Forma Therapeutics Announces First Patient Dosed in Phase 1 Clinical Trial Evaluating FT-7051 for the Treatment of Metastatic Castration-resistant Prostate Cancer (mCRPC)

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Phase 1 study includes late-line patients and patients with AR-v7 splice variants for whom there are no approved therapies

FT-7051 is a selective inhibitor of CREB-binding protein/E1A binding protein p300 (CBP/p300) and a co-activator of androgen receptor

In prostate cancer cell lines in vitro, FT-7051 demonstrated inhibition of AR-dependent gene expression and a reduction in androgen receptor expression; also demonstrated antiproliferative activity in AR-positive prostate cancer cell lines, including resistance variant AR-v7 positive models

WATERTOWN, Mass.--(BUSINESS WIRE)--Jan. 20, 2021-- Forma Therapeutics Holdings, Inc. (Nasdaq: FMTX), a clinical-stage biopharmaceutical company focused on rare hematologic diseases and cancers, today announced that the first patient has been dosed in a Phase 1 clinical trial evaluating FT-7051, a selective inhibitor of CBP/p300, a known co-activator of the androgen receptor (AR) in men with metastatic castration-resistant prostate cancer (mCRPC).

"While a patient with mCRPC may initially respond to standard anti-androgen therapies, a significant unmet need persists since nearly all patients ultimately become resistant to these treatments," said David N. Cook, Ph.D., chief scientific officer of Forma Therapeutics. "Initiating enrollment in this Phase 1 trial is an important step toward our goal of providing mCRPC patients with an additional therapeutic option to treat this severe illness."

Study Design

The Phase 1 trial is a multicenter, open-label evaluation of the safety and tolerability, preliminary anti-tumor activity (PSA and radiographic responses), and pharmacokinetics/pharmacodynamics (PK/PD) of FT-7051 in men with mCRPC who have progressed despite prior therapy and have been treated with at least one potent anti-androgen therapy. This is an adaptive trial design, intended to accelerate the escalation to potentially therapeutic doses and yield important safety information. More information about this trial may be accessed at Clinicaltrials.gov (identifier: NCT04575766).

About FT-7051

FT-7051 is a selective inhibitor of CREB-binding protein/E1A binding protein p300 (CBP/p300) and a co-activator of androgen receptor (AR). In prostate cancer cell lines *in vitro*, FT-7051 demonstrated inhibition of AR-dependent gene expression and reductions in androgen receptor expression. FT-7051 also demonstrated antiproliferative activity in AR-positive prostate cancer cell lines, including resistance variant AR-v7 positive models.

About Metastatic Castration-resistant Prostate Cancer

Prostate cancer is the second leading cause of cancer death for men in the U.S., and mCRPC is the most advanced form of this disease. Prostate cancer cell growth is driven by activity of the androgen receptor (AR). Primary treatments of mCRPC include therapies that reduce androgen synthesis or inhibit androgen binding and activation of the AR. Studies have shown that approximately 20% to 40% of mCRPC patients demonstrate primary resistance to enzalutamide and abiraterone acetate, two commonly used therapies, and virtually all patients who demonstrate initial clinical responses eventually acquire resistance. There are currently no approved therapies specifically aimed at mCRPC over-expressing AR variants, including AR-v7; therefore, a novel inhibitor of AR co-activator CBP/p300 may play a role in the suppression of mCRPC driven by AR aberrations.

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 guidance regarding our business plans and objectives for FT-7051, including the therapeutic potential and clinical benefits thereof as well as the planned study design, the timing and success of ongoing clinical trials, our growth as a company, and the potential impact of COVID-19 on patient retention, strategy, future operations and clinical trials. 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, our ability to execute on our strategy, that positive interim results from a clinical study may not be necessarily predictive of the results of future or ongoing clinical studies, the regulatory developments in the United States, the risks related to the competitive landscape, 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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Media Contact:
Megan McGrath, +1 781-591-3488
MacDougall
mmcgrath@macbiocom.com

Investor Contact:
Mario Corso, +1 781-366-5726
Forma Therapeutics
mcorso@formatherapeutics.com

Source: Forma Therapeutics Holdings, Inc.