



NEWS RELEASE

# Mast Therapeutics Reports Fourth Quarter And Full Year 2015 Financial Results

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SAN DIEGO, March 14, 2016 /PRNewswire/ -- **Mast Therapeutics, Inc.** (NYSE MKT: MSTX), a biopharmaceutical company developing novel, clinical-stage therapies for sickle cell disease and heart failure, today reported financial results for the fourth quarter and year ended December 31, 2015.

"Last month we announced that we had completed patient enrollment in our Phase 3 study of vepoloxamer in sickle cell crisis, known as the EPIC study. The study was conducted in 14 countries at more than 75 sites and is the largest placebo-controlled study in sickle cell disease ever concluded. It was a monumental effort to finish enrollment as quickly as possible and I commend the clinical investigators, the patients, and their families for this important achievement," stated Brian M. Culley, Chief Executive Officer. "Vepoloxamer remains the most clinically-advanced new drug in development for sickle cell disease and we look forward to seeing the top-line results of the EPIC study in the second quarter of 2016."

"We also recently announced positive data from a Phase 2a study of AIR001 in patients with heart failure with preserved ejection fraction conducted at Mayo Clinic," continued Mr. Culley. "In this blinded and placebo-controlled study, AIR001 showed a statistically significant improvement in pulmonary capillary wedge pressure during exercise, the pre-specified primary endpoint, and attenuated other hemodynamic derangements of cardiac failure that occur during exercise in HFpEF patients. We look forward to initiation of the next Phase 2 study of AIR001 in the third quarter of this year, a 100-patient multi-center trial to be conducted at the premier clinical centers that make up the Heart Failure Clinical Research Network."

## Fourth Quarter 2015 Operating Results

The Company's net loss for the fourth quarter of 2015 was \$10.2 million, or \$0.06 per share (basic and diluted),

compared to a net loss of \$7.3 million, or \$0.05 per share (basic and diluted), for the same period in 2014.

Research and development (R&D) expenses for the fourth quarter of 2015 were \$7.2 million, an increase of \$2.3 million, or 45%, compared to \$4.9 million for the same period in 2014. The increase was due mainly to increases of \$0.9 million in external nonclinical study fees and expenses related primarily to research-related manufacturing costs for vepoloxamer (\$0.4 million) and nonclinical toxicology studies of vepoloxamer to support a vepoloxamer NDA submission (\$0.4 million), \$0.9 million in external clinical study fees and expenses related primarily to EPIC study costs (\$0.5 million) and costs for the Phase 2 study of vepoloxamer in heart failure (\$0.4 million), and \$0.4 million in personnel expenses.

Selling, general and administrative (SG&A) expenses for the fourth quarter of 2015 were \$2.5 million, an increase of \$0.1 million, or 5%, compared to \$2.4 million for the same period in 2014.

## Year-to-Date Operating Results

The Company's net loss for the year ended December 31, 2015 was \$39.8 million, or \$0.25 per share (basic and diluted), compared to a net loss of \$28.7 million, or \$0.23 per share (basic and diluted), for the same period in 2014.

R&D expenses for the year ended December 31, 2015 were \$28.3 million, an increase of \$8.9 million, or 45%, compared to \$19.4 million for the same period in 2014. The increase was due to increases of \$5.1 million in external nonclinical study fees and expenses, \$2.9 million in external clinical study fees and expenses, \$0.7 million in personnel costs and \$0.2 million in share-based compensation expense. The increase in external nonclinical study fees and expenses resulted primarily from research-related manufacturing costs for vepoloxamer (\$2.9 million), nonclinical toxicology studies of vepoloxamer to support a vepoloxamer NDA submission (\$1.8 million) and consulting fees for NDA-readiness activities related to vepoloxamer (\$0.4 million). The increase in external clinical study fees and expenses was related primarily to increases in EPIC study costs (\$3.3 million) and the Phase 2 study of vepoloxamer in heart failure (\$0.9 million), offset by decreases in costs for the discontinued Phase 2 study of vepoloxamer in acute limb ischemia (\$0.8 million) and AIR001 clinical study expenses (\$0.5 million). The increase in personnel costs resulted primarily from additional regulatory, clinical operations and research-related manufacturing staff hired in 2015.

SG&A expenses for the year ended December 31, 2015 were \$11.0 million, an increase of \$1.5 million, or 16%, compared to \$9.5 million for the same period in 2014. The increase resulted primarily from increases in consulting expenses and personnel costs.

## 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)

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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 the Company's product candidates, including vepoloxamer for the treatment of vaso-occlusive crisis of sickle cell disease, and anticipated timing of achievement of development milestones, such as commencement and completion of clinical studies and announcement of study data. 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 Company's product candidates and the risk that its product candidates may not demonstrate adequate safety, efficacy or tolerability in one or more such studies, including vepoloxamer in EPIC; delays in the commencement or completion of clinical studies, including as a result of difficulties in obtaining regulatory agency agreement on clinical development plans or clinical study design, opening trial sites, enrolling study subjects, manufacturing sufficient quantities of clinical trial material, being subject to a "clinical hold," and/or suspension or termination of a clinical study, including due to patient safety concerns or lack of funding; delays in clinical study closeouts, including blinded data review and quality control and assurance procedures; 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; 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 the Company may be required to repay its outstanding debt obligations on an accelerated basis and/or at a time that could be detrimental to its 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; risks associated with the Company's ability to manage operating expenses and/or obtain additional funding to support its operations on a timely basis or on acceptable terms, or at all; 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 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.

[Tables to Follow]

Mast Therapeutics, Inc.  
Condensed Consolidated Statements of Operations  
(In thousands, except per share data)

	Three months ended December 31, (Unaudited)		Year ended December 31, <sup>(1)</sup>	
	2015	2014	2015	2014
Total net revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	7,158	4,933	28,264	19,435
Selling, general and administrative	2,515	2,396	10,963	9,488
Transaction-related expenses	-	-	-	271
Depreciation and amortization	41	25	146	85
Total operating expenses	<u>9,714</u>	<u>7,354</u>	<u>39,373</u>	<u>29,279</u>
Loss from operations	(9,714)	(7,354)	(39,373)	(29,279)
Interest income, interest expense and other income/(expense), net	<u>(449)</u>	<u>41</u>	<u>(469)</u>	<u>577</u>
Net loss	<u>\$ (10,163)</u>	<u>\$ (7,313)</u>	<u>\$ (39,842)</u>	<u>\$ (28,702)</u>

Net loss per share – basic and diluted	<u>\$ (0.06)</u>	<u>\$ (0.05)</u>	<u>\$ (0.25)</u>	<u>\$ (0.23)</u>
Weighted average shares – basic and diluted	<u>163,614</u>	<u>145,257</u>	<u>162,219</u>	<u>122,409</u>

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(1) The condensed consolidated statements of operations for the years ended December 31, 2015 and 2014 have been derived from the audited financial statements but do not include all of the information and footnotes required by accounting principles generally accepted in the United States for the complete financial statements.

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Mast Therapeutics, Inc  
Balance Sheet Data  
(In thousands)

	<u>December 31, 2015</u>	<u>December 31, 2014</u>
Cash, cash equivalents and investment securities	\$ 40,981	\$ 57,289
Working capital	19,079	49,965
Total assets	54,217	70,500
Total liabilities	30,328	11,842
Stockholders' equity	23,889	58,658

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To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/mast-therapeutics-reports-fourth-quarter-and-full-year-2015-financial-results-300235265.html>

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