

Biotechnology

Price:	\$11.97
Fair Value Estimate:	\$18.00
52-Week Range:	\$9.67 - \$30.00
Market Cap (MM):	\$268
Shr.O/S-Diluted (mm):	22.4
Average Daily Volume:	62,761
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	\$(1.65)E
Prior EPS:			NC
Consensus	NM	NM	-1.40

Quarterly EPS:

Q1	--	--	\$(0.40)E
Q2	--	--	\$(0.41)E
Q3	--	\$(0.39)A	\$(0.42)E
Q4	--	\$(0.28)A	\$(0.43)E

Quarterly Revenue (M):

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



April 21, 2015

Tokai Pharmaceuticals, Inc.

(TKAI) - BUY

Galeterone and Analogs Show Promise in Pre-Clinical Pancreatic Cancer Models

PORTFOLIO MANAGER BRIEF

Tokai Pharmaceuticals announced that the Njar Laboratory at the University of Maryland (UMD) presented preclinical data at the AACR meeting demonstrating that galeterone and its novel analogs showed anti-proliferative activity in human pancreatic adenocarcinoma (PDAC) cells. These molecules showed synergistic effects with gemcitabine in both gemcitabine-naïve and gemcitabine-resistant cell lines. These data indicate the potential for galeterone and its novel analogs in pancreatic cancer, a lethal disease with 3-5% survival rates.

ANALYST NOTES

- Galeterone and Novel Analogs Demonstrate Anti-proliferative Activity in Human Pancreatic Adenocarcinoma Cells. Tokai reported the presentation of pre-clinical data from the laboratory of Vincent Njar at UMD School of Medicine at AACR in Philadelphia. The pre-clinical study showed that Tokai's lead drug candidate galeterone and its novel analogs (androgen receptor degrading agents, ARDAs) showed anti-proliferative activity in human pancreatic adenocarcinoma (PDAC) cells. The drugs were evaluated for said activity in both gemcitabine-naïve and gemcitabine-resistant cell lines. Galeterone and its analogs not only demonstrated anti-proliferative activity in these cell lines but also showed synergistic activity with gemcitabine (gem), the standard therapy for pancreatic cancer.
- Pre-clinical Data Demonstrate Synergistic Anti-proliferative Activity Between Gem and ARDAs. The potential efficacy of galeterone and three ARDAs was investigated in in vitro models of PDAC – gemcitabine-naïve and gemcitabine/erlotinib resistant human pancreatic cancer cell lines. Treatment of these cell lines with ARDAs alone or in combination with gem demonstrated significant anti-proliferative activity; furthermore, pretreatment of the gem-resistant cells with ARDAs led to sensitization of the cells to gem treatment and showed a synergistic anti-proliferative effect. Biochemical analysis indicated that ARDAs improved sensitivity to gem by inhibiting the translational machinery responsible for the gem-resistance. These pre-clinical data provide support for the investigation of galeterone and other ARDAs as a potential therapeutic for PDAC in combination with gem.
- Mechanistic Rationale for Investigating Galeterone and Analogs in PDAC. The standard therapy for the treatment of PDAC is gem alone or in combination with erlotinib. Partly due to the development of resistance; however, these

treatments result in only a marginal survival benefit. Several preclinical and clinical studies have indicated that AR might play a role in the progression of PDAC. Furthermore, few studies have shown a potential therapeutic effect of anti-androgens on PDAC progression. Galeterone and its novel analogs work via a novel triple mechanism of action targeting androgen receptor (AR), including degradation of the AR protein. Furthermore, these drugs also affect the translational pathway responsible for causing resistance to gemcitabine, providing a strong rationale for investigation of the ARDAs as potential therapeutics in PDAC in combination with gem.

- Tokai to Initiate Phase III Trials for Galeterone in Castration Resistant Prostate Cancer (CRPC). Galeterone is being investigated for the treatment of CRPC. Phase II data from the ARMOR2 trial showed that galeterone was efficacious in the treatment of a subgroup of CRPC patients characterized by the AR-V7 variant of the C-terminal loss. These patients are not effectively treated with currently approved therapies including Zytiga and Xtandi. Following the ARMOR2 trial, Tokai designed a Phase III trial to investigate galeterone in C-terminal loss AR-V7 CRPC patients. Furthermore, Tokai gained exclusive rights from Qiagen to a companion diagnostic to detect AR-V7 positive patients for the trial. This collaboration brings in a partner with a leading portfolio of liquid biopsy solutions to help commercialize and ensure the time line for the trial which is set to begin 2Q:2015.

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.

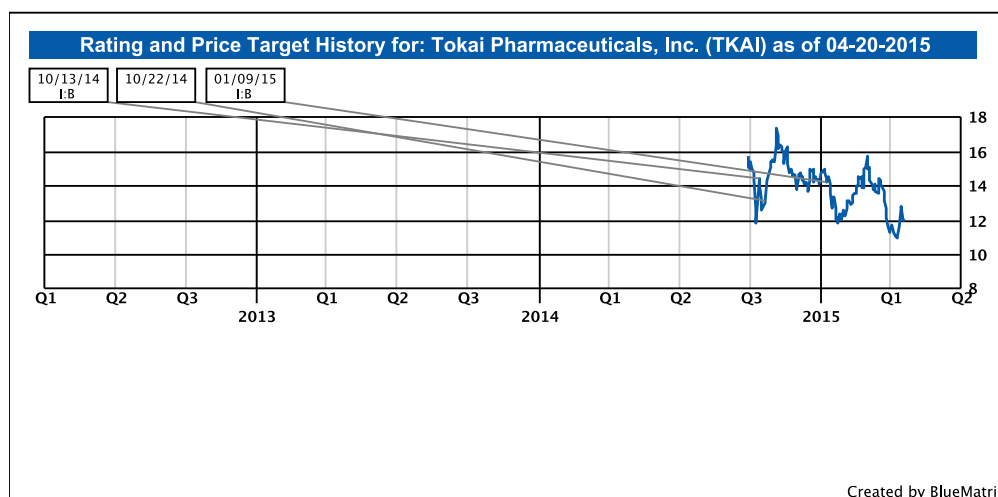
Definition of Ratings

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

Rating	Count	Percent	IB Serv./Past 12 Mos.	
			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

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