
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event reported): **December 7, 2014**

Onconova Therapeutics, Inc.

(Exact name of Registrant as specified in its charter)

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)

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 December 7, 2014, Onconova Therapeutics, Inc. (the "Company") issued two press releases regarding information presented at the American Society of Hematology (ASH) Annual Meeting. Copies of the press releases are attached hereto as Exhibit 99.1 and Exhibit 99.2 and are incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

99.1 Press release issued by the Company dated December 7, 2014.

99.2 Press release issued by the Company dated December 7, 2014.

SIGNATURE

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: December 10, 2014

Onconova Therapeutics, Inc.

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

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EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued by the Company dated December 7, 2014.
99.2	Press release issued by the Company dated December 7, 2014.

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Onconova Announces Data Presentation from Combination of Rigosertib and Azacitidine in MDS and Non-proliferative AML at the 2014 ASH Annual Meeting

— Results from Phase 1 Trial of Oral Rigosertib and Azacitidine Combination Indicate Encouraging Rate of Response in MDS and AML —

NEWTOWN, PA, December 7, 2014 — Onconova Therapeutics, Inc. (NASDAQ: ONTX), a clinical-stage biopharmaceutical company focused on discovering and developing novel products to treat cancer, today announced the presentation of data from clinical trials of rigosertib in myelodysplastic syndromes (MDS) and non-proliferative acute myeloid leukemia (AML) at the 56th American Society of Hematology (ASH) Annual Meeting in San Francisco, California, December 6-9, 2014.

Based on synergistic anti-leukemic activity of the combination of rigosertib and azacitidine demonstrated in non-clinical studies, an exploratory, dose-range finding study was conducted at Mount Sinai Medical Center (New York, NY) and the MD Anderson Cancer Center (Houston, TX).

“In this first-in-man Phase 1 trial, the combination of oral rigosertib and azacitidine was safely administered to patients with MDS or non-proliferative AML. Importantly, the addition of oral rigosertib to the standard dose of azacitidine did not worsen the adverse event profile compared to that reported for azacitidine alone,” said Lewis R. Silverman, M.D., lead investigator and Associate Professor of Medicine, Hematology and Medical Oncology, at the Icahn School of Medicine at Mount Sinai. “Furthermore, the rate of response observed in the Phase 1 portion of the study is promising and has led to the Phase 2 portion of this trial, which is now open at trial sites in the U.S. and Europe.”

A total of 18 patients with MDS or non-proliferative AML, who were either previously untreated with hypomethylating agents (HMAs), or who had failed or progressed on an HMA, were included in this study. The indicated dose of azacitidine (75 mg/m²/day) was given in combination with escalating doses of oral rigosertib in three successive cohorts (140-560 mg given two times daily). Oral rigosertib was administered from day one through day 21 of a 28-day cycle. Azacitidine was administered for seven days starting on day eight of the 28-day cycle.

Nine patients with MDS, eight patients with AML and one patient with CMML received the combination. Responses according to International Working Group (IWG) criteria were observed. Marrow complete remission (mCR) was achieved in five patients (2 AML; 3 MDS). Complete remission with incomplete recovery of blood counts (CRi) was observed in four patients (1 AML; 3 MDS), and stable disease (SD) was observed in two patients (1 MDS; 1 CMML). Measures of hematological improvement, including increases in platelet (1 AML; 2 MDS patients), erythroid (2 MDS patients) and neutrophil (2 MDS patients) counts were observed with the combination. Notably, two MDS patients who responded had previously failed treatment with a hypomethylating agent.

The most frequently reported adverse events in cycle 1 included constipation, diarrhea, nausea, fatigue, hypotension, and pneumonia. The adverse events did not differ significantly among the three dosing cohorts. The only adverse events of Grade 3 or greater that occurred in more than one patient were

pneumonia (4), neutropenia, (3), febrile neutropenia (2) and thrombocytopenia (2). Elevation in creatinine in one patient in the first cohort was deemed as a possible treatment-related Grade 3 dose-limiting toxicity that required subsequent expansion of the cohort. Overall, the adverse event profile did not appear to differ significantly from that reported for azacitidine alone. The Phase 2 segment of the study is underway in multiple centers to further assess the response to the combination.

“We are encouraged by the rate of response, as well as the tolerability profile observed with the combination of oral rigosertib and azacitidine in patients with MDS and AML. We believe these results support additional focused trials for rigosertib in MDS and myeloid malignancies,” stated Ramesh Kumar, Ph.D., President and CEO of Onconova.

Investor Event and Webcast

Onconova will host a webcast and live investor event on December 12th in New York, NY at 8:30 AM ET to review the clinical data presented at the ASH Annual Meeting. The event will provide access to key opinion leaders working with rigosertib clinical trials in MDS. A status update on our discussions with regulatory agencies will also be provided. A live webcast can be accessed by visiting “Events & Presentations” in the Investors and Media section of the Company’s website at www.onconova.com.

About Rigosertib

Rigosertib is a small molecule that inhibits cellular signaling by acting as a Ras mimetic. This is believed to be mediated by direct binding of rigosertib to the Ras-binding domain (RBD) found in many Ras effector proteins, including the Raf kinases and PI3K. The initial therapeutic focus for rigosertib is myelodysplastic syndromes (MDS), a group of bone marrow disorders characterized by ineffective formation of blood cells that often converts into acute myeloid leukemia (AML). Clinical trials with intravenous (IV) and oral formulations of rigosertib are being conducted at leading institutions in the U.S. and abroad. To date, more than 500 MDS patients have been enrolled in clinical trials with rigosertib. Rigosertib is covered under composition of matter patents issued worldwide. Orphan designation has been granted for rigosertib in MDS in the U.S., Europe, Australia and Japan.

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 clinical stage, 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, as amended, Section 21E of the Securities Exchange Act of 1934, as amended, 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, regulatory approvals, expectations regarding the sufficiency of Onconova's cash and other resources to fund operating expenses and capital expenditures, Onconova's anticipated milestones and 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 most recent Annual Report on Form 10-K and quarterly reports on Form 10-Q.

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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Onconova Announces ONTIME Data Presentations at the 2014 ASH Annual Meeting

— Detailed Data from Phase 3 ONTIME Trial Presented on Rigosertib Activity and Biological Plausibility in MDS Subgroups —

NEWTOWN, PA, December 7, 2014 — Onconova Therapeutics, Inc. (NASDAQ: ONTX), a clinical-stage biopharmaceutical company focused on discovering and developing novel products to treat cancer, today announced the presentation of data from clinical trials of rigosertib in myelodysplastic syndromes (MDS) at the 56th American Society of Hematology (ASH) Annual Meeting in San Francisco, California, December 6-9, 2014.

Three presentations from Dr. Guillermo Garcia-Manero, Dr. Lewis R. Silverman and Dr. Ghulam Mufti provided details of Phase 3 results from the ONTIME study of IV rigosertib in higher risk MDS.

“The ONTIME pivotal trial with IV rigosertib was the first randomized, controlled clinical trial in higher risk MDS patients who had progressed on, failed to respond to, or relapsed after prior therapy with hypomethylating agents (HMAs),” said Guillermo Garcia-Manero, M.D., lead investigator and Chief, Section of Myelodysplastic Syndromes, at the University of Texas MD Anderson Cancer Center. “Although the trial did not achieve its primary endpoint, rigosertib was found to improve overall survival in multiple patient subgroups, which represent a substantial proportion of MDS patients with the highest levels of unmet medical need. This group included patients who had progressed on or failed to respond to previous treatment with hypomethylating agents (primary HMA failures), as well as patients in the Revised International Prognostic Scoring System (IPSS-R) Very High Risk category, and patients with certain karyotypic abnormalities, such as, monosomy 7, del7q and trisomy 8. Patients in these subgroups have a very poor prognosis, and currently there is no approved drug available to treat their disease once they have failed HMA therapy.”

As announced previously, a top-line analysis for overall survival in the intent-to-treat (ITT) population from the ONTIME trial demonstrated a 2.3 month increase for rigosertib compared to best supportive care (BSC). The log-rank p-value was 0.33 and the hazard ratio was 0.87, which was quite different from the ratio of medians (0.72), a result of survival curves converging at 15 months. Further analysis revealed rigosertib treatment-related improvements in overall survival for various subgroups that were well balanced between rigosertib and BSC arms. Notably, rigosertib improved overall survival in primary HMA failure patients, representing 64% of all patients in the ONTIME trial. Primary HMA failure patients are those who do not benefit from front-line treatment with HMAs. In this group, with investigator assessment of primary HMA failure, the increase in overall survival was 3.3 months with a hazard ratio of 0.69 (p value = 0.04). In a similar analysis, with blinded centralized assessment for primary HMA failure, a hazard ratio of 0.63 (p value = 0.011) was noted. Additional analysis indicated that MDS patients who were in the IPSS-R Very High Risk category (45% of patients in the study) had a 4.4 month improvement in survival (7.6 months for treatment arm compared to 3.2 months with BSC; HR = 0.56, p value = 0.005). Patients with well-defined cytogenetic abnormalities also experienced a survival benefit with rigosertib treatment (monosomy 7 patients: HR = 0.24, p value = 0.003; del7q patients: HR = 0.38, p value = 0.14; and trisomy 8 patients: HR = 0.34, p value = 0.035).

In addition to IPSS-R and karyotype analyses, mutational sequencing was conducted across 24 myeloid genes. In the trial population samples that were analyzed (n=111), greater than 80% of samples carried mutations, and the frequency of mutation correlated with IPSS-R score and poor prognosis karyotypes. These analyses help establish a foundation for biological plausibility for rigosertib activity in MDS patients with poor prognoses.

Continuous intravenous infusion with rigosertib appeared to be well-tolerated. Median number of cycles was 5.0 and median dose intensity was 92%, with dose reduction observed in 5% of patients. Importantly, no significant compliance or operational issues, related to the administration of rigosertib by ambulatory continuous infusion, were reported.

“We are encouraged by the presentation of these results from the ONTIME study. We are currently in discussions with U.S. and European regulatory agencies concerning the paths for approval of rigosertib in higher risk MDS patients. We will provide development updates following the completion of these discussions,” stated Ramesh Kumar, Ph.D., President and CEO of Onconova.

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