Tokai Strengthens Development Team Through the Addition of Kelly Lindert, M.D., as Executive Vice President and Head of Development

March 21, 2016

BOSTON--(BUSINESS WIRE)--Mar. 21, 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 it has strengthened its development team with the addition of Kelly A. Lindert, M.D., as Executive Vice President and Head of Development.

“Kelly is joining Tokai’s senior leadership team at an important time for the company,” said Jodie P. Morrison, President and Chief Executive Officer of Tokai. “With substantial expertise in clinical development and a background in urology, we expect that she will help us execute on our ambitious clinical development goals for 2016, including driving completion of patient enrollment in our pivotal ARMOR3-SV clinical trial and expanding the galeterone clinical development portfolio. With Kelly responsible for execution of our overall development program, Karen Ferrante can now devote more attention to overseeing Tokai’s strategic development activities in her capacity as Chief Medical Officer.”

Dr. Lindert will be responsible for Tokai’s clinical development, medical affairs, pharmacovigilance, regulatory affairs and quality assurance activities. She joins the company from Novartis Vaccines and Diagnostics, where she worked for nearly eight years in roles of increasing responsibility, most recently as the Global Head of Development for the company’s influenza vaccines program. At Novartis, she was responsible for executing rapid and efficient clinical development programs and for the regulatory filings and approvals of several products. Before her time at Novartis, Dr. Lindert was engaged in the phase 1 through 4 clinical development of products in the fields of urology, nephrology, endocrinology and infectious disease at Altus Pharmaceuticals, Acambis (since acquired by Sanofi), Anesiva (formerly Corgentech Inc.) and ALZA Corporation (since acquired by Johnson & Johnson). She holds a Bachelor’s degree from Vassar College and an M.D. from the University of Chicago, each with honors, and she trained in urology at the Stanford University Hospitals.

“I’m looking forward to joining the Tokai team as we execute on our development goals,” said Dr. Lindert. “With more than 100 clinical trial sites open and actively screening patients for ARMOR3-SV, we are working diligently to complete enrollment in the study by year end, as well as to initiate two additional clinical studies of galeterone in the first half of 2016. We are also focused on raising awareness of the unmet needs of metastatic castration-resistant prostate cancer patients who are AR-V7-positive, and on engaging with the global oncology and urology communities about the potential role that galeterone may play.”

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 poor response 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 approximately 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. Enrollment in ARMOR3-SV is expected to be completed during the second half of 2016 and top-line results from the trial are anticipated by mid-2017.

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 distinct 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.

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.

Source: Tokai Pharmaceuticals Inc.

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