UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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 7, 2016

TOKAI PHARMACEUTICALS, INC.
(Exact Name of Company as Specified in Charter)

Delaware	001-36620	20-1000967
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

255 State Street, 6th floor
Boston, Massachusetts 02109
(Address of Principal Executive Offices) (Zip Code)

Company's telephone number, including area code: (617) 225-4305

(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 (*see* General Instruction A.2. below):

☐ 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 (17 CFR 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

From time to time, we intend to conduct meetings with third parties in which our current corporate slide presentation is presented. A copy of this slide presentation, dated January 7, 2016, is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information responsive to Item 7.01 of this Form 8-K and Exhibit 99.1 hereto 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 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01. Other Events

On January 7, 2016, we issued a press release providing an update on the conduct of our ARMOR3-SV clinical trial and the planned expansion of our galeterone clinical development program. A copy of this press release is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits

(d) The following exhibits are included in this report:

Exhibit No.	Description
99.1	Presentation dated January 7, 2016
99.2	Press release dated January 7, 2016

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

TOKAI PHARMACEUTICALS, INC.

Date: January 7, 2016

By: /s/ Gerald E. Quirk
Gerald E. Quirk
Executive Vice President, Business Operations and General Counsel

Exhibit 99.1

Tokai Pharmaceuticals

Corporate Overview

January 2016

Forward Looking Statements

Any statements contained in this presentation about our future expectations, plans and prospects, including statements about our strategy, future operations, intellectual property, cash resources, financial position and projected costs, and other statements containing the words “believes,” “anticipates,” “plans,” “expects,” and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995.

Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: whether our cash resources will be sufficient to fund our continuing operations for the period anticipated; whether necessary regulatory and ethics approvals to commence additional clinical trials for galeterone can be obtained; whether data from early clinical trials and preclinical studies will be indicative of the data that will be obtained from future clinical trials; whether galeterone will advance through the clinical trial process on the anticipated timeline and warrant submission for regulatory approval; whether such a submission would receive approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies on a timely basis or at all; whether a companion diagnostic for galeterone can be successfully developed and commercialized; whether, if galeterone obtains approval, it will be successfully distributed and marketed; and other factors discussed in the “Risk Factors” section of our Quarterly Report on Form 10-Q for the quarter ended September 30, 2015.

The forward-looking statements included in this presentation represent the views of our management as of the date of this presentation, and should not be relied upon as representing our views as of any subsequent date. Subsequent events and developments may cause our views to change. While we may elect to update these forward-looking statements at some point in the future, we specifically disclaim any obligation to do so.

Tokai Highlights

Focused on Developing Innovative Therapies for Prostate Cancer and Other Hormonally-Driven Diseases

Galeterone in AR-V7+ Prostate Cancer: Unmet Need Leads to Large Market Opportunity

- Galeterone: ***first-in-class androgen receptor degrader***
- ***Compelling Phase 2 clinical data***
- ***First precision medicine-based pivotal trial in prostate cancer*** targeting biomarker of resistance to current blockbuster therapies
- ***Pivotal Phase 3 trial enrolling:*** enrollment completion expected by 2H16; top-line data expected by mid-2017
- ***Fast Track status*** and ***global commercial rights***

Advancing Pipeline

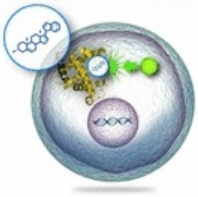
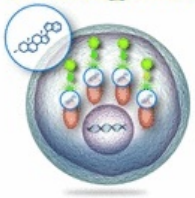
- ***Expansion in broader prostate cancer populations***
- Platform for ***second-generation AR degrading agents***
- Opportunities in ***other AR driven tumor types***

Strong Fundamentals

- ***Experienced management team***
- ***Strong cash position***

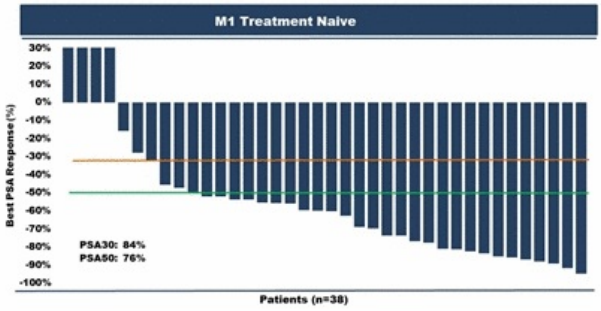
Galeterone: Highly Differentiated with First in Class MOA

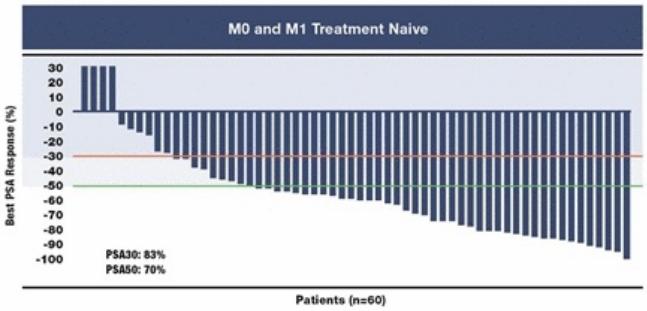
First in Class

	AR Degrader	CYP17 Inhibitor	AR Antagonist
	 Decreases AR Levels Differentiated MOA	 Inhibits Androgen Synthesis Validated MOA	 Blocks Androgen Binding Validated MOA
GALETERONE Differentiated Selective	Active in Full Length AND Active in C-Terminal Loss/ AR-V7 Splice Variants	Improved profile: No Steroids No Fasting	Improved profile: No Seizures

Galeterone Clinical Data Supports Broad Use in Prostate Cancer

- **Clinically meaningful PSA reductions in metastatic (M1) and non-metastatic (M0) CRPC population**

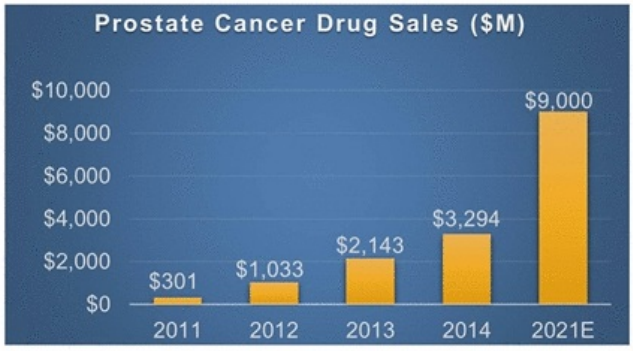




- **Galeterone has been well-tolerated to date and has a differentiated safety profile**
  - No required co-administration of steroids (prednisone must be co-administered with abiraterone)
  - No seizures to date in clinical trials (a risk associated with enzalutamide)

Prostate Cancer Represents a Large and Growing Market Opportunity

- **Prostate cancer is the most frequently diagnosed male cancer (except skin) in the US**
  - ~221,000 diagnoses in 2015
- **Prostate cancer is a leading cause of death in men in the US**
  - ~28,000 deaths in 2015
- **Market for oral prostate cancer drugs in 2014: $3.3B[1]**
  - 54% increase over prior year
- **Market for prostate cancer therapies expected to grow to $9B by 2021[2]**



[1] *Johnson & Johnson, Medivation and Astellas company reports*
[2] *Decision Resources*

Large Unmet Need Exists Despite Advances in mCRPC Treatment

- **A large subset (~20-40%) of CRPC patients experience little or no benefit to abiraterone and enzalutamide**
  - In Phase 3 trials, PSA50s of abiraterone and enzalutamide were 62% and 78%, respectively[1,2]
- **Even patients who initially respond are likely to develop resistance to therapy**

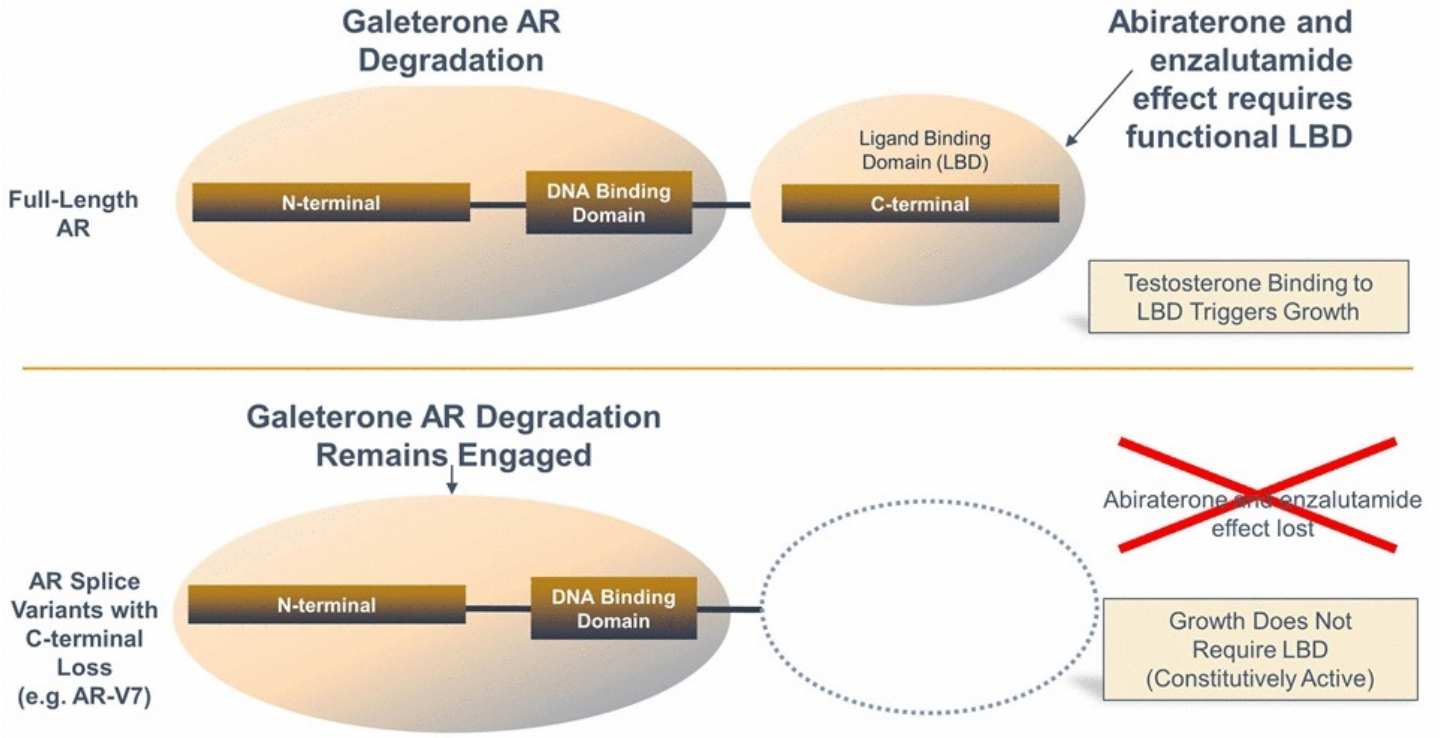
[1] *Ryan C.J. et al. NEJM, Dec 10, 2012*
[2] *Beer T.M. et al NEJM, June 1, 2014*

Galeterone AR Degradation Provides Unique Opportunity To Treat Unmet Need

- **Recent publications demonstrate poor response to current oral therapeutics in the presence of AR-V7 (a truncated form of the AR resulting in C-terminal loss)[1-4]**
- **AR degradation provides galeterone a unique opportunity to treat this unmet need**
  - Galeterone degrades both full length and truncated AR (e.g., AR-V7) through a proteasomal mechanism outside of the ligand binding domain
  - Galeterone selectively inhibits USP12 and USP46 enzymes, which are implicated in AR degradation[5]
  - Inhibition of USP12 and USP46 was not seen with abiraterone or enzalutamide[5]

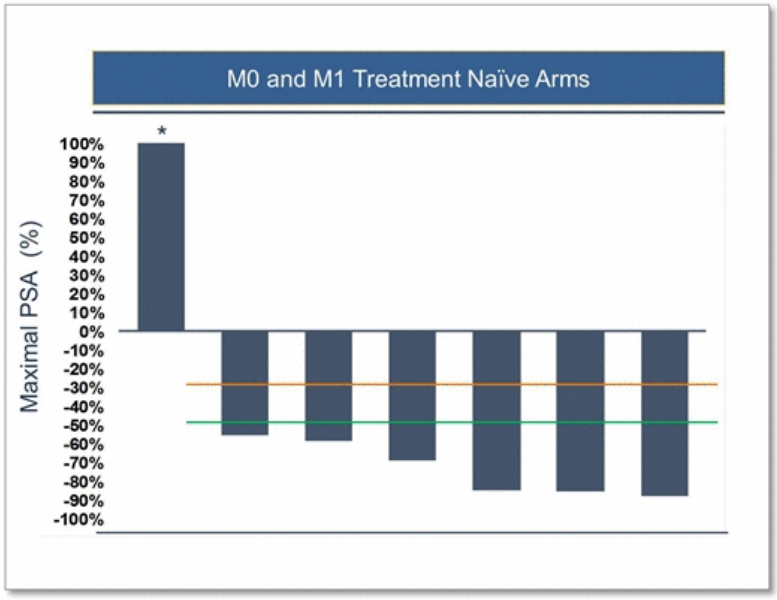
[1] *Antonarakis E et al, NEJM, 2014*
[2] *Scher H et al, ESMO, 2014*
[3] *Bambury RM et al, ESMO, 2014*
[4] *Efstathiou E et al, Eur. Urology, 2014*
[5] *Dransfield D et al, ASCO GU 2016*

Galeterone AR Degradation in C-Terminal Loss/AR-V7



Galeterone Active in C-Terminal Loss CRPC Patients in ARMOR2 Trial

ARMOR2 C-terminal loss patients[1]



- **Seven CRPC patients retrospectively identified in Phase 2 trial**
- **86% (6/7) had PSA50 response[1]**
  - Single non-responder did not receive full treatment*
  - One patient treated for ~585 days
  - Median time to PSA progression = 7.3 months

* *Patient discontinued therapy due to unrelated adverse event after ~6 weeks; did not complete primary study phase*
[1] *Taplin ME, EORTC, 2014, ASCO 2015*

MSKCC/Epic Study: C-Term Loss Associated with Non-Response to Existing Oral Drugs

- **Memorial Sloan Kettering Cancer Center (MSKCC) and Epic Sciences collaborated to characterize *de novo* resistance to abiraterone and enzalutamide[1,2]**
- **Study employed the same assay used in ARMOR2 to identify mCRPC patients with C-terminal loss**
- **PSA50 response to abiraterone/enzalutamide in C-terminal loss patients: 0% (n=6)**

[1] *Scher, ESMO 2014, Poster 238P*
[2] *Bambury, ESMO 2014, Poster 237*

JHU Study: Current Oral Therapies Lack Activity in AR-V7+ Disease

Prospective study in AR-V7+ mCRPC[1]

	Baseline AR-V7+	Response*	
		AR-V7 status	PSA50
Abiraterone (N=31)	19% (6/31)	+	**0%**
		–	68%
Enzalutamide (N=31)	39% (12/31)	+	**0%**
		–	53%

AR-V7 is most common form of C-terminal loss

[1]*Antonarakis E et al, NEJM, 2014*

Similar Outcomes Observed at Other Major Cancer Centers

- **MD Anderson: AR-V7 positivity correlates to primary resistance to enzalutamide[1]**
- **MD Anderson: AR-V7 positivity or C-terminal loss demonstrates primary resistance to sequential combination of enzalutamide and abiraterone[2]**
- **Tulane: AR-V7 positivity correlates with resistance to abiraterone and enzalutamide[3]**
- **These study results, combined with 86% PSA50 response rate in ARMOR2 patients with C-terminal loss, provide the rationale for conducting the pivotal Phase 3 trial of galeterone in AR-V7+ mCRPC**

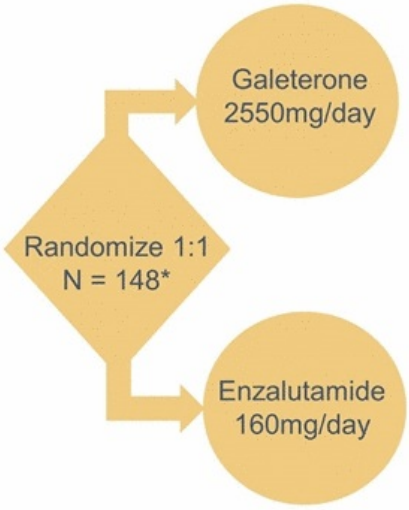
[1] *Efstathiou E et al. Eur Urol. May 29, 2014*
[2] *Efstathiou E et al, ASCO, 2014*
[3] *Liu X et al, Prostate Cancer Foundation 2014 Annual Scientific Meeting*

ARMOR3-SV: First Precision Medicine Prostate Cancer Pivotal Trial

Unique trial design finalized in consultation with FDA and EMA

Key Inclusion:
- Progressive metastatic (M1) disease on androgen deprivation therapy based on PCWG2
- Detectable AR-V7 from circulating tumor cells
- ECOG 0 or 1

Key Exclusion:
- Prior treatment with second generation anti-androgens (e.g. abiraterone, enzalutamide)
- Prior treatment with chemotherapy for CRPC



Primary Endpoint:
- Radiographic Progression Free Survival

Secondary Endpoints:
- Time to cytotoxic therapy
- Overall Survival
- PSA Changes
- Safety

- Independent Data Monitoring Committee
- Powered to detect an 82% increase in median rPFS (blinded central radiographic review)

*Over 100 clinical sites to be activated to support screening requirement (>1500 patients)

ARMOR3-SV Endpoints Supported by Prior Clinical Data

Galeterone data in C-terminal loss patients show higher PSA50 rates and longer time to PSA progression

Treatment	PSA50	PSA Progression (mos)	rPFS (mos)	OS (mos) (95% CI)
Xtandi in AR-V7+[1] (n=12 patients with AR-V7+ disease)	0%	1.4 (PSA Progression Free Survival)	2.1	7.4 (3.9–NR)
ARMOR2 Galeterone in C-terminal Loss (n=7) [2]	86%	7.3 (Time to PSA Progression)	UNK (≥7.3)	UNK

Extension of PSA progression supports potential for ≥ 82% rPFS improvement

PSA Progression ▶ Scan Progression ▶ Death

PREVAIL and COU-AA-302 show concordance among PSA, rPFS and OS
JHU data shows that this remains true in AR-V7+ patients

AR-V7 Companion Diagnostic

The NEW ENGLAND JOURNAL of MEDICINE

"A biomarker with 100% specificity in predicting lack of treatment response would be a major step forward and would probably achieve rapid adoption."

- P. Nelson (U. of Wash)[1]

- **AR-V7 clinical trial assay implemented and currently being used to pre-screen for ARMOR3-SV**
- **Assay detecting both AR-V7 and full-length AR**
- **Collaboration with Qiagen to develop clinical trial assay and commercialize companion diagnostic worldwide**
- **Assay technology licensed from JHU (published in NEJM); CLIA certified 2015**
- **AR-V7 could become part of standard of care and key to reimbursement for prostate cancer drugs**

[1] *Nelson P, N Engl J Med, 2014; 371(11)*

Galeterone Portfolio Strategy

AR-V7+ mCRPC: Fast to Patient Strategy

- **Fast to market strategy by focusing on AR-V7+ unmet need**
- **Phase 2 data support potential for success in Phase 3**
- **Phase 3 trial underway globally**
  - > 85 clinical sites open; over 100 open by 1Q16
  - Enrollment completion expected 2H16; top-line data anticipated by mid-2017
  - Other NDA-enabling activities ongoing
  - Fast track status should facilitate expeditious regulatory review process

Expansion Opportunities

- **Opportunities to expand reach**
  - Phase 2 data shows clinical activity in broader prostate cancer populations
  - Additional Phase 2 expansion expected to begin 1H16

Galeterone in Broader CRPC Populations

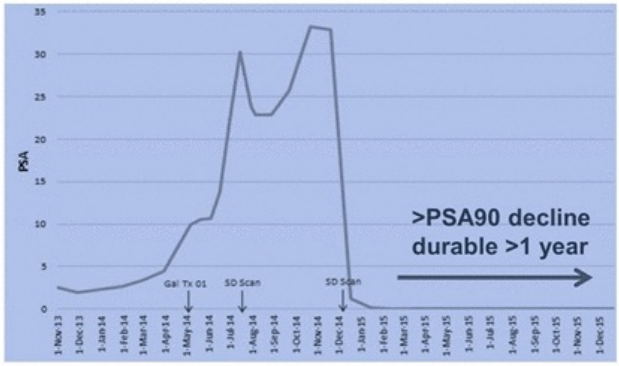
Evaluating activity of galeterone in patients who are primary refractory to available AR-targeted agents

- **Phase 2 study in mCRPC patients who rapidly progress on abiraterone or enzalutamide**
  - Part 1: Assessment of PSA response and safety; n=~36
  - Part 2: Randomize vs. next alternate AR-directed therapy; Assessment of PSA response, time to PSA progression, rPFS and safety
- **Trial expected to initiate in 1H16**

Galeterone in Broader CRPC Populations

Evaluating activity of galeterone in patients refractory to enzalutamide following an initial response

- **ARMOR2 cohort expanded to evaluate mCRPC patients who have progressed after response to enzalutamide**
  - Expanded as a result of a >90% PSA response in a post-enzalutamide patient
    - Delayed response seen following 7 months of galeterone treatment
    - PSA response has been durable with level ≤0.1 ug/L for >1 year
  - Assessment of PSA response and safety planned



- **Trial expected to initiate in 1H16**

Active Discovery Program for Second Generation Androgen Receptor Degraders

- **Discovery platform to identify novel compounds that degrade the androgen receptor**
  - Targeting compounds with high potency
  - Selectivity to AR degradation
  - Enhanced IP position
- **Opportunity to expand into several AR-driven tumor types (*e.g.* breast, ovarian, pancreatic, bladder)**
- **Options for monotherapy or combinations with other drugs**

Tokai Controls Global Galeterone Rights

- **Tokai controls global development and commercialization rights**
- **Commercial planning underway**

- **Any relationship for ex-U.S. commercial rights must be value-creating and recognize scarcity of unencumbered Phase 3 assets in major tumor type**
- **Worldwide CDx partnership with Qiagen**

Strong Cash Position

- **$73.1M in cash and equivalents at Sept. 30, 2015**
- **No operating debt**
- **Cash expected to fund planned operations into 2017**
  - ARMOR3-SV top-line data expected by mid-2017
  - Opportunity to retain global commercial rights through Phase 3 data and negotiate ex-U.S. commercial partnerships from a position of strength
- **~22.5M shares issued and outstanding at Sept. 30, 2015**

Experienced Management Team

Jodie Morrison **President and CEO**	• Former COO, Vice President, Clinical, Tokai Pharmaceuticals • Prior clinical leadership roles at Dyax, Curis, Diacrin • Involved in development of Kalbitor® • Boston Business Journal 2015 Women to Watch in Science and Technology
Karen Ferrante, MD **Chief Medical Officer and Head of R&D**	• Former CMO and Head of R&D (shared), Millennium / Takeda Pharmaceuticals • Prior roles at Pfizer, Bristol-Myers Squibb, New England Deaconess (Hem/Onc) • Involved in development of Taxol®, Tarceva®, Sutent®, Velcade®, Adcetris®, Entyvio®
Lee Kalowski **Chief Financial Officer**	• Former Vice President, Global Biotechnology Equity Research, Credit Suisse • Prior roles at Johnson and Johnson, Sanford C. Bernstein and Prudential Equity Group • Involved in healthcare equity research including companies with prostate cancer drugs
John McBride **Chief Operating Officer**	• Former COO/CFO, Gloucester Pharmaceuticals • Prior roles at University of Kansas, Cytotherapeutics, Pharmacia • Involved in development of Hexalen®, Ethyol®, Neutrexin®, Sutent®, Istodax®
Gerald Quirk **EVP, Business Operations and General Counsel**	• Former Partner & Chair, Life Sciences Practice Group, Choate Hall & Stewart • Prior legal and business operations roles at Infinity Pharmaceuticals and Genzyme • Involved in development of duvelisib, Clolar® and Campath®
Lisa Taylor **SVP, Commercial Development**	• Former Vice President of Commercial Development, Medivation • Long-term commercial consultant to Genentech and Johnson & Johnson • Involved in development/launch of Xtandi®

Tokai Highlights

Focused on Developing Innovative Therapies for Prostate Cancer and Other Hormonally-Driven Diseases

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- ***First precision medicine-based pivotal trial in prostate cancer*** targeting biomarker of resistance to current blockbuster therapies
- ***Pivotal Phase 3 trial enrolling:*** enrollment completion expected by 2H16; top-line data expected by mid-2017
- ***Fast Track status*** and ***global commercial rights***

Advancing Pipeline

- ***Expansion in broader prostate cancer populations***
- Platform for ***second-generation AR degrading agents***
- Opportunities in ***other AR driven tumor types***

Strong Fundamentals

- ***Experienced management team***
- ***Strong cash position***

Exhibit 99.2

Tokai Announces Update on ARMOR3-SV and Expanded Galeterone Clinical Development Program

Top-line Data for ARMOR3-SV Expected by Mid-2017

Expanded Clinical Program for Galeterone Planned for First Half of 2016

BOSTON—January 7, 2016—Tokai Pharmaceuticals Inc. (NASDAQ: TKAI) today provided an update on its clinical development program evaluating galeterone in the treatment of men with metastatic castration-resistant prostate cancer (mCRPC).

ARMOR3-SV Update

Tokai is enrolling patients in its ARMOR3-SV study, a Phase 3 registration clinical trial of galeterone in AR-V7+ mCRPC. The company now expects to complete enrollment in this trial during the second half of 2016 and to have top-line data available by mid-2017. This change in guidance reflects the timing for implementation of the AR-V7 clinical trial assay as well as a delay in initiating clinical sites in Western Europe and Australia during the fourth quarter of 2015. The AR-V7 assay has now been implemented in all regions. Patients are being screened at more than 85 clinical sites globally and the number of clinical sites is expected to exceed 100 by the end of the first quarter. Notably, AR-V7 prevalence observed in ARMOR3-SV to date has been consistent with the company's expectations and is in line with the published literature.

"With our rapidly growing number of open ARMOR3-SV clinical sites globally and the implementation of new recruitment initiatives, we believe in our ability to recruit to our revised guidance," said Jodie Morrison, President and Chief Executive Officer of Tokai. "Interest in AR-V7 as a marker for resistance to other therapies continues to increase throughout the prostate cancer community, and we remain focused on our goal of completing ARMOR3-SV as rapidly as possible."

2016 Galeterone Expansion Plans

With the ARMOR3-SV trial building momentum, Tokai now plans to expand galeterone development into broader mCRPC populations, including the initiation of two additional studies during the first half of 2016 in patients who have shown resistance following treatment with either abiraterone or enzalutamide.

The first of these studies is an open-label, two-part Phase 2 clinical trial designed to evaluate galeterone in men whose mCRPC rapidly progressed following treatment with either

abiraterone or enzalutamide. The first part of the study will evaluate the rates of prostate specific antigen (PSA) decline in approximately 36 patients. Following completion of the first part of the study, Tokai may then expand the study to a second, randomized phase that will compare galeterone to the next alternate androgen signaling inhibitor, with efficacy endpoints to include time to PSA progression and rPFS. Tokai plans to evaluate all patients enrolled in this open-label study for the presence of AR-V7, but AR-V7+ status is not a criterion for inclusion in the trial.

The second study is an expansion of an arm of the ongoing Phase 2 clinical trial of galeterone (ARMOR2) in mCRPC patients who have progressed following an initial response to enzalutamide. The expansion of the cohort from nine to 30 patients follows a compelling response seen in a post-enzalutamide patient. This patient did not initially show a PSA response until after seven months of galeterone treatment, at which time the patient's PSA level rapidly dropped by over 90% and has remained at less than 0.1 µg/L for over a year. This expanded post-enzalutamide cohort will assess reduction in PSA levels and safety.

About Tokai Pharmaceuticals

Tokai Pharmaceuticals is a biopharmaceutical company focused on developing and commercializing innovative therapies for prostate cancer and other hormonally driven diseases. The company's lead drug candidate, galeterone, is an oral small molecule that utilizes the mechanistic pathways of current second-generation anti-androgens, while also introducing a unique third mechanism – androgen receptor degradation. Tokai is developing galeterone for the treatment of patients with metastatic castration-resistant prostate cancer. The company's ARDA drug discovery program is focused on the identification and evaluation of compounds that are designed to disrupt androgen receptor signaling through enhanced androgen receptor degradation and are targeted to patients with androgen receptor signaling diseases, including prostate cancer. For more information on the company and galeterone, please visit www.tokaipharma.com.

About ARMOR3-SV

ARMOR3-SV is Tokai's pivotal Phase 3 clinical trial of galeterone in men with metastatic castration-resistant prostate cancer (mCRPC) whose tumor cells express the AR-V7 splice variant, a truncated form of the androgen receptor that has been associated with non-responsiveness to commonly-used oral therapies for mCRPC. ARMOR3-SV is designed to evaluate whether administration of galeterone results in a statistically significant increase in radiographic progression free survival as compared to Xtandi® (enzalutamide) in 148 treatment-naive mCRPC patients whose prostate tumor cells express the AR-V7 splice variant. ARMOR3-SV is the first pivotal trial in prostate cancer to employ a precision medicine approach for patient selection. Top-line results from ARMOR3-SV are anticipated by mid-2017.

Forward-looking Statements

Any statements in this press release about our future expectations, plans and prospects, including statements about our strategy, future operations, intellectual property, and other statements containing the words “believes,” “anticipates,” “plans,” “expects,” and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: whether our cash resources will be sufficient to fund our continuing operations for the period anticipated; whether necessary regulatory and ethics approvals to commence additional clinical trials for galeterone can be obtained; whether data from early clinical trials of galeterone will be indicative of the data that will be obtained from future clinical trials; whether galeterone will advance through the clinical trial process on the anticipated timeline; whether a companion diagnostic based on an AR-V7 clinical trial assay can be developed successfully and on a timely basis; whether the results of ARMOR3-SV will warrant submission for regulatory approval of galeterone and whether such submission will receive approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies; whether, if galeterone obtains such approval, it will be successfully distributed and marketed; and other factors discussed in the “Risk Factors” section of our quarterly report on Form 10-Q for the three months ended September 30, 2015. Any forward-looking statements contained in this press release speak only as of the date hereof and not of any future date, and we expressly disclaim any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

Contacts:

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or

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dan@tenbridgecommunications.com

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