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Mirati Therapeutics Reports Second Quarter 2015 Financial Results and Provides Business Update

SAN DIEGO, Aug. 6, 2015 /PRNewswire/ -- Mirati Therapeutics, Inc. ("Mirati") (NASDAQ: MRTX) today reported financial results for the second quarter ended June 30, 2015 and provided an update on its drug development programs.

"At this year's ASCO meeting, we presented initial clinical data on our lead tyrosine kinase inhibitor, MGCD265, which clearly demonstrated significant tumor regression in non-small lung cancer patients with MET gene alterations. With pre-clinical and clinical data showing anti-tumor activity, we are confident that targeting MET driver alterations is a clinically valid approach, and we look forward to initiating a Phase 2 registration-enabling study by the end of the year," said Charles M. Baum, M.D., Ph.D., president and CEO, Mirati. "We also recently announced a clinical trial collaboration with our spectrum-selective HDAC inhibitor, mocetinostat. The Phase 1-2 study will evaluate the safety and efficacy of mocetinostat, in combination with durvalumab, an investigational anti-PD-L1 immune checkpoint inhibitor, in patients with non-small cell lung cancer. We are excited about this combination, as mocetinostat may enhance the efficacy of immune checkpoint inhibitors, potentially leading to improved therapies for patients."

Recent and Upcoming Pipeline Highlights

MGCD265: Molecularly targeted kinase inhibitor

- 2015 American Society of Clinical Oncology (ASCO) Annual Meeting: Presented data demonstrating preliminary evidence of clinical activity in non-small cell lung cancer (NSCLC) patients, including clear tumor regression and improvement in clinical symptoms such as pain and shortness of breath
  - The first three patients selected for MET gene alterations in the dose expansion cohort showed clear evidence of tumor regression as early as the first scan. All three patients have extensive disease and failed several prior therapies before being treated with MGCD265
  - Demonstrated that MGCD265 was well tolerated
  - The poster can be found on the Company's website at www.mirati.com
  - Additional information about this clinical trial of MGCD265 is available at www.clinicaltrials.gov using identifier: NCT00697632

- The Company expects to initiate a single arm Phase 2 registration-enabling study in NSCLC by the end of the year

MGCD516: Molecularly targeted kinase inhibitor

- 2015 ASCO Annual Meeting: Presented the clinical trial design of the Phase 1, open label, single agent study designed to evaluate the safety, pharmacokinetics/pharmacodynamics (PK/PD) and clinical activity of MGCD516 in patients with advanced solid tumors, with an initial focus on NSCLC
  - The poster can be found on the Company's website at www.mirati.com
  - Additional information about this clinical trial of MGCD516 is available at www.clinicaltrials.gov using identifier: NCT02219711

- The Company expects to establish a Phase 2 dose and initiate expansion cohorts in selected patients by the end of the year

Mocetinostat: Molecularly targeted epigenetic inhibitor

- Announced a clinical trial collaboration to evaluate the safety and efficacy of mocetinostat in combination with durvalumab (MEDI4736), an investigational anti-PD-L1 immune checkpoint inhibitor. The initial Phase 1-2 study will be evaluated in patients with NSCLC

- 2015 Annual ASCO Meeting: Presented the clinical trial design of the mocetinostat Phase 2 study in patients with previously treated, locally advanced, unresectable or metastatic urothelial carcinoma of the bladder harboring inactivating mutations or deletions of the histone acetyltransferase genes CREBBP and/or EP300
  - The poster can be found on the Company's website at www.mirati.com

- Additional information about this clinical trial of mocetinostat is available at www.clinicaltrials.gov using identifier: NCT02236195

- The two Phase 2 trials evaluating mocetinostat (one in bladder cancer, the other in diffuse large B-cell lymphoma and follicular lymphoma) are ongoing with initial clinical data anticipated later in the year

Second Quarter 2015 Financial Results
Cash, cash equivalents, and short-term investments were $58.9 million at June 30, 2015, compared to $29.3 million at December 31, 2014. In February 2015, the Company successfully completed a public offering of 2.6 million shares of its common stock, generating net proceeds of $48.4 million.

Research and development expenditures for the second quarter of 2015 were $11.3 million, compared to $7.1 million for the same period in 2014. Research and development expenses for the six months ended June 30, 2015 were $19.5 million, compared to $12.1 million for the same period in 2014. The increases in research and development expenses primarily reflect costs to advance the clinical development of its three oncology development programs, MGCD265, MGCD516 and mocetinostat. General and administrative expenses for the first quarter of 2015 were $4.2 million, compared to $3.0 million for the same period in 2014. General and administrative expenses for the six months ended June 30, 2015 were $8.0 million, compared to $5.7 million for the same period in 2014. The increases in general and administrative expenses primarily reflect higher, non-cash stock-based compensation expense.

Other income and expense, net, for the second quarter of 2015 was income of $0.1 million compared to expense of $0.9 million for the same period in 2014. Other income and expense, net, for the six months ended June 30, 2015 was income of $0.1 million compared to expense of $6.6 million for the same period in 2014. Other income and expense, net, for the second quarter and six months ended June 30, 2014 primarily reflects losses arising from the change in fair value of our warrant liability. During 2014, we amended the warrant agreements to allow for the warrants to be denominated in U.S. dollars. The amended warrants qualified for equity classification and were reclassified into stockholders' equity.

Net loss for the second quarter of 2015 was $15.4 million, or $0.95 per share, compared to net loss of $11.0 million, or $0.82 per share for the same period in 2014. Net loss for the six months ended June 30, 2015 was $27.4 million, or, $1.74 per share, compared to net loss of $24.7 million, or $1.83 per share for the same period in 2014.

About Mirati Therapeutics
Mirati Therapeutics develops molecularly targeted cancer treatments intended to inhibit tumor growth. Mirati's approach combines the three most important factors in oncology drug development, 1) researching and developing drug candidates that target genetic and epigenetic drivers of cancer, 2) designing creative and agile clinical development strategies that select for patients whose tumors are dependent on specific driver alterations, and 3) leveraging a highly accomplished precision medicine leadership team. The Mirati team uses a blueprint - proven by their prior work - for developing potential breakthrough cancer therapies, with accelerated development paths, in order to improve outcomes for patients. Mirati is advancing three drug candidates through clinical development for multiple oncology indications. More information is available at www.mirati.com.

Forward Looking Statements
Certain statements contained in this news release, other than statements of fact that are independently verifiable at the date hereof, contain "forward-looking" statements, within the meaning of the Private Securities Litigation Reform Act of 1995, that involve significant risks and uncertainties. For more detailed disclosures and discussions regarding such forward looking statements, please refer to Mirati's filings with the U.S. Securities and Exchange Commission ("SEC"), including without limitation Mirati's filings on Forms 10-K, 10-Q, and 8-K. Forward looking statements are based on the current expectations of management and upon what management believes to be reasonable assumptions based on information currently available to it. Such statements can usually be identified by the use of words such as "may," "would," "believe," "intend," "plan," "anticipate," "estimate," "expect," and other similar terminology, or by statements that certain actions, events or results "may" or "would" be taken, occur or be achieved. Such statements include, but are not limited to, statements regarding Mirati's development plans and timelines, potential regulatory actions, expected use of cash resources, the timing and results of clinical trials, and the potential benefits of and markets for Mirati's product candidates. Forward looking statements involve significant risks and uncertainties and are neither a prediction nor a guarantee that future events or circumstances will occur. Such risks include, but are not limited to, potential delays in development timelines or negative clinical trial results, reliance on third parties for development efforts, changes in the competitive landscape, changes in the standard of care, as well as other risks described in Mirati's filings with the SEC. We are including this cautionary note to make applicable, and to take advantage of, the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 for forward-looking statements. The information in this news release is given as of the date above and Mirati expressly disclaims any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

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Mirati Therapeutics, Inc.
Consolidated Balance Sheets
(in thousands)

	June 30, 2015	December 31, 2014
Assets	(unaudited)	
Current assets		
Cash, cash equivalents and short-term investments	$ 58,877	$ 29,303
Other current assets	2,016	3,354
Total current assets	**60,893**	**32,657**
Property and equipment, net	693	496
Other assets	288	326
Total assets	**$ 61,874**	**$ 33,479**
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable and accrued liabilities	7,096	5,396
Other liability	58	21
Total liabilities	**7,154**	**5,417**
Stockholders' equity	**54,720**	**28,062**
Total liabilities and stockholders' equity	**$ 61,874**	**$ 33,479**

Mirati Therapeutics, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands except per share data, unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2015	**2014**	**2015**	**2014**
Expenses				
Research and development	$ 11,276	$ 7,149	$ 19,483	$ 12,109
General and administrative	4,240	2,986	8,019	5,671
Restructuring costs	-	-	-	334
Total operating expenses	**15,516**	**10,135**	**27,502**	**18,114**
Loss from operations	**(15,516)**	**(10,135)**	**(27,502)**	**(18,114)**
Other income (expense), net	70	(903)	116	(6,580)
Net loss	**$(15,446)**	**$(11,038)**	**$(27,386)**	**$ (24,694)**
Unrealized gain (loss) on available-for-sale investments	(9)	24	(4)	34
Comprehensive loss	**$ (15,455)**	**$ (11,014)**	**$ (27,390)**	**$ (24,660)**
Basic and diluted net loss per share	$ (0.95)	$ (0.82)	$ (1.74)	$ (1.83)
Weighted average number of shares used in computing net loss per share, basic and diluted	16,235	13,499	15,728	13,467

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/mirati-therapeutics-reports-second-quarter-2015-financial-results-and-provides-business-update-300124587.html

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