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Mirati Therapeutics Reports Financial Results And Provides Business Update For The Fourth Quarter And Full Year 2016

Following successful public offering, Company well positioned to deliver key data points for glesatinib, sitravatinib and immuno-oncology combinations in 2017

SAN DIEGO, March 9, 2017 /PRNewswire/ -- Mirati Therapeutics, Inc. (NASDAQ: MRTX) ("the Company," "we," "our," "us," or "Mirati") today reported financial results for the fourth quarter and year ended December 31, 2016 and provided an update on its product development programs.

"We have made significant progress which positions us to report key data from all of our programs in 2017," said Charles M. Baum, M.D., Ph.D., President and CEO of Mirati. "Earlier this year, we presented glesatinib data demonstrating clinical responses in non-small cell lung cancer patients with MET driver alterations. In addition, preliminary data from our Phase 1b trial of sitravatinib has shown clinical benefit in patients with RET mutations. We plan to provide updates for both glesatinib and sitravatinib in the second half of this year.

We are excited about our immuno-oncology programs which combine sitravatinib or mocetinostat with checkpoint inhibitors. There is strong scientific rationale that sitravatinib or mocetinostat can significantly enhance the efficacy of checkpoint inhibitors. Following our successful public offering in January, we are well positioned to achieve the 2017 milestones in each of our programs with funding into late 2018."

Single Agent Programs

Glesatinib (MGCD265)

The Company is enrolling patients in its registration-enabling Phase 2 non-small cell lung cancer (NSCLC) AMETHYST clinical trial, which is evaluating single agent glesatinib for the treatment of NSCLC patients with MET driver alterations. In January 2017, the Company reported early data that demonstrated promising activity in these molecularly selected patients. In NSCLC patients with MET Exon 14 deletion mutations treated with glesatinib, across both the Phase 1b and Phase 2 trials, tumor reduction was observed in 11 of 13 patients, with confirmed and unconfirmed partial responses in 6 of 13 evaluable patients. Glesatinib also demonstrated clinical benefit in NSCLC patients with MET gene amplification, including tumor reduction in six of eight patients as well as two unconfirmed partial responses out of eight evaluable patients. The Company expects to provide an update on efficacy data from the AMETHYST trial in the second half of 2017.

Sitravatinib (MGCD516)

The Company is enrolling patients in its Phase 1b expansion clinical trial, which is evaluating single agent sitravatinib for the treatment of NSCLC patients with RET, CHR4q12 and CBL genetic alterations. In January 2017, the Company reported that six NSCLC patients with RET fusion mutations had been enrolled and all four evaluable patients showed tumor reductions with one confirmed and one unconfirmed response. The Company expects to provide an update on efficacy data in the third quarter of 2017.

Immuno-oncology Combination Programs

Sitravatinib plus nivolumab

Sitravatinib is a potent inhibitor of the TAM (Tyro, Axl, Mer) and split (KDR, KIT) tyrosine kinase families which have been shown in preclinical studies to enhance anti-tumor immunity and the effects of checkpoint inhibitors. In November 2016, the Company initiated enrollment in a multicenter Phase 2 NSCLC clinical trial evaluating sitravatinib in combination with nivolumab, a PD-1 checkpoint inhibitor approved for the treatment of patients with NSCLC. The trial is enrolling patients who have relapsed after treatment with a checkpoint inhibitor. The Company expects to provide initial results from this combination trial in the second half of 2017.

Mocetinostat (MGCD103) plus durvalumab

The Company is collaborating with MedImmune/Astra Zeneca on a Phase 1b/2 clinical trial combining mocetinostat, an orally administered spectrum-selective Class 1 HDAC inhibitor, and durvalumab, MedImmune's monoclonal antibody inhibiting PD-L1. Preclinical data have shown that mocetinostat significantly enhances the efficacy of the checkpoint inhibitor through its

effects on the tumor microenvironment. The combination trial is exploring the potential of mocetinostat to enhance the effectiveness of durvalumab in NSCLC patients and the Company expects to provide an update in mid 2017.

Preclinical Programs

The Company's lead preclinical programs to develop inhibitors of LSD1 and KRAS are expected to have meaningful milestones in 2017. The Company's LSD1 inhibitor is highly-potent and potentially best-in-class with potential for rapid clinical proof-of-concept in small cell lung cancer and/or acute myeloid leukemia. An investigational new drug (IND) submission is planned for this compound in the fourth quarter of 2017. The Company has identified a mutant-selective KRAS inhibitor which is advancing to the candidate selection phase. Prototype inhibitors have demonstrated marked tumor regression in KRAS mutant tumor models and the Company anticipates selecting an IND candidate in the second half of 2017.

Financing

In January 2017, the Company strengthened its balance sheet by completing a public offering of common stock and pre-funded common stock warrants generating net proceeds of \$66.8 million. Following this offering, the Company expects that its available cash, cash equivalents and short-term investments are sufficient to fund operations into late 2018.

Fourth Quarter and Full Year Financial Results

Cash, cash equivalents, and short-term investments were \$56.7 million on December 31, 2016, as compared to \$122.3 million on December 31, 2015.

Research and development expenses for the fourth quarter of 2016 were \$16.0 million, compared to \$14.9 million for the same period in 2015. Research and development expenses for the year ended December 31, 2016 were \$68.5 million, compared to \$49.0 million for the same period in 2015. The increases in research and development expenses for both periods primarily reflect costs to advance the clinical development of the Company's glesatinib and sitravatinib oncology development programs, an increase in salaries and related expense, which is due to an increase in research and development employees during 2016 compared to the same period of 2015, and an increase in early discovery expenses.

General and administrative expenses for the fourth quarter of 2016 were \$3.9 million, compared to \$3.6 million for the same period in 2015. General and administrative expenses for the year ended December 31, 2016 were \$15.3 million, compared to \$15.8 million for the same period in 2015. The comparable level of expenses for both periods reflect a consistent level of general and administrative activities during both periods.

Other income, net, was \$0.1 million for both the fourth quarter of 2016 and 2015. Other income, net, for the year ended December 31, 2016 was \$0.6 million compared to \$0.2 million for the same period in 2015.

Net loss for the fourth quarter of 2016 was \$19.7 million, or \$0.99 per share basic and diluted, compared to net loss of \$18.4 million, or \$0.96 per share basic and diluted for the same period in 2015. Net loss for the year ended December 31, 2016 was \$83.1 million, or \$4.20 per share basic and diluted, compared to net loss of \$64.5 million, or \$3.82 per share basic and diluted for the same period in 2015.

About Mirati Therapeutics

Mirati Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on developing a pipeline of targeted oncology products intended to treat specific genetic and epigenetic drivers of cancer in selected subsets of cancer patients with unmet needs. Our clinical pipeline consists of three product candidates: glesatinib, sitravatinib and mocetinostat. Both glesatinib and sitravatinib are orally bioavailable, spectrum-selective kinase inhibitors with distinct target profiles that are in development for the treatment of patients with NSCLC and other solid tumors. Glesatinib targets the MET receptor tyrosine kinase family and is in Phase 2 clinical development. Sitravatinib targets RET rearrangements, CHR4q12 amplifications (encompassing KDR, PDGFRA and KIT), and CBL and AXL mutations, and is in Phase 1b clinical development as a single agent. Sitravatinib is also being evaluated in a Phase 2 combination with nivolumab, a PD-1 inhibitor, for the treatment of patients with NSCLC. Sitravatinib is a potent inhibitor of the TAM (Tyro, Axl, Mer) and split (KDR, KIT) tyrosine kinase families, which regulate multiple stages in the cancer immunity cycle and are thought to enhance anti-tumor immunity by improving the efficacy of immune checkpoint (PD-1/PD-L1) inhibitors. Our third product candidate is mocetinostat, an orally bioavailable, spectrum-selective Class 1 histone deacetylase inhibitor. Mocetinostat is in Phase 1b/2 clinical development in combination with durvalumab, MedImmune's PD-L1 immune checkpoint inhibitor, for the treatment of patients with NSCLC. More information is available at www.mirati.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Any statements in this press release regarding the business of the Company that are not historical facts may be considered "forward-looking statements," including, but 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 are typically, but not always, identified by the use of words such as "may," "would," "believe," "intend," "plan," "anticipate," "estimate," "expect," and other similar terminology. Forward-looking statements are based on current expectations of management and upon what management believes to be reasonable assumptions based on information currently available to it, and are subject to risks and uncertainties. Such risks and uncertainties may cause actual results to differ materially from the expectations set forth in the forward-looking statements. Such risks and uncertainties 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 detailed in Mirati's recent filings on Forms 10-K and 10-Q with the United States Securities and Exchange Commission. Mirati undertakes no obligation to update any forward-looking statements to reflect new information, events or circumstances, or to reflect the occurrence of unanticipated events.

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

| | December 31, 2016 | December 31, 2015 |
|---|----------------------|----------------------|
| Assets | | |
| Current assets | | |
| Cash, cash equivalents and short-term investments | \$ 56,734 | \$ 122,327 |
| Other current assets | 2,821 | 3,075 |
| Total current assets | 59,555 | 125,402 |
| Property and equipment, net | 629 | 614 |
| Other assets | 3,260 | 2,001 |
| Total assets | \$ 63,444 | \$ 128,017 |
| Liabilities and Stockholders' Equity | | |
| Current liabilities | | |
| Accounts payable and accrued liabilities | \$ 15,002 | \$ 9,798 |
| Total current liabilities | 15,002 | 9,798 |
| Other liabilities | 133 | 43 |
| Total liabilities | 15,135 | 9,841 |
| Stockholders' equity | 48,309 | 118,176 |
| Total liabilities and stockholders' equity | \$ 63,444 | \$ 128,017 |

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

| | Three Months Ended December 31, | | Twelve Months Ended December 31, | |
|---------------------------------|------------------------------------|-----------------|-------------------------------------|-----------------|
| | 2016 | 2015 | 2016 | 2015 |
| (unaudited) | | | | |
| Expenses | | | | |
| Research and development | \$ 15,952 | \$ 14,913 | \$ 68,487 | \$ 48,959 |
| General and administrative | 3,901 | 3,575 | 15,292 | 15,755 |
| Total operating expenses | 19,853 | 18,488 | 83,779 | 64,714 |
| Loss from operations | (19,853) | (18,488) | (83,779) | (64,714) |

| | | | | |
|---|---------------------------|---------------------------|---------------------------|---------------------------|
| Other income, net | <u>131</u> | <u>71</u> | <u>661</u> | <u>170</u> |
| Net loss | <u>\$ (19,722)</u> | <u>\$ (18,417)</u> | <u>\$ (83,118)</u> | <u>\$ (64,544)</u> |
| Unrealized gain (loss) on available-for-sale investments | <u>(51)</u> | <u>35</u> | <u>(25)</u> | <u>37</u> |
| Comprehensive loss | <u>\$ (19,773)</u> | <u>\$ (18,382)</u> | <u>\$ (83,143)</u> | <u>\$ (64,507)</u> |
| Basic and diluted net loss per share | <u>\$ (0.99)</u> | <u>\$ (0.96)</u> | <u>\$ (4.20)</u> | <u>\$ (3.82)</u> |
| Weighted average number of shares used in computing net loss per share, basic and diluted | <u>19,929</u> | <u>19,271</u> | <u>19,787</u> | <u>16,902</u> |



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