



## **Metacrine Announces MET409 Receives FDA Fast Track Designation for the Treatment of NASH**

August 25, 2020

SAN DIEGO, Aug. 25, 2020 (GLOBE NEWSWIRE) -- Metacrine, Inc., a clinical-stage biopharmaceutical company focused on discovering and developing differentiated therapies to treat patients with liver and gastrointestinal diseases, today announced that the U.S. Food & Drug Administration (FDA) has granted Fast Track designation to MET409, the company's lead farnesoid X receptor (FXR) agonist, for the treatment of non-alcoholic steatohepatitis (NASH).

"We are very pleased that MET409 has received this important regulatory designation," said Preston Klassen, M.D., MHS, president and chief executive officer of Metacrine. "Fast Track designation underscores the significant need for treatments for people with NASH, who currently do not have any approved options, as well as MET409's potential as a differentiated FXR agonist in NASH patients."

Fast Track is a process designed to facilitate the development and expedite the review of drugs designed to treat serious diseases or conditions and that have the potential to fill an unmet medical need for such diseases or conditions. Through the Fast Track designation, the company may be eligible to submit sections of its New Drug Application on a rolling basis, and there are opportunities for more frequent interactions and written communications with the FDA around the drug's development plan. A Fast Track-designated product may also be eligible for accelerated approval and priority review if the criteria for those programs are satisfied. This designation was granted to MET409 based on data from a completed Phase 1b study in NASH patients as well as preclinical studies.

### **About Non-alcoholic Steatohepatitis (NASH)**

Non-alcoholic steatohepatitis, or NASH, is a liver disease characterized by excess liver fat, inflammation and fibrosis. In 2015, there were an estimated 17 million people in the United States with NASH, which is expected to increase to an estimated 27 million people by 2030. Left untreated, patients' disease may progress to liver failure, which is life-threatening without a successful liver transplant. NASH is expected to become the leading cause for liver transplants in the United States. Additionally, patients with NASH often present with metabolic disease and other co-morbidities, which is likely to require combination therapy. Currently, there are no approved therapies for NASH.

### **About Metacrine**

Metacrine is a clinical-stage biopharmaceutical company building a differentiated pipeline of therapies to treat liver and gastrointestinal (GI) diseases. The company's most advanced programs, MET409 and MET642, target the farnesoid X receptor (FXR), which is central to modulating liver and GI diseases. Both MET409 and MET642 are currently being investigated in clinical trials as a potential new treatment for non-alcoholic steatohepatitis (NASH). For additional information, please visit [www.metacrine.com](http://www.metacrine.com).

### **Contact:**

Caton Morris  
THRUST Strategic Communications  
336.403.0669  
[investors@metacrine.com](mailto:investors@metacrine.com)