



NEWS RELEASE

Mast Therapeutics Announces Issuance Of Composition Of Matter Patent Covering Vepoloxamer

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SAN DIEGO, Aug. 3, 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 the issuance of United States Patent No. 9,403,941 for "Poloxamer Composition Free of Long Circulating Material and Methods for Production and Uses Thereof" (the "'941 patent") by the United States Patent and Trademark Office (USPTO). The patent includes claims covering composition of matter, methods of use, and methods of making certain purified forms of poloxamer 188, including vepoloxamer, and should provide key intellectual property protection in the U.S. for the Company's vepoloxamer programs. The '941 patent will expire no earlier than July 2035. The Company also has filed corresponding patent applications that will allow it to seek similar patent protection for vepoloxamer in key markets throughout the world, including Europe and Japan.

The Company believes that the '941 patent will be eligible for listing in the U.S. Food and Drug Administration's (FDA) Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, should vepoloxamer receive FDA approval for the treatment of patients with sickle cell disease or heart failure.

"The issuance of this patent is an important development relating to maintaining exclusivity for vepoloxamer," 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, "The issuance of this patent by the USPTO is a key milestone for our vepoloxamer programs and is encouraging for the corresponding applications pending in other economically important territories around the

world."

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 earlier this year. 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 Phase 2 studies of AIR001 in patients with HFpEF are ongoing, including a 100-patient, multicenter, randomized, double-blind, placebo-controlled, Phase 2 study in patients with HFpEF being conducted by the Heart Failure Clinical Research Network. More information can be found on the Company's web site at 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 "believe," "intend," "expect," "plan," "anticipate," among others, and include, but are not limited to, statements relating to prospects for successful development and commercialization of vepoloxamer for the treatment of patients with sickle cell disease, heart failure and other serious or life-threatening diseases and market exclusivity for vepoloxamer in the U.S. and foreign territories. 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 risk that the validity and/or enforceability of the '941 patent may be challenged and that such a challenge may be successful, resulting in loss of the patent or loss or reduction in the scope of one or more of the claims of the patent; the potential for competitors to design around the '941 patent in which case a competitor's product may not infringe on the '941 patent, allowing the competitor to compete with the Company's products before the '941 patent expires; the potential that key claims in corresponding patent applications filed in other territories will not be allowed; the inherent uncertainty of outcomes in ongoing and future studies of vepoloxamer and the risk that vepoloxamer may not demonstrate adequate safety, efficacy or tolerability in one or more such studies,

including in the EPIC study; the risk that, even if EPIC study results are positive, the FDA may require a second Phase 3 study or other clinical or nonclinical studies to demonstrate substantial evidence of vepoloxamer's effectiveness for sickle cell patients or to provide additional safety and tolerability data or that the FDA may require changes to manufacturing controls or processes that could delay filing of 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 sufficient 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 its 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 October 14, 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.

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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To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/mast-therapeutics-announces-issuance-of-composition-of-matter-patent-covering-vepoloxamer-300308192.html>

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Mast Therapeutics, Ioana C. Hone (ir@mastthera.com), 858-552-0866 Ext. 303