

**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): **January 29, 2018**

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 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
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01. Other Events.

On January 29, 2018, Onconova Therapeutics, Inc. (the "Company") updated its corporate presentation (the "Presentation"), which is attached hereto as Exhibit 99.1 hereto and incorporated herein by reference.

Forward Looking Statements

This report contains forward-looking statements about the Company based on management's current expectations which are subject to known and unknown uncertainties and risks. The Company has attempted to identify forward-looking statements by terminology including "believes," "estimates,"

“anticipates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “should,” “approximately” or other words that convey uncertainty of future events or outcomes. The Presentation assumes the Company raises capital for disclosed product development plans. The Company’s actual results could differ materially from those discussed due to a number of factors, including, but not limited to, the Company’s ability to raise additional financing on favorable terms, the success of the Company’s clinical trials and the Company’s ability to obtain regulatory approvals and other risk factors outlined in the Company’s annual and quarterly reports filed with the Securities and Exchange Commission. The Company is providing this information as of the date of this presentation and do not undertake any obligation to update any forward-looking statements, whether written or oral, that may be made from time to time, as a result of new information, future events or otherwise, except as required by law.

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Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Exhibit</u>
99.1	Corporate Presentation dated January 29, 2018

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EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Corporate Presentation dated January 29, 2018

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SIGNATURES

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: January 30, 2018

Onconova Therapeutics, Inc.

By: /s/ Mark Guerin
Name: Mark Guerin
Title: Chief Financial Officer

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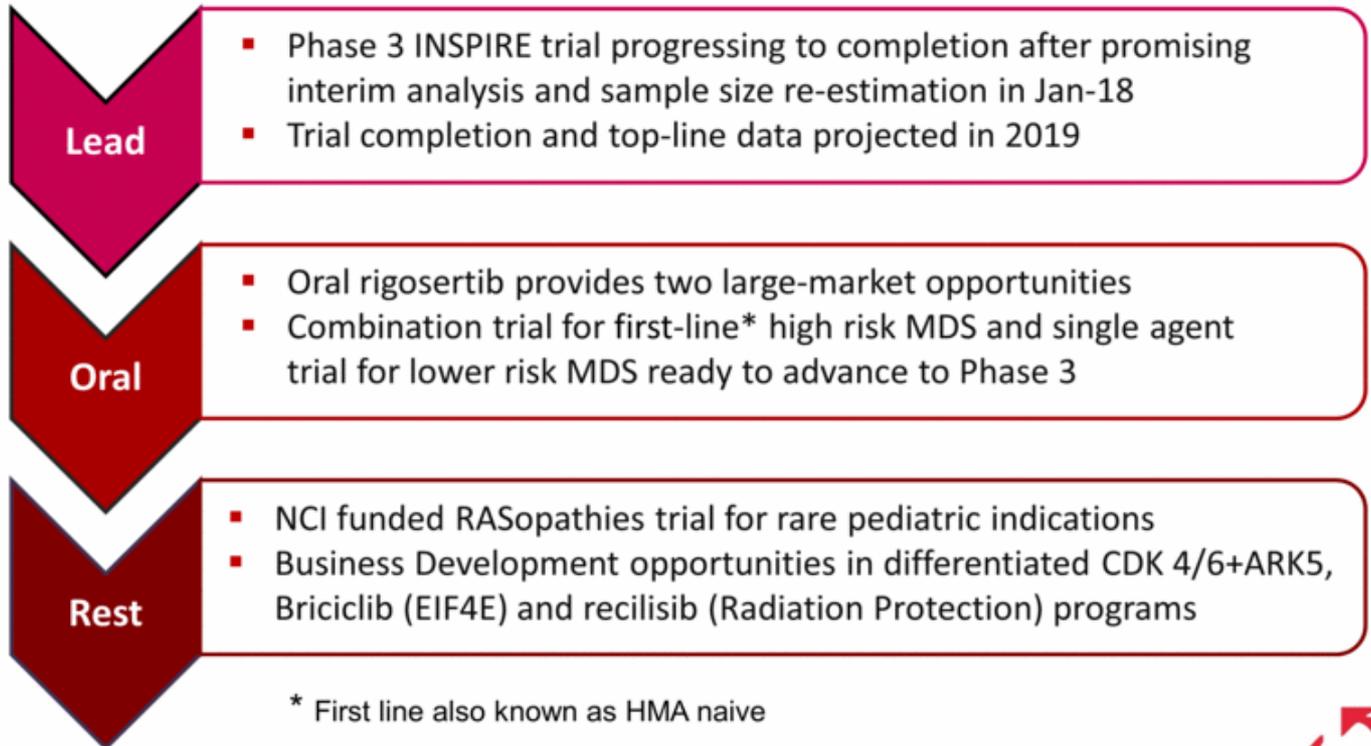
ONCONOVA
THERAPEUTICS

Corporate Update

January 29, 2018 | Nasdaq: ONTX

This presentation contains forward-looking statements about Onconova Therapeutics, Inc. based on management's current expectations which are subject to known and unknown uncertainties and risks. Onconova has attempted to identify forward-looking statements by terminology including "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "should," "approximately" or other words that convey uncertainty of future events or outcomes. This presentation assumes the Company raises capital for disclosed product development plans. Our actual results could differ materially from those discussed due to a number of factors, including, but not limited to, our ability to raise additional financing on favorable terms, the success of our clinical trials and our ability to obtain regulatory approvals and other risk factors outlined in our annual and quarterly reports filed with the Securities and Exchange Commission. We are providing this information as of the date of this presentation and do not undertake any obligation to update any forward-looking statements, whether written or oral, that may be made from time to time, as a result of new information, future events or otherwise except as required by law.

INVESTIGATIONAL RIGOSERTIB AND OTHER OPPORTUNITIES



ONCONOVA AT A GLANCE

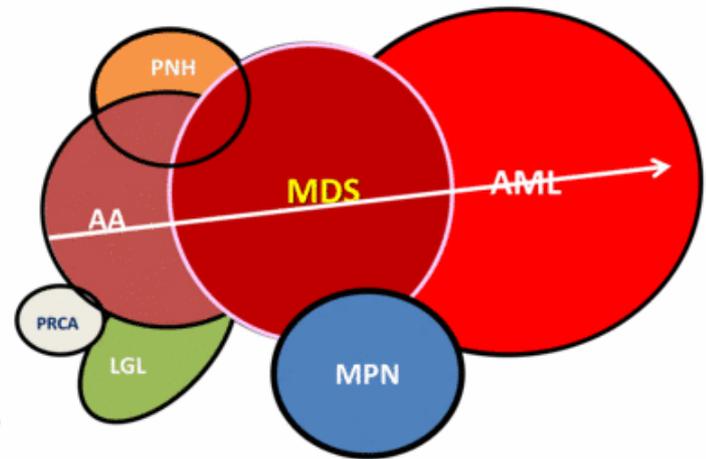
- Founded in 1998; IPO in 2013 (Nasdaq: ONTX)
- **Phase 3 stage clinical candidate: rigosertib**
 - Targets RAS effector pathways (Cell, 2016)*
 - Focused on Myelodysplastic Syndromes (MDS)
- Rigosertib partnered with Symbio in Japan/Korea
 - Additional partnerships sought
- Broad pipeline with earlier stage drug candidates
 - Recilisib with Phase 1 data
 - CDK4/6 +ARK5 inhibitor undergoing IND-enabling studies

*Divakar, S.K., Vasquez-DelCarpio R., et al. (2016). A small molecule RAS-mimetic disrupts RAS association with effector proteins to block signaling. Cell 165: 643-655



MDS RELATED TO OTHER BONE MARROW-DERIVED DISEASES

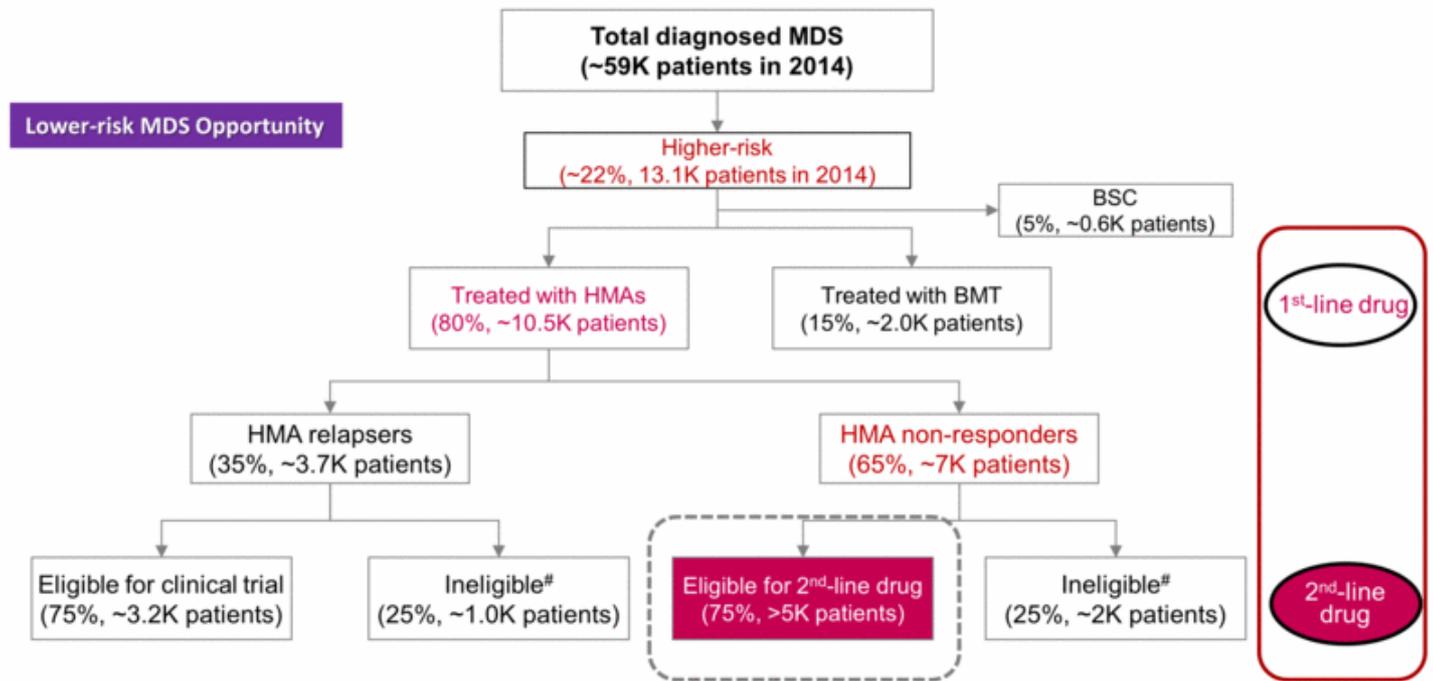
- MDS: malignant bone marrow disorder characterized by:
 - Bone marrow failure leading to low blood counts
 - 30% of patients progress to AML
- US prevalence is 59,000
 - ~13,000 have higher risk (HR) MDS
 - ~10,000 second-line patients
- Treatment options primarily limited to hypomethylating agents (HMAs)
 - Vidaza (Celgene); Dacogen (Eisai/J&J)
 - Approved more than a decade ago; now off-patent



https://www.clinicaloptions.com/Oncology/Treatment%20Updates/Myelodysplastic%20Syndromes%202016/Module/Myelodysplastic_Syndromes/Pages/Page%202.aspx



RIGOSERTIB POTENTIAL IN MYELOYDYSPLASTIC SYNDROMES



- Rigosertib for 2nd-line patients (INSPIRE Phase 3 trial)
- For 1st-line patients, in combination with Azacitidine, the current standard of care
- Oral rigosertib for transfusion dependent lower-risk patients



RIGOSERTIB CLINICAL STAGE PROGRAMS

Disease	Formulation	Indication	Stage	Expected Timelines	Potential Market Opportunity (US)/Benefit	
MDS*	Intravenous	HR-2 nd line. No approved product following HMA failure	Phase 3	Interim analysis completed Phase 3 completion 2019	~5,000 patients	No directly competing FDA approved product in the market
	Oral	HR-1 st line In combination with AZA	Phase 2	Phase 3 protocol, SPA process, in 2018	~18,000	No oral NCE approved since 2005
	Oral	Lower Risk	Phase 2	Select patient population in 2018	>10,000	Longer potential duration of treatment
RASopathies [^]	Intravenous and oral	JMML/other Ras Pathway diseases	Phase 1	<ul style="list-style-type: none"> NIH CRADA signed Proof of concept in 2019 	Rare disease	Pediatric clinical trial

*Myelodysplastic Syndromes (MDS) are bone marrow diseases related to failure of cellular production and possible transformation to acute leukemia (MSKCC website, other academic resources.)

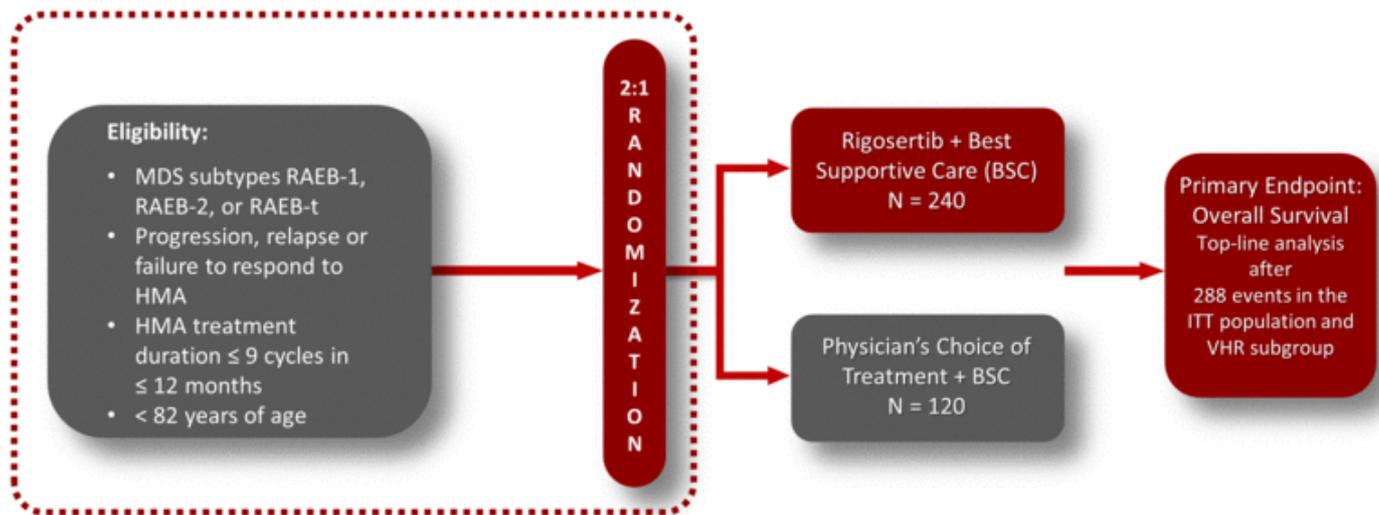
[^]RASopathies are rare inherited diseases of children that include cancer and cardiovascular disease (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4115674/pdf/nihms604870.pdf>)



LEAD INDICATION: RIGOSERTIB IN 2nd LINE HIGHER-RISK MDS
Advanced Phase 3-stage program



INSPIRE TRIAL DESIGN FOR GLOBAL PHASE 3 TRIAL

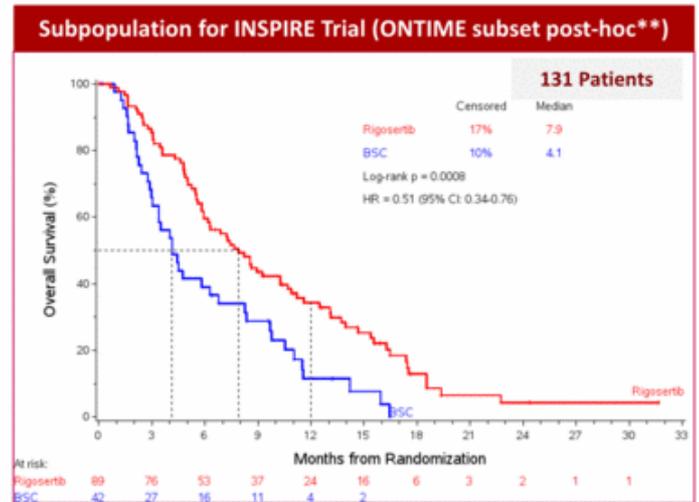
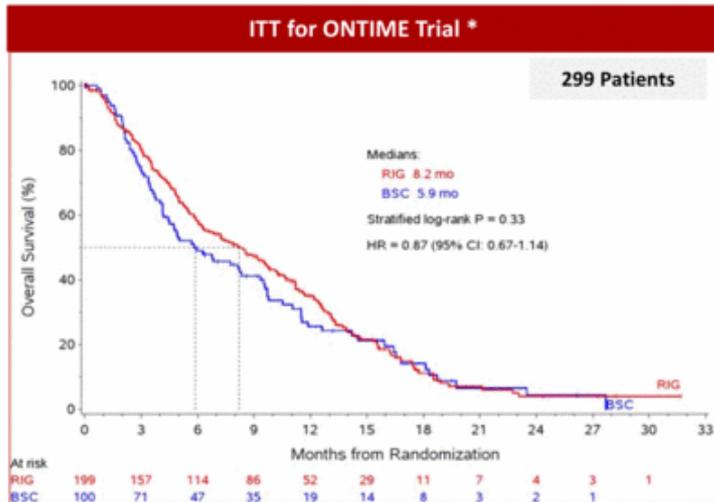


- **Survival endpoint with two successive analyses planned**
 - VHR patients currently constitute >70% of patients enrolled to date
 - Second primary endpoint of IPSS-Very High Risk (VHR) predefined group



SELECTING PATIENT POPULATION FOR PHASE 3 INSPIRE TRIAL

Data from ONTIME paper* published in *Lancet Oncology*



ITT OS analysis of ONTIME – HR= 0.87; NS survival benefit *

ITT OS of proposed INSPIRE population (ONTIME subset post-hoc) – HR = 0.51; P = 0.0008 **

*Guillermo Garcia-Manero, Pierre Fenaux, Aref Al-Kali, Maria R Baer, Mikkael A Sekeres, Gail J Roboz, et al. Rigosertib versus best supportive care for patients with higher-risk myelodysplastic syndromes after failure of hypomethylating drugs (ONTIME): a randomised, controlled, Phase 3 trial; *The Lancet Oncology* 2016 (17): 496–508 (published online March 16,2016); additional post-hoc analysis of ONTIME data

** Data on file.



INTERIM ANALYSIS

- Sample-size re-estimation implemented after DMC meeting
 - Interim analysis conducted behind a firewall
 - Trial expansion recommended
 - 135 patients to be added to increase power of trial
 - ITT and VHR successive analyses intact
 - Trial Executive Committee unanimously approves continuing the trial

- Top-line analysis to be performed after 288 events
 - Analysis results expected 2019

- **Outreach after interim analysis announcement**
 - File revised SAP with health authorities
 - Discuss DMC recommendation with study investigators
 - Advisory group to solicit ideas for enhancing rate of enrollment



INCREASING ENROLLMENT AFTER INTERIM ANALYSIS

- Outreach to all open sites
 - Closing inefficient sites
 - Using KOL support to encourage community physicians to refer patients
- Addition of new sites
 - Sites which had competing trials when first approached
 - Explore initiating Korea, India and Latin/Central America
 - Indication from Indian KOL that 40+ patients could be enrolled within one year
 - Azacitidine widely available in Latin American countries with motivation to enroll patients in 2nd line trials
- Provide trial convenience to patients
 - Potential home nursing services for clinical trial ambulatory pump services
- Support from patient advocacy groups
 - MDS Foundation has reached out to support trial expansion
 - Leukemia & Lymphoma Society will be approached to resume support



FACTORS INFLUENCING INSPIRE TRIAL AND TOP-LINE DATA

- Interim Analysis promising results may spur interest in the trial
 - Enrollment rate may increase
 - Potential for patient advocacy support
- High proportion of VHR subgroup in the trial enrolled so far
 - ONTIME trial had 43% of the patients in the VHR subgroup
 - INSPIRE eligibility criteria informed by ONTIME results
- INSPIRE trial is directed to a significant unmet medical need in MDS
 - Currently no other program is believed to be in advanced trials

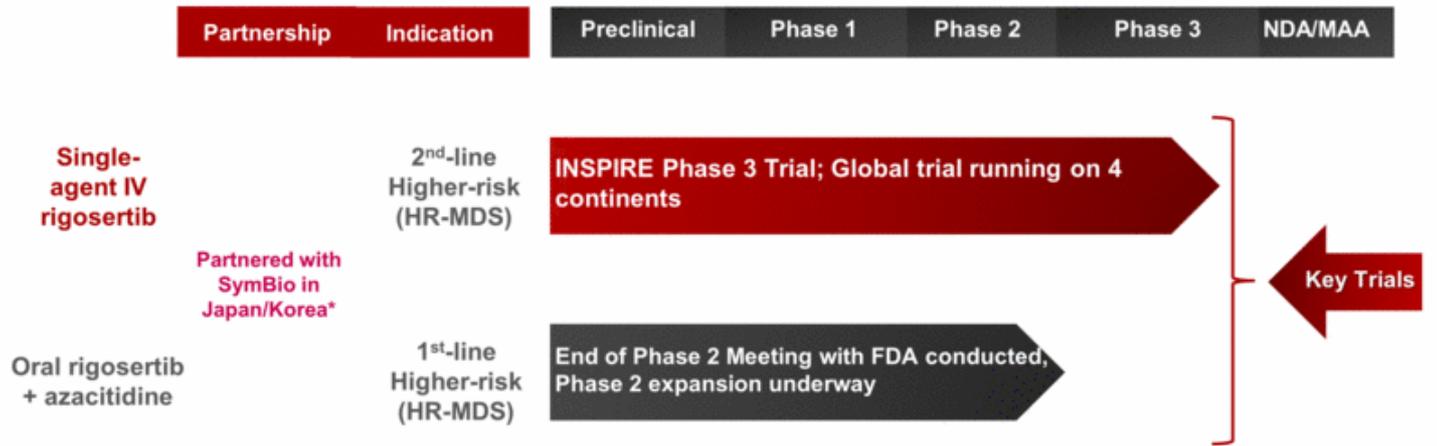


COMBINATION THERAPY WITH RIGOSERTIB IN MDS

Phase 2 stage, expect to advance to Phase 3 in 2018



ONCONOVA MDS FOCUS



IV product for infusion



Oral soft gel capsules

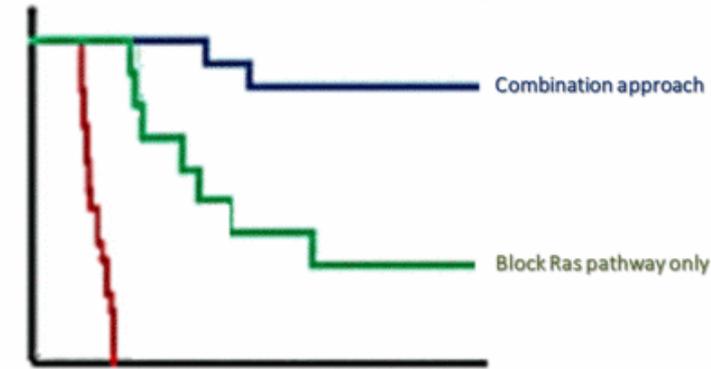


MECHANISTIC RATIONALE FOR COMBINATION THERAPY WITH RIGOSERTIB + AZACITIDINE

Preclinical evidence supports synergism of rigosertib + azacitidine combination

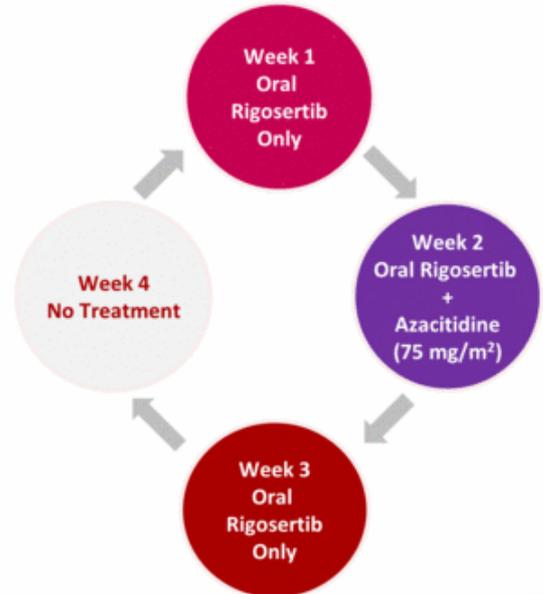
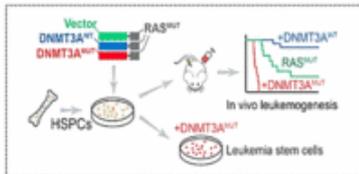
AML Animal Model

Validation of combination approach



Block methylation only

Lu et al., 2016 *Cancer Cell*



More than 80 patients enrolled in combination trial including expansion cohort



RESPONSE DATA FOR ONGOING COMBINATION TRIAL

An additional ~40 patients are currently being enrolled in the expanded Phase 2 trial

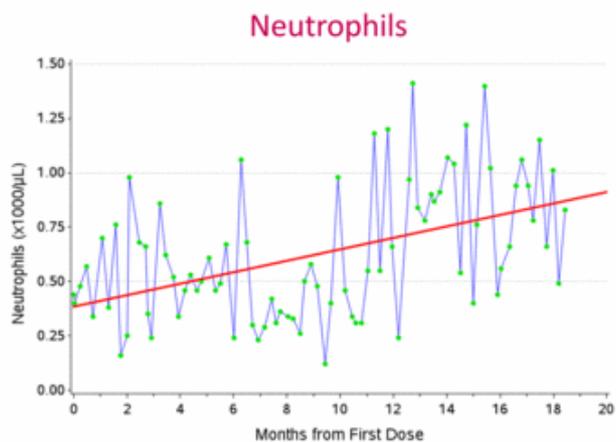
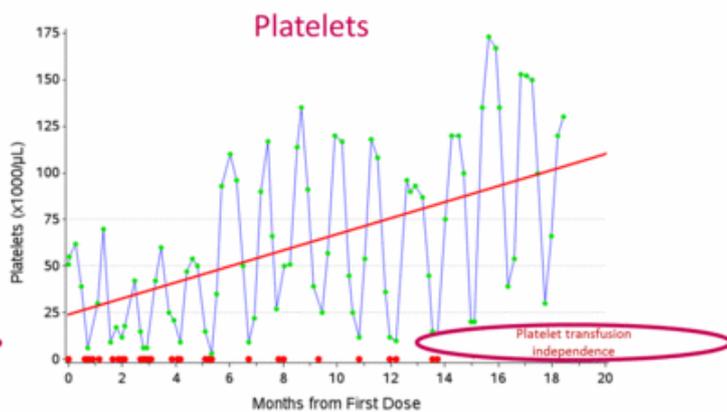
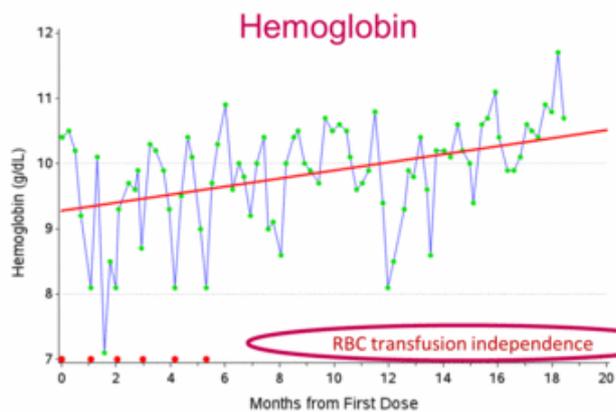
Response Criteria	Response per IWG 2006		
	Overall evaluable (N=33)	No prior HMA (N=20)	HMA resistant (N=13)
Complete Remission*	8 (24%)	7 (35%)	1 (8%)
Marrow CR + Hematologic Improvement (HI)	10 (30%)	6 (30%)	4 (31%)
Marrow CR alone	6 (18%)	3 (15%)	3 (23%)
Hematologic Improvement alone	1 (3%)	1 (5%)	0
Stable Disease	8 (24%)	3 (15%)	5 (38%)
Overall IWG Response	25 (76%)	17 (85%)	8 (62%)
Clinical Benefit Response	19 (58%)	14 (70%)	5 (38%)

*All responders had CR and no PR was noted in this study



COMBINATION THERAPY MAY LEAD TO TRANSFUSION INDEPENDENCE

Single patient case data*:



- 12 cycles of AZA – stable disease
- RBC and platelet transfusions
- Blasts 7%
- Monosomy 7
- Runx-1
- AZA + RIG in 09-08 for 20+ months
- **Complete remission**
 - RBC transfusion independence
 - <5% blasts
 - PB CR criteria

* Individual patient response data may vary



KEY HEMATOLOGIC SAFETY DATA FROM ONGOING RIGOSERTIB COMBINATION TRIAL IN MDS AND AML (STUDY 09-08)

Oral Rigosertib + Aza

Adverse Events	Grade ≥ 3
Hematuria	6.0%
Anemia	11.0%
Neutropenia	19.0%
Thrombocytopenia	20.0%

N=54. For additional adverse event information, see ASH 2016 poster presentation on Onconova's website <https://onconovatherapeutics.gcs-web.com/static-files/7027eacd-f87d-423b-b8f7-e7e2ba1e5d64>



NEXT STEPS FOR RIGOSERTIB + AZACITIDINE DEVELOPMENT

Key Parameters for Oral Rigosertib + Azacitidine Phase 3 Program

Phase 3 Design	Randomized Placebo Controlled	1:1 randomization between Aza + oral rigosertib and Aza + oral placebo
Patient Population	First-line MDS	Higher risk patients with indication for azacitidine (Vidaza)
Primary Endpoint	Composite Response	Complete and Partial Remission per IWG 2006 criteria for MDS
Trial Start	2018 expected	After regulatory discussions on SPA are completed

- **Phase 2 trial expanded**
 - Up to 40 additional patients in multiple US sites
 - Dose (increase to 1120 mg daily) and schedule optimization
 - To gain additional efficacy and safety data
- Phase 3 protocol synopsis drafted
- Scientific advice obtained from EMA



COMBINATION THERAPY: NEXT STEPS AND TIMELINES

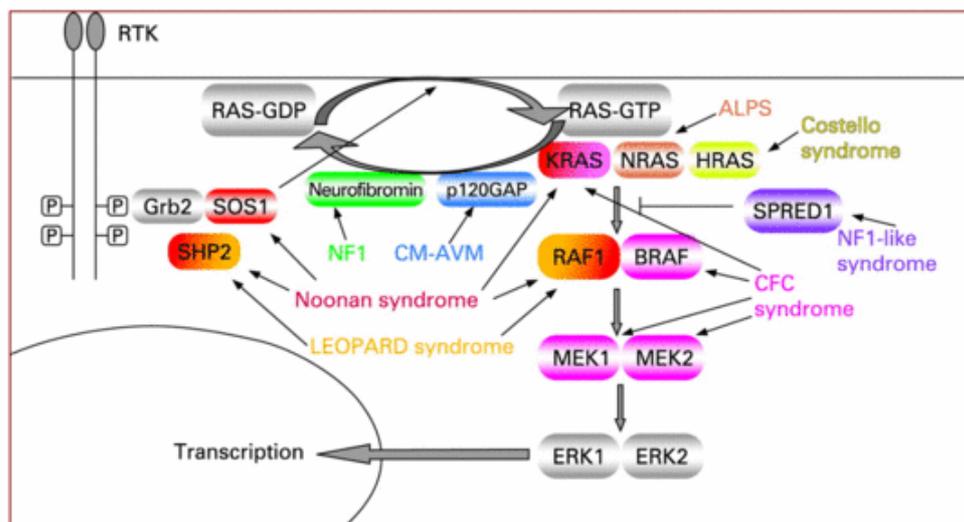
Step	Start	Complete	Remarks
Phase 2 expansion	Q1-2017	Q1-2018	<ul style="list-style-type: none">▪ Total daily dose of 1120 mg to be explored*▪ Enrollment to end in Q1-18▪ Efficacy assessment underway
Phase 3 protocol	Q1-2018	Q2-2018	<ul style="list-style-type: none">▪ Synopsis created▪ SPA submission after complete efficacy assessment
Phase 3 trial	Q4-2018	Q2-2020	<ul style="list-style-type: none">▪ Global trial including developing countries▪ Response endpoint may be achieved in <6-9 months after patient is enrolled

**Dose justification based on safety data from expansion trial and the recently presented oral rigosertib data in Lower-Risk MDS (ASH 2017)*



RASOPATHIES: RIGOSERTIB FOR RARE PEDIATRIC DISEASES

- *Rigosertib mechanism of action warrants exploration in RAS mediated cancers*
- *NCI-funded clinical trial permits broad exploration in many Ras pathway diseases in pediatric populations*
- *Potential JMML program with UCSF could provide another area of development*



Milestones

- NCI CRADA signed January 2018
- NCI Clinical trial IRB review in Process
- Potential for first patient in 2018
- UCSF non-clinical program initiated
 - Funded by LLS
- JMML clinical program could initiate in 2019



NEW PROGRAM: NEXT GENERATION CDK INHIBITOR

Current generation CDK inhibitors

- Recently launched IBRANCE® (Palbociclib, Pfizer), Kisquali® (Ribociclib, Novartis) and Verzenio® (Abemaciclib, Lilly) have been considered to be potential breakthroughs in cancer therapy
 - First FDA approval for CDK 4/6 inhibitor in breast cancer
- ON 123300 differentiated features
 - In addition to CDK4/6 also targets ARK5 controlling cellular metabolism and survival
 - Potential to act as single agent
 - Differentiated pre-clinical effect
 - Blood-brain barrier penetrating properties

Partnership with HanX

- Announced December 19, 2017
- License for Greater China
 - Onconova retains ROW rights
- HanX to fund IND-enabling studies
 - HanX to file in China
 - Onconova to file in US
- Upfront, milestones, royalties
- HanX a specialty Oncology company
 - Phase 1 stage PD-1 antibody
 - Checkpoint blockade and CDK inhibition believed to be synergistic
- Next Milestone is IND



FINANCIAL DETAILS & SUMMARY

Onconova founded in 1998; public since 2013

Ticker	Nasdaq ONTX	Debt	\$0
Stock Information	<ul style="list-style-type: none">• 10.8 million shares outstanding• Public float >84%• 52-week range: \$1.36 - \$3.22• 52-week average daily volume: 120,000• 4Q17 average daily volume: 198,000	Liquidity	<ul style="list-style-type: none">• Cash and cash equivalents of \$7.6 million as of 9-30-2017 (excluding Nov-17 raise of \$1.4 million)• S-3 effective Dec-17, S-1 filed Dec-17
Ownership	Tyndall, Tavistock, Sabby, Shire; insiders including management	Burn-rate	Average \$5.6 million per quarter over the last 5 quarters
Analyst Coverage*	H.C. Wainwright, Laidlaw, Maxim, LifeSci Capital, Van Leeuwenhoeck Research (VLR). SeeThru Equity, Dawson James	Partnerships	<ul style="list-style-type: none">• Rigosertib is partnered with Symbio Pharmaceuticals in Japan/Korea; Onconova retains rights to the rest of the world• CDK 4/6 & ARK-5 compound partnered with HanX for Greater China



MANAGEMENT TEAM



Ramesh Kumar, Ph.D.
President & CEO
Co-founder

- Bristol-Myers Squibb
- DNX
- Baxter
- Kimeragen
- Princeton University



Steven M. Fruchtman, M.D.
Chief Medical Officer

- Novartis
- Janssen
- Syndax
- Allos Therapeutics
- Spectrum Pharmaceuticals
- Mount Sinai



Mark Guerin
Chief Financial Officer

- Barrier Therapeutics
- Cardiokine
- PriceWaterhouseCooper

Manoj Maniar, Ph.D.

Senior VP,
 Product Development

Alcon, SRI

Wolfgang Meyer, Ph.D.

Sr. VP Regulatory Affairs
 GM, Onconova GmbH

Amgen, Micromet, GPC, Fujisawa

Michael Petrone, M.D.

VP Clin. Dev. Medical Affairs and
 Pharmacovigilance

GSK, Roberts, GPC



ONCONOVA HIGHLIGHTS

- Company founded in 1998 and public since 2013 (Nasdaq: ONTX)
 - Targeting underserved needs in Myelodysplastic Syndromes (MDS)
 - Lead drug Rigosertib in Phase 3 “INSPIRE” trial for Higher-risk MDS
 - Currently no approved drugs for 2nd line patients
 - Designing Phase 3 trial for Oral rigosertib + azacitidine combination
- Key upcoming milestones
 - INSPIRE (IV) Phase 3 promising interim analysis announced in **January 2018**
 - Full trial enrollment and Top-line Phase 3 data next key milestones in **2019**
- Actively seeking partnerships
 - Rigosertib licensed to SymBio in Japan; other territories in discussion
 - High value preclinical stage next generation CDK4/6 inhibitor





ONCONOVA
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