



Forma Therapeutics Announces Four Presentations on Etavopivat and Olutasidenib at Upcoming 2021 ASH Annual Meeting

November 4, 2021

Two oral presentations on etavopivat include data from Forma's Phase 1 open label extension trial in sickle cell disease demonstrating a favorable tolerability profile consistent with previously-reported results

Additional data supports improvement in markers of red blood cell health for people living with sickle cell disease

One oral and one poster presentation include data from ongoing Phase 2 trial of olutasidenib as a single agent and in combination with azacitidine supporting a favorable tolerability profile, clinical activity and induction of a durable composite complete remission (CR) or CR plus CR with partial hematologic recovery (CRh) in high-risk patients with mIDH1 AML

WATERTOWN, Mass.--(BUSINESS WIRE)--Nov. 4, 2021-- [Forma Therapeutics Holdings, Inc.](#) (Nasdaq: FMTX), a clinical-stage biopharmaceutical company focused on sickle cell disease, prostate cancer and other rare hematologic diseases and cancers, today announced that four abstracts have been accepted for presentation – including three oral presentations and one poster presentation – at the 63rd American Society of Hematology (ASH) Annual Meeting taking place Dec. 11-14, 2021.

Two oral presentations will feature clinical data on a Phase 1 trial of etavopivat, the company's oral, once-daily, selective pyruvate kinase-R (PKR) activator for the treatment of sickle cell disease (SCD). One abstract evaluates the ability of etavopivat to improve anemia and decrease intravascular hemolysis. A second abstract shows the effects of etavopivat on improving red blood cell health and lifespan, as well as reduction in systemic markers of inflammation and hypercoagulability. A third abstract highlights clinical data from the Phase 2 trial of olutasidenib, the company's selective inhibitor for cancers with mutations in isocitrate dehydrogenase 1 (IDH1m) being evaluated in patients with relapsed/refractory acute myeloid leukemia (R/R AML).

"We're pleased that these abstracts were selected for oral and poster presentation at the ASH annual meeting," said Patrick Kelly, M.D., chief medical officer of Forma Therapeutics. "We look forward to sharing updated data at the meeting on the profile of etavopivat in sickle cell patients to not only increase hemoglobin but also to improve markers of hemolysis, as well as red blood cell health and red blood cell lifespan. In addition, the new olutasidenib results indicate potential for use as a single agent and in combination therapy with azacitidine to provide benefit in patients with relapsed/refractory AML."

The abstracts are currently available on the [ASH website](#).

Oral Presentations:

Title: FT-4202, Activation of Pyruvate Kinase-R with Etavopivat (FT-4202) Is Well Tolerated, Improves Anemia, and Decreases Intravascular Hemolysis in Patients with Sickle Cell Disease Treated for up to 12 Weeks

Date/Time: Saturday, Dec. 11, at 9:45 AM ET

Session: 114

Abstract: 147091

Presenter: R. Clark Brown, MD, PhD

Title: FT-4202, Etavopivat, an Allosteric Activator of Pyruvate Kinase-R, Improves Sickle RBC Functional Health and Survival and Reduces Systemic Markers of Inflammation and Hypercoagulability in Patients with Sickle Cell Disease: An Analysis of Exploratory Studies in a Phase 1 Study

Date/Time: Saturday, Dec. 11, at 10:00 AM ET

Session: 114

Abstract: 147078

Presenter: Theodosia A. Kalfa, MD, PhD

Title: FT-2102, Olutasidenib (FT-2102) in Combination with Azacitidine Induces Durable Complete Remissions in Patients with mIDH1 Acute Myeloid Leukemia

Date/Time: Monday, Dec. 13, at 3:00 PM ET

Session: 616

Abstract: 144905

Presenter: Jorge E. Cortes, MD

Poster Presentation:

Title: FT-2102, Molecular Characteristics of Response to Olutasidenib (FT-2102) in Patients with Relapsed/Refractory mIDH1 Acute Myeloid Leukemia

Date/Time: Sunday, December 12th at 6:00-8:00 PM ET

Session: 616

Abstract: 144912

Presenter: Stéphane de Botton, MD, PhD

About Etavopivat

Etavopivat is an investigational, once-daily, selective red blood cell (RBC) pyruvate kinase-R (PKR) activator designed to be a disease-modifying therapy for the treatment of sickle cell disease (SCD). Employing a multimodal approach, etavopivat is designed to work by activating the RBCs' natural PKR activity to decrease 2,3-DPG levels, which leads hemoglobin to hold on to oxygen molecules longer to reduce polymerization and RBC sickling. Etavopivat-mediated PKR activation also increases ATP levels, the fuel that provides energy to cells, to improve RBC health and survival. Together, these effects are anticipated to increase hemoglobin levels and decrease painful vaso-occlusive crises. In preclinical safety studies, etavopivat did not inhibit aromatase activity or affect steroidogenesis, important biological processes responsible for sexual development. Etavopivat has been granted Fast Track, Rare Pediatric Disease and Orphan Drug designations from the U.S. Food and Drug Administration (FDA), and Orphan Drug Designation from the European Commission based on a positive opinion from the Committee for Orphan Medicinal Products of the European Medicines Agency for the treatment of patients with SCD.

About Olutasidenib

Olutasidenib is an oral, potent, small-molecule investigational agent designed to selectively bind to and inhibit mutated IDH1 enzymes. This targeted treatment has the potential to provide therapeutic benefit by reducing 2-HG levels and restoring normal cellular differentiation. With the conclusion of the Phase 2 R/R AML trial, Forma has begun preparing a new drug application (NDA) for submission to the U.S. Food and Drug Administration (FDA).

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 6-8% of patients with AML and as many as 70 to 80% of patients with grade II/III gliomas and secondary glioblastoma. 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. Treatment options for relapsed glioma are limited.

About Forma Therapeutics

Forma Therapeutics is a clinical-stage biopharmaceutical company focused on the research, development and commercialization of novel therapeutics to transform the lives of patients with rare hematologic diseases and cancers. Our R&D engine combines deep biology insight, chemistry expertise and clinical development capabilities to create drug candidates with differentiated mechanisms of action focused on indications with high unmet need. Our work has generated a broad proprietary portfolio of programs with the potential to provide profound patient benefit. For more information, please visit www.FormaTherapeutics.com or follow us on Twitter @FORMAInc and LinkedIn.

Forward-looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, express or implied statements regarding future plans for etavopivat and olutasidenib, including expectations regarding timing, success and data announcements of our current ongoing clinical trials; therapeutic potential, clinical benefits, mechanisms of action and safety of our product candidates; planned regulatory submissions, including an NDA for olutasidenib; and our planned presentation of data at the ASH annual meeting. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, those risks and uncertainties related to the advancement of our clinical programs and other risks identified in our SEC filings, including those risks discussed under the heading "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, as well as other risks detailed in our subsequent filings with the SEC. We caution you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. We disclaim any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent our views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

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