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Onconova Therapeutics, Inc.

**ONTX - BUY** 

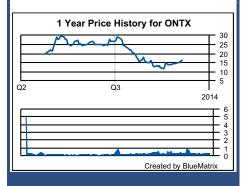
**December 9, 2013** 

## **Biotechnology**

### Onconova Therapeutics, Inc.

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Price: Fair Value Esti 52-Week Rang Market Cap (M Shr.O/S-Dilute Average Daily	e: IM): ed (mm):	\$16.22 \$40.00 \$11.73-\$31.13 \$347 21.4 230,079		
FYE: Dec EPS: Prior EPS: P/E Ratio:	2011A  NC 	2012A \$(11.50)A NA		
Quarterly EPS: Q1 Q2 Q3 Q4	:   	  	\$(1.03)E \$(5.21)E \$(1.34)E \$(1.02)E	
FYE: Dec Revenue (M):		2012A \$46.0A		
Quarterly Reve Q1 Q2 Q3 Q4	enue (M):   	  	\$1.1E \$0.6E \$1.1E \$1.1E	



Equity Research
Note

# **ONTX: Key Takeaways From ASH**

#### INVESTMENT CONCLUSION:

We highlight key points from the ASH conference. Overall, we were pleased with the level of response from rigosertib-treated patients. From the data, we continue to believe that rigosertib is a well-tolerated, highly differentiated small molecule therapy targeting significant market opportunities. The key differentiating factors for this drug are its lack of myelosuppression, its ability to target numerous different cancer types safely with high selectivity and its unique mechanism of action that allows for improved efficacy and reduced toxicity, all important factors in treating MDS patients. We recommend ONTX shares based on a burgeoning pipeline, near-term milestones, strong management team and compelling valuation.

#### **KEY POINTS:**

- Our discussions with the lead investigator suggest rigosertib may sensitize patients refractory to erythrocyte stimulating agents (ESAs) or provide synergy with ESA, but the effect of ESAs remain unclear. Transfusion independence (TI) data is similar to prior datasets. Of 33 patients (3 with del5q) on intermittent dosing treated for at least 8 consecutive weeks, 15 (45%) achieved transfusion independence (TI or no RBC transfusion for at least 8 consecutive weeks) lasting 8 to 53+ weeks (median=17 weeks). Intent-to-treat analysis showed 17/48 (35%) patients achieved TI. Recall that 50% of patients (13 patients out of 26) achieved transfusion independence in an earlier analysis. Regardless of prior ESA therapy, 5/18 or 28% of patients were responders who received no more than one dose of ESA while 11/26 or 42% were responders who received at least two doses of ESA. As historically, patients on ESAs demonstrated a 16% response rate, it is evident from today's dataset that rigosertib induces transfusion independence either alone or in combination with ESAs.
- New intermittent dosing minimizes urinary toxicities. Continuous dosing was stopped after 9 patients due to a higher urinary toxicity resulting in 39 patients receiving intermittent dosing. Six out of 48 patients (12%) experienced reversible Grade 3 urinary toxicity (dysuria, hematuria, cystitis, and urinary urgency) while 17/48 (35%) experienced Grade 2 urinary toxicity. Importantly, there were no signs of significant treatment emergent myelosuppression. Dosing was modified to a total daily dose of 840 mg (560 mg am/280 mg afternoon) to improve urinary tolerability. Other measures to manage urinary symptoms include hydration, sodium bicarbonate and dose reduction or interruption. Thirteen patients received the new dosing regimen, and only one patient so far has developed Grade 2 urinary tract infection. In prior datasets, there were higher rates of Grade 2 and 3 urinary events (56% Grade 2 and 3 hematuria/cystitis/bladder inflammation; 44% Grade 2 and 3 urinary urgency/frequence; 22% Grade 2 and 3 dysuria).
- Genomic methylation signature may help pre-select potential responders. Pre-therapy bone marrow mononuclear cells from 32 patients (including 4 from the prior Phase I study previously reported in ASH 2011) were analyzed. Seven had complete response or CR (TI + increase in Hb >2Gm/dL), 10 had partial response or PR (TI without Hb increase) and 15 had no response or NR. Functional annotation of the hypo and hypermethylated genes demonstrated that the genes most affected by methylation were related to regulation of transcription followed by genes involved in cell-cell adhesion, inflammatory response, apoptosis and proliferation.

Research Analyst Certifications and Important Disclosures are on pages 2 - 3 of this report

#### IMPORTANT DISCLOSURES

#### **Research Analyst Certification**

I, Kimberly Lee, the Primarily Responsible Analyst for this research report, hereby certify that all of the views expressed in this research report accurately reflect my personal views about any and all of the subject securities or issuers. No part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views I expressed in this research report.

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Janney Montgomery Scott LLC currently acts as a market-maker in the securities of Onconova Therapeutics, Inc..

Janney Montgomery Scott LLC managed or co-managed a public offering of securities for Onconova Therapeutics, Inc. in the past 12 months.

Janney Montgomery Scott LLC received compensation for investment banking services from Onconova Therapeutics, Inc. in the past 12 months.

Janney Montgomery Scott LLC intends to seek or expects to receive compensation for investment banking services from Onconova Therapeutics, Inc. in the next three months.

The research analyst is compensated based on, in part, Janney Montgomery Scott's profitability, which includes its investment banking revenues.

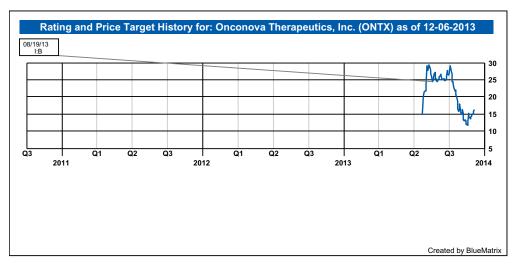
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**BUY:** Janney expects that the subject company will appreciate in value. Additionally, we expect that the subject company will outperform comparable companies within its sector.

**NEUTRAL:** Janney believes that the subject company is fairly valued and will perform in line with comparable companies within its sector. Investors may add to current positions on short-term weakness and sell on strength as the valuations or fundamentals become more or less attractive.

**SELL:** Janney expects that the subject company will likely decline in value and will underperform comparable companies within its sector.

#### **Price Charts**



#### Janney Montgomery Scott Ratings Distribution as of 9/30/13

IB Serv./Past 12 Mos.

Rating	Count	Percent	Count	Percent
BUY [B]	244	51.80	38	15.60
NEUTRAL [N]	221	46.90	21	9.50
SELL [S]	6	1.30	0	0.00

# \*Percentages of each rating category where Janney has performed Investment Banking services over the past 12 months.

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