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Janney CAPITAL MARKETS

Biotechnology

June 24, 2015

Tokai Pharmaceuticals, Inc. (TKAI) - BUY

ARMOR3-SV Phase III Trial of Galeterone in mCRPC Initiated; Enrollment Ongoing

Price:	$13.89
Fair Value Estimate:	$18.00
52-Week Range:	$9.67 - $30.00
Market Cap (MM):	$311
Shr.O/S-Diluted (mm):	22.4
Average Daily Volume:	102,722
Book Value:	$4.81
Yield:	0.0%
Cash/Share:	$(3.26)
FCF Yield:	NA
Debt/Cap:	0%

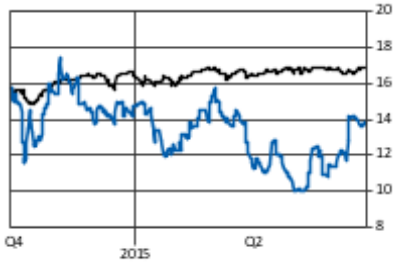
FYE: Dec	2013A	2014A	2015E
EPS:	$(1.29)A	$(3.60)A	$(2.09)E
Prior EPS:			NC
Consensus	NM	NM	-2.00

Quarterly EPS:

Q1	--	--	$(0.59)A
Q2	--	--	$(0.49)E
Q3	--	$(0.39)A	$(0.50)E
Q4	--	$(0.28)A	$(0.51)E

Quarterly Revenue (M):

Q1	$0A	$0A	$0E
Q2	$0A	$0A	$0E
Q3	$0A	$0A	$0E
Q4	$0A	$0A	$0E
Year:	$0A	$0A	$0E



1 Year Price History for TKAI

PORTFOLIO MANAGER BRIEF

Keeping in line with prior guidance, Tokai announced the initiation of ARMOR3-SV, the pivotal Phase III trial investigating galeterone as a treatment for mCRPC patients with the AR-V7 variant. The company reported initiation of patient enrollment at 15 centers, and that the diagnostic assay to screen for the variants has been finalized and will be used starting in July. Eligible patients will be treated with either galeterone or comparator and evaluated for rPFS. Topline data from the trial are expected by YE:2016.

ANALYST NOTES

- Phase III Trials for Galeterone in mCRPC Initiated. Earlier this morning, Tokai reported the initiation of the pivotal Phase III trial, ARMOR3-SV, investigating galeterone as a treatment for patients with metastatic castration resistant prostate cancer (mCRPC), characterized by the AR-V7 form of C-terminal loss (CTL) in the androgen receptor (AR). Trial initiation is in line with prior guidance. The study has been designed to compare galeterone and Xtandi (enzalutamide) in eligible patients who will be selected using a clinical trial assay developed by Johns Hopkins University and Qiagen and licensed exclusively to Tokai. The company reported that the assay has been finalized for use in the trial and is expected to start screening eligible patients in July. Top line data from the study is expected to be available by the end of 2016.
- Enrollment for Trial Ongoing, Patients to be Evaluated for Radiographic Progression Free Survival (rPFS). ARMOR3-SV is a Phase III, randomized, open-label, multicenter controlled clinical trial comparing galeterone with enzalutamide in men with AR-V7 mCRPC. The company has initiated the enrollment of mCRPC patients at more than 15 sites in the US, with more site initiations to follow in Canada, UK and other regions. The study will enroll 148 patients with mCRPC, detectable AR-V7 from circulating tumor cells (CTCs), and an ECOG performance status of 0 or 1. Enrolled patients will be randomized to receive either galeterone (2550 mg/day) or enzalutamide (160 mg/day). Following 12-weeks of treatment, patients will primarily be evaluated for rPFS and for several other safety and efficacy endpoints.
- Companion Diagnostic Finalized with Partner Qiagen; Global Deployment of Assay Underway. In order to screen for mCRPC patients with the AR-V7 form of CTL in AR, Tokai is using a companion diagnostic assay, which it has

RESEARCH ANALYST CERTIFICATIONS AND IMPORTANT DISCLOSURES ARE ON PAGES 3 - 4 OF THIS REPORT

exclusively licensed from partner Qiagen. The company also reported that the diagnostic assay has been finalized for the Phase III trial. The assay should be ready to implement in July. This diagnostic has been developed in collaboration with Johns Hopkins University and Qiagen and detects AR-V7 in circulating tumor cells of patients using RT-PCR. While the CTCs are obtained via a simple blood draw, the assay also utilizes Qiagen's recently acquired CTC enrichment technology. This agreement brings in a partner with a leading portfolio of liquid biopsy solutions.

- Patients with AR-V7 Variant of C-terminal Deletion in AR Respond to Galeterone. An estimated 12-30% of CRPC patients, characterized by CTL in AR are non-responsive to leading mCRPC therapies such as Zytiga and Xtandi, leaving these patients with limited treatment options. Investigation of galeterone as a treatment for mCRPC indicated that C-terminal loss patients responded well to the treatment, particularly those with the AR-V7, the most frequent form of C-terminal loss. While Zytiga and Xtandi work by disrupting androgen receptor signaling pathway either by antagonizing AR (Xtandi) or disrupting the synthesis of androgen (Zytiga), the unique multi-pronged mechanism of galeterone sets it apart. The drug disrupts the pathway by antagonizing AR, disrupting synthesis of androgen and also by contributing to androgen receptor degradation.
- Phase II Data from ARMOR2 Trial Provides Clinical Rationale to Initiate Phase III Trial. The ARMOR2 Phase II trial was an open-label, 2-part trial investigating galeterone as a treatment of patients with mCRPC, including those who were abiraterone or enzalutamide refractory. Initial data analysis showed that the results from the treatment of the broad population were positive, with 77% of pretreated and 70% of treatment naïve CRPC patients achieving PSA50. Retrospective analysis of patients from the trial indicated that treatment of patients with the AR-V7 variant showed maximal PSA50 reductions in six out of seven patients (86%), despite Zytiga and Xtandi being ineffective in this group. Median time to PSA progression in these patients was 7.3 months. These data support the strong potential for galeterone treatment of AR-V7 CRPC patients.

Company Description

Tokai Pharmaceuticals biopharmaceutical company, focuses on developing novel proprietary therapies for the treatment of prostate cancer and other hormonally-driven diseases. Its lead drug candidate includes galeterone, an oral small molecule drug candidate, which is about to enter a Phase III clinical study for the treatment of castration resistant prostate cancer.

IMPORTANT DISCLOSURES

Research Analyst Certification

I, David Lebowitz, 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.

Janney Montgomery Scott LLC ("Janney") Equity Research Disclosure Legend

Tokai Pharmaceuticals, Inc. currently is, or during the past 12 months was, a Janney Montgomery Scott LLC client. Janney Montgomery Scott LLC, provided investment banking related services.

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

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

Janney Montgomery Scott LLC intends to seek or expects to receive compensation for investment banking services from Tokai Pharmaceuticals, 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.

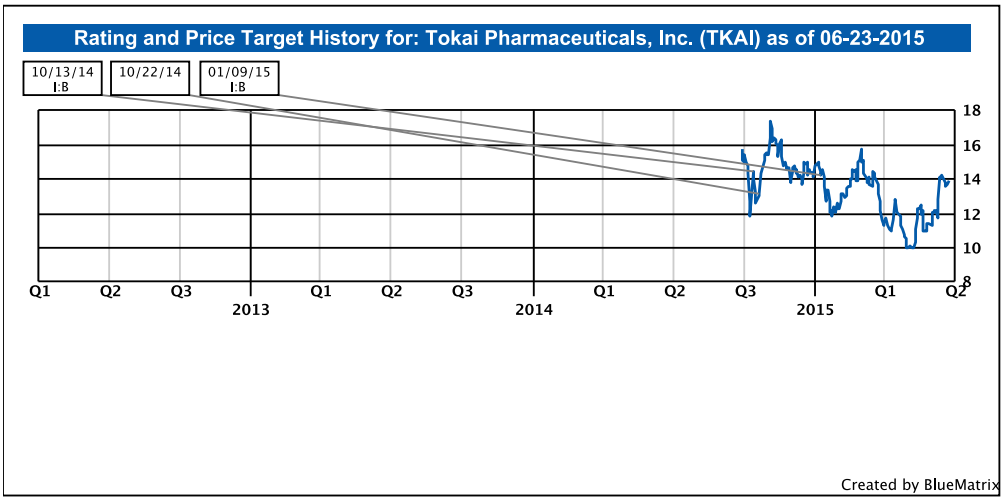
Definition of Ratings

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 3/31/15

			IB Serv./Past 12 Mos.	
Rating	**Count**	**Percent**	**Count**	**Percent**
BUY [B]	140	50.36	21	15.00

NEUTRAL [N]	137	49.28	14	10.22
SELL [S]	1	0.36	0	0.00

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

Other Disclosures

Janney Montgomery Scott LLC, is a U.S. broker-dealer registered with the U.S. Securities and Exchange Commission and a member of the New York Stock Exchange, the Financial Industry Regulatory Authority and the Securities Investor Protection Corp.

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