



NEWS RELEASE

# Mast Therapeutics Receives Notice Of Allowance Of Composition Of Matter Patent Application Covering Vepoloxamer

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SAN DIEGO, June 8, 2016 /PRNewswire/ -- **Mast Therapeutics, Inc.** (NYSE MKT: MSTX), a biopharmaceutical company developing novel, clinical-stage therapies for sickle cell disease and heart failure, today announced that the United States Patent and Trademark Office (USPTO) has issued a notice of allowance for its patent application entitled, "Poloxamer Composition Free of Long Circulating Material and Methods for Production and Uses Thereof" (U. S. Patent Application No. 14/793,670). Upon issuance, the patent will provide key intellectual property protection for the Company's vepoloxamer programs that is expected to expire no earlier than July 2035.

The allowed claims cover composition of matter, methods of use, and methods of making certain purified forms of poloxamer 188, including vepoloxamer. The notice of allowance concludes substantive examination of the patent application, which is expected to issue as a patent once the issue fee is paid and the USPTO concludes administrative procedures. Mast also has filed corresponding patent applications that will allow the Company to seek similar patent protection for vepoloxamer in key markets throughout the world, including Europe and Japan.

"This milestone is an important contribution to our intellectual property strategy," stated Brian M. Culley, Chief Executive Officer of Mast Therapeutics. "We believe this patent not only will provide protection for vepoloxamer in sickle cell disease beyond the seven-year orphan market exclusivity period anticipated in the U.S., but also strengthen the commercial opportunities for development of vepoloxamer in non-orphan indications such as heart failure and stroke."

Martin Emanuele, Ph.D., Senior Vice President, Development of Mast Therapeutics and primary inventor, commented, "We are gratified that the USPTO has recognized the novelty and uniqueness of vepoloxamer. We plan



to continue to strengthen our intellectual property protection for vepoloxamer to further enhance its potential value as a therapeutic intervention in a wide range of diseases and conditions characterized by impaired microvascular blood flow and/or damaged cell membranes."

## About Mast Therapeutics

Mast Therapeutics, Inc. is a publicly traded biopharmaceutical company headquartered in San Diego, California. The Company is developing two clinical-stage investigational new drugs for serious or life-threatening diseases and conditions. Vepoloxamer, the Company's lead product candidate, is in Phase 3 clinical development for the treatment of vaso-occlusive crisis in patients with sickle cell disease and in Phase 2 clinical development for the treatment of patients with heart failure. Enrollment in the Company's 388-patient Phase 3 study of vepoloxamer in patients with sickle cell disease, known as the EPIC study, was completed in February 2016. Enrollment in the Company's Phase 2 study of vepoloxamer in patients with chronic heart failure is ongoing. AIR001, the Company's second product candidate, is in Phase 2 clinical development for the treatment of patients with heart failure with preserved ejection fraction (HFpEF). Enrollment in a Phase 2a study of AIR001 in patients with HFpEF is ongoing and AIR001 was recently selected by the Heart Failure Clinical Research Network for evaluation in a 100-patient, multicenter, randomized, double-blind, placebo-controlled, Phase 2 study in patients with HFpEF. More information can be found on the Company's web site at [www.masttherapeutics.com](http://www.masttherapeutics.com). (Twitter: [@MastThera](https://twitter.com/MastThera))

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## Forward Looking Statements

Mast Therapeutics cautions you that statements included in this press release that are not a description of historical facts are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are based on the Company's current expectations and assumptions. Such forward-looking statements may be identified by the use of forward-looking words such as "intend," "plan," "anticipate," "believe," "expect," among others, and include, but are not limited to, statements relating to prospects for successful development and commercialization of vepoloxamer for the treatment of vaso-occlusive crisis of sickle cell disease, heart failure and other serious or life-threatening diseases and market exclusivity for vepoloxamer. There are a number of factors that could cause or contribute to material differences between actual events or results and the expectations indicated by the forward-looking statements. These factors include, but are not limited to: the inherent uncertainty of outcomes in ongoing and future studies of the vepoloxamer and the risk that vepoloxamer may not demonstrate adequate safety, efficacy or tolerability in one or more such studies, including vepoloxamer in EPIC; the risk that, even if current and planned clinical studies are successful, the FDA or other regulatory agencies may determine they are not sufficient to support a new drug application; the potential that, even if clinical studies of a product candidate in one indication are successful, clinical studies in another indication may not be successful; risks associated with the Company's ability to manage operating expenses and obtain additional capital as needed; the

Company's potential inability to continue as a going concern if it does not raise additional capital as needed; uncertainty related to the Company's ability to remain in compliance with the terms and restrictions under its debt facility and the potential that it may be required to repay outstanding debt obligations on an accelerated basis and/or at a time that could be detrimental to the Company's financial condition, operations and/or business strategy, including the prepayment of \$10 million of the principal balance if results from the EPIC study are not positive and/or not available on or before July 31, 2016; the potential for the Company to significantly delay, reduce or discontinue current and/or planned development and commercial-readiness activities or sell or license its assets at inopportune times if it is unable to raise sufficient additional capital as needed; the Company's dependence on third parties to assist with important aspects of development of its product candidates, including conduct of its clinical studies and supply and manufacture of clinical trial material, and, if approved, commercial product, and the risk that such third parties may fail to perform as expected, leading to delays in product candidate development or approval or inability to meet market demand for approved products, if any; the risk that, even if the Company successfully develops a product candidate in one or more indications, it may not realize commercial success and may never achieve profitability; the risk that the Company is not able to obtain and maintain effective patent coverage or other market exclusivity protections for its products, if approved, without infringing the proprietary rights of others; and other risks and uncertainties more fully described in the Company's press releases and periodic filings with the Securities and Exchange Commission. The Company's public filings with the Securities and Exchange Commission are available at [www.sec.gov](http://www.sec.gov).

You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date when made. Mast Therapeutics does not intend to revise or update any forward-looking statement set forth in this press release to reflect events or circumstances arising after the date hereof, except as may be required by law.

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SOURCE Mast Therapeutics, Inc.

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