on rare hematologic diseases and cancers, today announced positive Phase 1b/2 results from an ongoing study in patients with IDH1-mutated gliomas. The data, presented at the 2019 Society for NeuroOncology Annual Meeting (SNO), demonstrate blood-brain barrier penetrance, as exhibited by cerebrospinal fluid exposure, and disease response to olutasidenib, a next-generation IDH1m inhibitor.

"The safety profile and clinical activity observed to date with olutasidenib in patients with recurrent and often life-threatening gliomas are exciting," said Patrick Kelly, M.D., chief medical officer at FORMA Therapeutics. "In patients with a predominantly enhancing relapsed/refractory glioma, we achieved a clinical response with half of the patients still on study treatment at four months. Particularly for patients with late-stage gliomas where the disease progresses quickly, maintaining disease control holds promise."

FORMA is conducting a Phase 1b/2 study evaluating the safety, efficacy and pharmacokinetics/pharmacodynamics of olutasidenib for patients with advanced solid tumors and gliomas. The trial, 2102-ONC-102, is an open-label, single-agent dose-confirmation study in up to five cohorts (glioma, hepatobiliary tumors, chondrosarcoma, intrahepatic cholangiocarcinoma and other IDH1 mutant solid tumors). Results announced today are based on continuous oral treatment for 24 patients with advanced IDH1 mutant glioma.

"These data create a compelling profile for olutasidenib as a next generation IDH1m inhibitor," said Frank Lee, chief executive officer of FORMA Therapeutics. "Our goal at FORMA is to offer patients first-in-class and best-in-class medicines, and the early results announced today bring us closer to this goal."

Phase 2 of FORMA's study is ongoing, evaluating both olutasidenib monotherapy and olutasidenib in combination with azacitidine in patients with confirmed IDH1 gene-mutated advanced glioma. Full study results will be reported in 2020.

Presentation Overviews

Phase 1b/2 study of FT-2102, an inhibitor of mutant IDH1, in patients with relapsed/refractory IDH1 mutant gliomas: preliminary safety and clinical activity

E-talk Presentation by Macarena de la Fuente, M.D., Sylvester Cancer Center, University of Miami

Findings presented regarding olutasidenib monotherapy in the Phase 1 cohort of 24 patients with confirmed IDH1 gene-mutated advanced glioma, the majority of which were enhanced and high-grade glioma. Dr. de la Fuente discusses data that:

- Demonstrate blood-brain barrier penetration as measured by cerebrospinal fluid exposure and disease control;
- Confirm partial response in one patient and stable disease in 10 patients with enhancing glioma with a median duration of treatment of 3.7 months;
- Indicate steady-state olutasidenib plasma concentrations in glioma patients within two weeks of initiation of dosing, which remained consistent over time;
- Demonstrate acceptable safety profile in patients with relapsed/refractory IDH1-mutated glioma at 150 mg BID; and
- Report no trial discontinuations due to treatment-emergent adverse events (TAEs). Grade 3-4 TAEs in greater than 10 percent of patients included increased ALT, increased AST, decreased platelet count, vomiting and hemiparesis. Transaminase elevations resolved without consequential impact in all patients.

FT-2102 – A Potent and Selective Brain Penetrant Inhibitor of Mutant Isocitrate Dehydrogenase

Oral presentation by Maria Ribadeneira, Ph.D., executive director of DMPK and clinical pharmacology at FORMA Therapeutics

Data demonstrate broad in vitro activity against the major IDH1-R132 mutations observed in glioma. Olutasidenib was observed to be more than 1000-fold selective in R132H, the more common mutation observed in glioma, as compared to IDH1 wild type, and showed potent in vivo suppression of tumor 2-HG in a mouse xenograft (cellular accumulation of 2-HG impairs cell differentiation and promotes tumorigenesis). Data also show olutasidenib to be highly brain penetrant in a rat model.

About Olutasidenib (FT-2102)

FORMA Therapeutics' most advanced clinical asset, olutasidenib, is designed to be a potent and selective next generation inhibitor of mutated isocitrate dehydrogenase 1 (IDH1m) to treat patients with relapsed/refractory acute myeloid leukemia (R/R AML) or myelodysplastic syndrome (MDS), as well as patients with glioma and other solid tumors with an IDH1 mutation. IDH1 is a natural enzyme that is part of the normal metabolism of all cells; when mutated, its activity can promote blood malignancies and solid tumors. IDH1 mutations are present in 7-14% of patients with AML and more than 70% of patients with gliomas. In gliomas, IDH1 mutations occur early in the tumor pathogenesis and persist throughout progression from a neural stem or progenitor cell. Gliomas are the most common, aggressive and difficult-to-treat primary brain tumors, and high-grade gliomas are associated with poor long-term prognosis, with a median survival ranging from five to seven years. Treatment options for relapsed glioma are limited.

About FORMA Therapeutics

FORMA Therapeutics is focused on the discovery, development and commercialization of transformative medicines for patients with rare hematologic diseases and cancers. A fully-integrated biopharmaceutical company, FORMA's validated, proprietary R&D engine combines

deep biology insight, chemistry expertise and clinical development capabilities to create differentiated drug candidates with best-in-class or first-in-class potential. FORMA has delivered high-value clinical candidates to its partners and generated a broad proprietary portfolio of programs, ranging from preclinical to pivotal-stage, with the potential to provide profound patient benefit. For more information, please visit the company website at www.formatherapeutics.com or follow us on Twitter @FORMAInc and LinkedIn.

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