



Tokai Announces Publication of Three Abstracts on Galeterone at the 2016 ASCO Annual Meeting

May 18, 2016

Abstracts feature a review of ARMOR2 trial results, ARMOR3-SV trial-in-progress and a review of galeterone's unique mechanism of action

BOSTON--(BUSINESS WIRE)--May 18, 2016-- Tokai Pharmaceuticals Inc. (NASDAQ: TKAI), a biopharmaceutical company focused on developing and commercializing innovative therapies for prostate cancer and other hormonally driven diseases, today announced that data related to galeterone will be presented in two posters at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting, which will take place from June 3-7, 2016, in Chicago. Galeterone, Tokai's lead product candidate, is being developed for the treatment of men with metastatic castration-resistance prostate cancer.

- Title: *Galeterone in treatment-naïve patients with castration-resistant prostate cancer with C-terminal androgen receptor loss: Results from ARMOR2*

Presenting author: Mary-Ellen Taplin, M.D., Associate Professor, Medicine, Harvard Medical School, and Chair, Executive Committee for Clinical Research, Dana-Farber Cancer Institute

Date/time: Saturday, June 4, 2016, 1 - 4:30 p.m. CDT

Location: Hall A

Abstract: [5064](#)

- Title: *Randomized, open-label, multicenter, controlled study of galeterone vs enzalutamide in men with metastatic castration-resistant prostate cancer (mCRPC) expressing AR-V7 splice variant (ARMOR3-SV)*

Presenting author: Emmanuel Antonarakis, M.D., Associate Professor of Oncology and Urology at the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center

Date/time: Saturday, June 4, 2016, 1 - 4:30 p.m. CDT

Location: Hall A

Abstract: [TPS5085](#)

A third abstract, "Galeterone targets proteasomal degradation of the androgen receptor in prostate tumor cells: A novel mechanism of action for treatment of AR-V7+ CRPC," was accepted for publication.

Additional information, including the presentation schedule and full abstracts, may be found at abstracts.asco.org. A copy of each presentation will be available on the "Publications & Presentations" page of Tokai's website, www.tokaipharmaceuticals.com, after being presented at the meeting.

About Galeterone

Galeterone is an oral small molecule that utilizes the established pathways, including CYP17 enzyme and androgen receptor inhibition, of the current second-generation hormonal therapies abiraterone and enzalutamide. Galeterone also introduces a distinct third mechanism – androgen receptor degradation – that impairs the function of androgen receptors, decreasing their sensitivity to androgen activity and reducing tumor growth. Tokai is developing galeterone for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC). ARMOR3-SV, the company's pivotal Phase 3 study of galeterone in treatment-naïve mCRPC patients whose prostate tumors express the AR-V7 splice variant, is evaluating whether administration of galeterone results in a statistically significant increase in radiographic progression-free survival as compared to enzalutamide. Tokai is also evaluating galeterone in mCRPC patients who have shown resistance following treatment with second-generation hormonal agents. Tokai has worldwide development and commercialization rights to galeterone.

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.tokaipharmaceuticals.com.

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 annual report on Form 10-K for the year ended December 31, 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.



View source version on businesswire.com: <http://www.businesswire.com/news/home/20160518006567/en/>

Source: Tokai Pharmaceuticals Inc.

Tokai Pharmaceuticals Inc.

Investors:

Lee Kalowski, 617-225-4305

Chief Financial Officer

lkalowski@tokaipharma.com

or

Argot Partners

David Pitts/Maeve Conneighton, 212-600-1902

david@argotpartners.com

maeve@argotpartners.com

or

Media:

Ten Bridge Communications

Dan Quinn, 781-475-7974

dan@tenbridgecommunications.com