

**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): **November 5, 2015**

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))

Item 7.01. Regulation FD Disclosure.

On November 5, 2015, Onconova Therapeutics, Inc. (the "Company") issued a press release announcing that an abstract related to the Company's Phase 2 clinical trial of oral rigosertib and azacitidine in higher-risk myelodysplastic syndromes (HR-MDS) and acute myeloid leukemia (AML) was accepted for oral presentation at the 57th American Society of Hematology (ASH) Annual Meeting in Orlando, Florida, to be held on December 5-8, 2015. Details of the presentation are listed in the press release, which is attached hereto as Exhibit 99.1 and incorporated herein by reference.

On November 5, 2015, ASH released the abstract to the public by posting it on its website. The full text of the abstract is attached to this Current Report on Form 8-K as Exhibit 99.2 and is incorporated herein by reference.

The information in Item 7.01 of this Form 8-K, and the related exhibits, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

- (d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by the Company dated November 5, 2015.
99.2	<i>A Phase II Study of the Combination of Oral Rigosertib and Azacitidine in Patients with Myelodysplastic Syndromes (MDS)</i>

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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: November 5, 2015

Onconova Therapeutics, Inc.

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

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EXHIBIT INDEX

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**Onconova Announces Data Presentation from Phase 2 Combination Trial of Oral Rigosertib and Azacitidine at the 2015 ASH Annual Meeting
—MDS/AML Data Selected for Oral Presentation—**

NEWTOWN, PA, November 5, 2015 — Onconova Therapeutics, Inc. (NASDAQ: ONTX), a clinical-stage biopharmaceutical company focused on discovering and developing novel products to treat cancer, today announced that an abstract relating to the Company's Phase 2 clinical trial of oral rigosertib and azacitidine in higher-risk myelodysplastic syndromes (HR-MDS) and acute myeloid leukemia (AML) has been selected for oral presentation at the 57th American Society of Hematology (ASH) Annual Meeting in Orlando, Florida, which takes place December 5-8, 2015.

Details for the presentation are listed below.

Abstract Number: 910

Title: A Phase II Study of the Combination of Oral Rigosertib and Azacitidine in Patients with Myelodysplastic Syndromes (MDS)

Session Name: 637. Myelodysplastic Syndromes – Clinical Studies I

Date: Monday, December 7, 2015

Presentation Time: 7:00 PM EST

Location: Orange County Convention Center, W311ABCD

Presenter: Shyamala C. Navada, MD, Division of Hematology/Oncology, Icahn School of Medicine at Mount Sinai, New York, NY

About Onconova Therapeutics, Inc.

Onconova Therapeutics is a Phase 3 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>.

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 for rigosertib are being conducted at MDS Centers of Excellence in the United States, Europe, and the Asia-Pacific region. Rigosertib is protected by issued patents (earliest expiry in 2026) and has been awarded Orphan Designation for MDS in the United States, Europe and Japan.

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 Onconova's need for additional financing and current plans and future needs to scale back operations if adequate financing is not obtained, the success and timing of Onconova's clinical trials and regulatory approval of protocols, and those discussed under the heading "Risk Factors" in Onconova's 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. Onconova undertakes 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.

CONTACT: Onconova Therapeutics

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Abstract Number 910

A Phase II Study of the Combination of Oral Rigosertib and Azacitidine in Patients with Myelodysplastic Syndromes (MDS)

Shyamala C. Navada, MD(1), Lewis R. Silverman, MD(1), Katherine Hearn, RN(2), Rosalie Odchimar-Reissig, RN(1), Erin Demakos, RN(1), Yesid Alvarado, MD(2), Naval Daver, MD(2), Courtney DiNardo, MD(2), Marina Konopleva, MD(2), Gautam Borthakur, MD(2), Pierre Fenaux, MD(3), Steven Fruchtman, MD(4), Nozar Azarnia, PhD(4), Guillermo Garcia-Manero, MD(2)

(1)Division of Hematology/Oncology, Icahn School of Medicine at Mount Sinai, New York, NY

(2)MD Anderson Cancer Center, Houston, TX

(3)Hospital St Louis, Paris, France

(4)Onconova Therapeutics, Inc., Newtown, PA

Background: Rigosertib (RIG) is a Ras-mimetic that inhibits the PI3K and PLK cellular signaling pathways by binding directly to the Ras-binding Domain found in Ras effector proteins. It has been tested as a single agent in patients (pts) after failure of hypomethylating agents (HMAs). In vitro, the combination of RIG with azacitidine (AZA) inhibits growth and induces apoptosis of leukemic cells in a sequence-dependent fashion (RIG administered prior to AZA) (Skidan et al 2006). Phase I results of this study in pts with MDS or AML showed combination of oral RIG and standard-dose AZA to be well-tolerated with evidence of efficacy (Navada et al, Blood 2014). Phase II was initiated to further study the combination in pts with MDS.

Methods: Results from pts in Phase II with MDS previously untreated with an HMA, or who had failed to respond to or progressed on a prior HMA, are presented, while response data from Phase I MDS pts are updated. Pts with CMML are analyzed separately. Oral RIG was administered twice daily on Day 1-21 of a 28-day cycle at the recommended Phase II dose (RPTD: 560 mg qAM and 280 mg qPM). AZA 75 mg/m²/d SC or IV was administered for 7 days starting on Day 8. A CBC was performed weekly and a bone marrow aspirate and/or biopsy was performed at baseline, day 29, and then every 8 weeks thereafter.

Results: The combination of oral RIG and AZA has been administered to a total of 45 pts within Phase I (N=18) and Phase II (N=27). Pts were classified into the following MDS risk categories per the IPSS (Greenberg et al, Blood 1997): intermediate-1 (4), intermediate-2 (10), high-risk (14), and IPSS classification pending (4). Five pts had CMML and 8 had AML. Median age was 66 years; 69% of pts were male; and ECOG performance status was 0, 1, and 2 in 27%, 67%, and 6%, respectively. Twelve pts [MDS (9), CMML (3)] received prior HMA therapy: AZA (11 pts), decitabine (1 pts). Patients have received 1-21+ cycles of treatment to date (median, 3 cycles), with median duration of treatment of 14 weeks.

Among 15 evaluable MDS pts treated with the RPTD (1 pt in Phase I, 14 pts in Phase II), marrow responses were observed in 10: marrow CR (mCR) (8), marrow PR (mPR) (2). Responses according to IWG criteria were observed in 10 pts: complete remission (CR) (1), mCR (7), hematologic improvement (HI) (2).

Table 1: Responses for MDS Patients Treated at the Recommended Phase II Dose

Pt	Prior HMA	Best BMBL at Nadir(1)	IWG Response(2)	Hematologic Improvement
102-008	None	mCR	mCR	Platelet
101-010	None	mCR	CR	Erythroid & Neutrophil
101-011	None	mCR	mCR	None
101-013	None	mCR	mCR	Erythroid
102-010	None	SD	SD	None
101-014	AZA	PD	PD	None
102-011	AZA	mPR	HI	Erythroid & Platelet
101-016	AZA	SD	SD	None
101-017	AZA	mCR	mCR	None
102-013	None	NE	NE	NE
101-019	None	SD	SD	None
101-021	None	PD	PD	None
101-024	None	mCR	mCR	None
101-022	AZA	mCR	mCR	None
101-025	None	mCR	mCR	None
101-026	AZA	NE	NE	NE
101-027	None	NE	NE	NE
102-016	None	mPR	HI	Platelet

(1)Silverman et al, Hematol Oncol 2014

(2)IWG = International Working Group (Cheson et al, Blood 2006)

NE = not evaluable

BMBL = bone marrow blast

Overall, in pts with MDS treated on Phase I and Phase II, marrow responses were observed in 15 out of 20 evaluable pts: mCR (13), mPR (2). Responses according to IWG 2006 criteria were observed in 14 out of 19 evaluable MDS pts: CR (2), mCR (10), HI (2). Among the 7 evaluable pts with MDS in both the Phase I and Phase II who had failed to respond or progressed on prior treatment with an HMA, 5 had a response after RIG was added: CR (1), mCR (3), HI (1). Analyzed as a separate subgroup, 2 out of 5 (40%) pts with CMML had a mCR.

The most frequent adverse events (AEs) in Cycle 1 included nausea (21%) and fatigue (15%), which were also the most frequent AEs in all cycles (fatigue, 28%; nausea, 26%).

Six deaths have been observed so far. Three pts were treated for more than 1 year and continue on study.

Conclusions: The combination of oral rigosertib and standard-dose AZA was well tolerated in repetitive cycles in pts with MDS. Marrow CR was observed in 65% of pts, both with de novo MDS and after failure of prior HMA therapy. In pts who received the RPTD, 67% of pts with MDS had a bone marrow blast and IWG response. These results suggest potential synergistic interaction of the combination and support continued study of this unique combination in patients with MDS.
