

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

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**FORM 8-K**

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**CURRENT REPORT**

**PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934**

Date of Report (Date of earliest event reported): **February 19, 2014**

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**Onconova Therapeutics, Inc.**

(Exact name of Registrant as specified in its charter)

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**Delaware**  
(State or Other Jurisdiction  
of Incorporation or Organization)

**001-36020**  
(Commission  
File Number)

**22-3627252**  
(I.R.S. Employer  
Identification No.)

**375 Pheasant Run  
Newtown, PA 18940  
(267) 759-3680**

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

**Not Applicable**

(Former name or former address, if changed since last report)

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 8.01 Other Events**

On February 19, 2014, Onconova Therapeutics, Inc. issued a press release, a copy of which is attached hereto as Exhibit 99.1 and incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits**

(d) Exhibits.

99.1 Press release issued by Onconova Therapeutics, Inc. dated February 19, 2014.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: February 20, 2014

Onconova Therapeutics, Inc.

By: /s/ Ajay Bansal  
Name: Ajay Bansal  
Title: Chief Financial Officer

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EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by Onconova Therapeutics, Inc., dated February 19, 2014.

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February 19, 2014

## Onconova Announces Results From Phase 3 ONTIME Trial of Rigosertib in Higher Risk Myelodysplastic Syndromes (MDS)

-Rigosertib vs. Best Supportive Care did not meet the primary endpoint of statistically significant improvement in median overall survival-

-Post-hoc analysis demonstrates statistically significant improvement in median overall survival in patients who had progressed on or failed prior treatment with hypomethylating agents-

-Additional analysis of data will be discussed with regulatory authorities and presented at the 2014 ASCO Annual Meeting-

-Management to Host Conference Call at 4:30 PM ET-

NEWTOWN, Pa., Feb. 19, 2014 (GLOBE NEWSWIRE) — Onconova Therapeutics, Inc. (Nasdaq:ONTX) a clinical-stage biopharmaceutical company focused on discovering and developing novel products to treat cancer, today announced that the Phase 3 ONTIME trial of intravenous (IV) rigosertib in patients with higher risk myelodysplastic syndromes (MDS) who had progressed on, failed or relapsed after prior therapy with hypomethylating agents (HMAs) did not meet the primary endpoint of overall survival compared to best supportive care (BSC). The ONTIME trial enrolled 299 patients including 199 patients in the IV rigosertib plus BSC arm. Median overall survival in the IV rigosertib plus BSC arm was 8.2 months compared to 5.8 months in BSC only arm. Treatment with IV rigosertib plus BSC did not demonstrate a statistically significant improvement in median overall survival when compared to BSC only (Hazard Ratio=0.86; p-value=0.27).

However, a post-hoc analysis demonstrated a statistically significant increase in median overall survival in the subset of patients who had progressed on or failed previous treatment with HMAs (i.e., had not responded to HMAs), thus demonstrating potential activity of rigosertib in these MDS patients. In this subset of patients (184 of 299 enrolled patients), the median overall survival was 8.5 months in the IV rigosertib plus BSC arm compared to 4.7 months in BSC only arm (Hazard Ratio=0.67; p-value=0.022). Among this patient population, 127 patients were in the treatment arm, and 57 patients were in the BSC arm. The other subset which was comprised of patients who had relapsed after responding to previous treatment with HMAs (115 of 299 patients enrolled), did not show a statistically significant survival benefit. Additional analysis is underway to identify potential survival benefit in other subsets of patients.

Preliminary safety analysis indicates that rigosertib was generally well tolerated in the study population. Severe adverse events were uncommon, with a similar profile of serious adverse events in both study arms. Grade 3/4 treatment-related hematologic and non-hematologic adverse events were reported in less than 7% and 3% of patients, respectively. Incidence of all grades of treatment-related nausea, diarrhea, fatigue and constipation were 22%, 17%, 17%, and 15%, respectively. All other treatment-related adverse events were reported in less than 10% of patients. Additional details, including secondary endpoints, will be presented at the 2014 ASCO Annual Meeting.

“While we are disappointed that the ONTIME trial did not meet its primary endpoint, we are encouraged by the significant treatment benefit seen in the subset of patients who had progressed on or failed HMAs i.e., patients who had not responded to prior HMA treatment. We look forward to presenting additional information after data analysis is completed,” said Ramesh Kumar, Ph.D., President and Chief Executive Officer of Onconova. “We are working closely with our partners, Baxter and Symbio, as we evaluate the results of this study. We plan to engage with the U.S. Food and Drug Administration (FDA) and European regulatory agencies with the goal of determining the next steps in advancing development of rigosertib for this underserved patient population. We remain committed to advancing rigosertib to address important medical needs in MDS and solid tumors. Ongoing efforts include trials of oral rigosertib in transfusion-dependent lower risk MDS patients, where, after consultation with regulatory agencies, we are planning to initiate a Phase 3 trial as soon as possible,” continued Dr. Kumar.

### About the ONTIME Trial

The ONTIME Trial is a Phase 3 multi-center, randomized, controlled study to assess efficacy and safety of rigosertib 72-hour continuous intravenous infusion plus BSC compared to BSC alone, in higher risk MDS patients with excess blasts (5% to 30% bone marrow blasts), who had progressed on, failed or relapsed after treatment with HMAs. Two hundred ninety-nine MDS patients were enrolled at 89 sites in the U.S. and Europe. Patients were randomized at a 2:1 ratio into two treatment arms: best supportive care plus rigosertib 1,800 mg/24 hours administered as a 72-hr continuous infusion on Days 1, 2, and 3 of a 2-week cycle for the first eight 2-week cycles, then every 4 weeks thereafter versus BSC alone. The primary endpoint of the trial is median overall survival. Secondary endpoints include overall response, complete bone marrow response, hematological improvements, transition time to acute myeloid leukemia, and quality of life improvement. The

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ONTIME trial was conducted under a Special Protocol Agreement (SPA) from the FDA and following Scientific Advice from European regulatory agencies.

### Conference Call Information

Onconova will host a conference call and webcast today, February 19, at 4:30 PM ET, to discuss the trial results. To participate in the conference call, please dial (877) 312-5881 (domestic) or (253) 237-1173 (international) five minutes prior to the start of the call and provide the passcode 2442205. The recorded, listen-only webcast of the conference call can be accessed under “Events & Presentations” in the Investor and Media section of the Company’s website at [www.onconova.com](http://www.onconova.com). A replay of the webcast will be available shortly after the conclusion of the call and archived on the Company’s website for two weeks following the call.

### About Rigosertib

Rigosertib is a small molecule inhibitor of two important cellular signaling pathways, phosphoinositide 3-kinase, or PI3K, and polo-like kinase, or PLK, both of which are frequently activated in cancer cells. Recently, it was shown that rigosertib inhibits these pathways by interacting with the Ras Binding Domain

(RBD) of several signaling molecules. Due to the dual effects of inhibiting PI3K and PLK pathways, rigosertib has shown activity in a variety of cancers including solid tumors and hematological malignancies. Clinical trials with IV and oral formulations of rigosertib have been conducted at leading institutions in the U.S. and abroad. To date, more than 1,100 patients with solid tumors or hematological diseases have been enrolled in clinical trials with rigosertib. Rigosertib has been granted orphan drug status for MDS in the U.S., Europe and Japan. Rigosertib is being developed in partnership with Baxter International (commercialization rights in Europe) and SymBio Pharmaceuticals (Japan and Korea). Onconova has retained all other territories for commercialization.

### **About Onconova Therapeutics, Inc.**

Onconova Therapeutics is a clinical-stage biopharmaceutical company focused on discovering and developing novel products to treat cancer. Onconova's clinical and pre-clinical stage drug development candidates are derived from its extensive chemical library and are designed to work against specific cellular pathways that are important in cancer cells, while causing minimal damage to normal cells. In addition to rigosertib, the Company's most advanced product candidate, two other candidates are in clinical trials, and several candidates are in pre-clinical stages. For more information, please visit <http://www.onconova.com>.

### **Forward Looking Statements**

Some of the statements in this release are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995, which involve risks and uncertainties. These statements relate to future events or Onconova Therapeutics, Inc.'s future operations, clinical development of Onconova's product candidates and presentation of data with respect thereto, and Onconova's future expectations and plans and prospects. Although Onconova believes that the expectations reflected in such forward-looking statements are reasonable as of the date made, expectations may prove to have been materially different from the results expressed or implied by such forward-looking statements. Onconova has attempted to identify forward-looking statements by terminology including "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately" or other words that convey uncertainty of future events or outcomes. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors, including those discussed under the heading "Risk Factors" in our Registration Statement on Form S-1 originally filed with the Securities and Exchange Commission on June 14, 2013, as amended (Registration No. 333-189358).

Any forward-looking statements contained in this release speak only as of its date. We undertake no obligation to update any forward-looking statements contained in this release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

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