Forma Therapeutics Reviews 2020 Highlights and Outlines Key 2021 Milestones

January 11, 2021

Strong pipeline progress in 2020 positions company well for 2021

Established proof of concept in SCD for FT-4202

Potential transformative treatment profile for IDH1 inhibitor olutasidenib in R/R/ AML

Enrolling Phase 1 FT-7051 trial for prostate cancer - including patient with AR-v7 splice variants

Completed successful IPO and follow-on equity offering

WATERTOWN, Mass.--(BUSINESS WIRE)--Jan. 11, 2021-- Forma Therapeutics Holdings, Inc. (Nasdaq: FMTX), a clinical-stage biopharmaceutical company focused on rare hematologic diseases and cancers, today provided a review of corporate highlights from 2020 and outlined anticipated key clinical program milestones for 2021.

"While 2020 was marked by tremendous challenges due to the COVID-19 pandemic, Forma made important strides due to the courage of patients and the dedication of our employees. We reported promising results from our clinical programs including FT-4202 in sickle cell disease, olutasidenib in both AML and glioma, and FT-7051 in prostate cancer, and also raised approximately $695 million in public equity offerings," said Frank Lee, president and chief executive officer of Forma. "In this coming year, we anticipate continued progress, and look forward to advancing drug candidates that we believe have the potential to significantly impact patients living with rare hematologic diseases and cancers."

Clinical Program Highlights and Milestones

PKR Program in Sickle Cell Disease (SCD):

FT-4202 is a novel investigational selective red blood cell pyruvate kinase R (PKR) activator Forma is actively evaluating in a multi-center, placebo-controlled Phase 1 trial in individuals with sickle cell disease ages 12 years and older.

- **In June 2020, encouraging single dose cohort data were reported at the 25th European Hematology Association (EHA) Annual Congress.** Initial findings from Forma's Phase 1 trial of FT-4202 in patients with SCD demonstrated a favorable tolerability profile and biologic effects, with evidence of pharmacodynamic activity.
- **In December 2020, clinical proof-of-concept data were presented at the 62nd American Society of Hematology (ASH) Annual Meeting and Exposition.** Forma presented data from a multi-dose cohort of its Phase 1 trial of FT-4202 in patients with SCD, showing that 86% of patients dosed with 300 mg of FT-4202 for 14 days achieved a hemoglobin increase of greater than 1 g/dL from baseline. The observed reduction in hemolysis in conjunction with the biomarker analysis showing improved deformability and hydration of RBCs supports the hypothesis that pyruvate kinase activation may have an impact on vaso-occlusive crises (VOCs).
- **Additional clinical data anticipated from the ongoing Phase 1 randomized placebo-controlled trial in SCD patients.** Data from the MAD2 600 mg cohort of the Phase 1 trial is expected to be reported in the first quarter of 2021, followed by results from the 12-week open-label extension in the second quarter of 2021.
- **Expanding FT-4202 development program.** Forma has initiated a global pivotal Phase 2/3 trial of FT-4202 in SCD patients, with plans to initiate a Phase 2 trial in thalassemia in the second half of 2021, and a pediatric SCD trial in the first half of 2022.

IDH1 Program in AML and Glioma:

Olutasidenib (FT-2102) is a selective inhibitor for cancers with IDH1 mutations Forma is evaluating for the treatment of acute myeloid leukemia (AML) and glioma. Olutasidenib is currently being studied in a registrational Phase 2 trial for relapsed/refractory (R/R) AML and an exploratory Phase 1 trial for glioma.

- **In May 2020, positive data for olutasidenib in glioma was announced at the American Society of Clinical Oncology (ASCO).** Forma announced positive preliminary Phase 1 data for olutasidenib in refractory, enhancing glioma at ASCO 2020, suggesting the potential for response and prolonged disease control in relapsed/refractory IDH1-mutated glioma patients.
- **In October 2020, positive data for olutasidenib in a registrational trial for R/R AML was announced.** Forma announced positive results from the planned interim analysis of the Phase 2 registration trial of olutasidenib in R/R AML patients with IDH1 gene mutations. Olutasidenib as a monotherapy demonstrated a favorable tolerability profile and achieved a composite complete remission (CR/CRh) rate of 33.3% (30% CR and 3% CRh), the primary efficacy endpoint.

While a median duration of CR/CRh has not yet been reached, a sensitivity analysis indicated the median duration of CR/CRh to be 13.8 months. Further data analysis indicates an estimated 87% survival rate at 18 months in patients who respond to treatment with olutasidenib. Olutasidenib's potential transformative treatment profile is based upon three key indicators: durability of response and increased survival for responders, favorable tolerability suggesting ability to combine with other therapies, and properties to support indication expansion to other IDH1 mutated cancers.

- **Forma has begun preparing for a new drug application for olutasidenib in R/R AML**.

CPB/p300 Program in Prostate Cancer:

FT-7051 is a potent and selective CBP/p300 inhibitor Forma is evaluating for the treatment of metastatic prostate cancer resistant to androgen receptor (AR) signaling inhibitor therapy.

- **In April 2020, preclinical data on FT-6876 (a research compound related to FT-7051) in breast cancer was presented at the American Association for Cancer Research (AACR).** Forma presented preclinical data that demonstrated antitumor activity of FT-6876 in AR-dependent breast cancer cell lines, suggesting that FT-6876 could serve as a treatment for patients with other AR-dependent tumors, such as prostate cancer.
- **Phase 1 underway in 2021.** In December 2020, Forma initiated recruitment in a Phase 1 trial of FT-7051 in men with metastatic castration-resistant prostate cancer including those with AR-v7 splice variants. Dosing in this trial is anticipated to begin in early in the first quarter of 2021. Forma plans to disclose initial safety, tolerability and preliminary response data in the second half of 2021.

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 our beliefs and expectations regarding its: our business plans and objectives; future plans for FT-4202, FT-7051, and olutasidenib, including expectations regarding timing and success of the current ongoing clinical trials as well as planned future clinical trials, therapeutic potential and clinical benefits thereof, and upcoming milestones for our other product candidates; the planned timing and potential submission of new drug applications for olutasidenib in R/R AML, growth as a company and the anticipated contribution of our employees and the members of our board of directors to our operations and progress; presentation of additional data at upcoming scientific conferences, and other preclinical data in 2021; the potential commercial and collaboration opportunities, including potential future collaborators and parties, as well as value and market, for our product candidates; uses of capital, expenses and other 2021 financial results or in the future, and the potential impact of COVID-19 on patient retention, strategy, future operations, clinical trials or IND submissions. 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 September 30, 2020, 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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