

PRESS RELEASES

September 11, 2019

FORMA Therapeutics Announces Data For IDH1m Inhibitor Olutasidenib In Glioma To Be Presented At The 2019 Society For NeuroOncology Annual Meeting

– Data to highlight the penetration of olutasidenib across the blood brain barrier and preliminary safety and clinical activity from an ongoing Phase 1b/2 study –

WATERTOWN, Mass. – September 11, 2019 – FORMA Therapeutics announced today that abstracts for the company’s next generation IDH1m inhibitor, olutasidenib (FT-2102), have been accepted for two presentations at the 2019 Society for NeuroOncology Annual Meeting, taking place November 20-24, 2019 in Phoenix, Arizona. Olutasidenib was designed to have a differentiated efficacy, durability and safety profile, as well as blood brain barrier penetrance, and is intended to treat all cancers with IDH1 mutations, including acute myeloid leukemia (AML), myelodysplastic syndrome (MDS), gliomas and other solid tumors.

“I am proud of the progress FORMA has made in the first eight months of 2019 and am truly excited for this next phase of growth for our company centered on our wholly-owned therapeutic pipeline focused on rare hematologic diseases and cancers,” said Frank Lee, CEO of FORMA Therapeutics.

Olutasidenib Status in Gliomas/Solid Tumors:

- An ongoing [Phase 1b/2 study](#) of olutasidenib is enrolling patients with gliomas or other advanced solid tumors with an IDH1 mutation.
- Data from olutasidenib clinical trials have been submitted for presentation at medical meetings in the fourth quarter of 2019. Abstracts accepted for presentation at SNO include:
 - Oral Presentation: *FT-2102 – A Potent and Selective Brain Penetrant Inhibitor of Mutant Isocitrate Dehydrogenase*
Date and Time: Wednesday, November 20, 2019, 9:45-9:55 AM, MST
Oral Abstract Session: BBB Physiology at the SNO-SCIDOT Joint Conference on Therapeutic Delivery to the CNS
Presenter: Maria Ribadeneira, PhD, FORMA Therapeutics
 - E-Talk Presentation: *Phase 1 study of FT-2102, an inhibitor of mutant IDH1, in patients with relapsed/refractory IDH1 mutant gliomas: preliminary safety and clinical activity*
Date and Time: Saturday, November 23, 2019, 5:20 PM – 5:24 PM, MST
E-Talks Session: Group 1: Adult Therapeutics/Immunology Rare Tumors
Presenter: Macarena de la Fuente, MD, Sylvester Cancer Center, University of Miami

About Olutasidenib (FT-2102)

FORMA's most advanced clinical asset, olutasidenib was designed as a potent and selective next generation inhibitor of mutated isocitrate dehydrogenase 1 (IDH1m) intended to treat patients with relapsed/refractory acute myeloid leukemia (RR/AML) or myelodysplastic syndrome (MDS), and 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, but when mutated its activity can promote blood malignancies and solid tumors. IDH1 mutations are present in up to 16% of patients with AML and over 80% of patients with low-grade gliomas. In AML, hypermethylation driven by IDH mutations inhibits normal differentiation of progenitor cells leading to accumulation of immature blasts. Quality of life declines with each successive line of treatment for AML and well-tolerated treatments in relapsed disease remain an unmet need. 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 5 to 7 years. Treatment options for relapsed glioma are limited. The rationale for targeting IDH1m is to reverse the oncogenic hypermethylated state to reduce tumor burden through induction of differentiation of immature blasts in AML and by slowing or stopping cancer cell growth in glioma.

In addition to the ongoing Phase 1b/2 study in patients with gliomas and other advanced solid tumors with an IDH1 mutation, a [multi-cohort study](#) with olutasidenib as a single agent and in combination with azacitidine is currently enrolling patients with AML and MDS, including a pivotal arm with olutasidenib as a single agent in R/R AML. Patients with treatment-naïve AML and R/R MDS with IDH1m are also being evaluated. Top-line data in patients with R/R AML are expected in the first half of 2020. If there is a positive outcome in R/R AML patients, a new drug application (NDA) is expected to be filed in the second half of 2020.

About FORMA

FORMA Therapeutics is a privately-held, clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of transformative medicines that will make a difference for patients in need. 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 pre-clinical to pivotal-stage, with the potential to provide profound patient benefit in hematologic, oncologic, and metabolic indications. For more information, please visit the company website at www.formatherapeutics.com.

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