# Tokai Pharmaceuticals and Otic Pharma Enter into Share Purchase Agreement

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Transaction to create NASDAQ-listed pharmaceutical company focused on the development and commercialization of ear, nose, and throat (ENT) products

Gregory J. Flesher to be Named President and Chief Executive Officer of the Combined Company

BOSTON, Mass., IRVINE, Calif., & REHOVOT, Israel--(BUSINESS WIRE)--Dec. 22, 2016-- Tokai Pharmaceuticals Inc. (NASDAQ:TKAI) and Otic Pharma Ltd., a privately-held, clinical-stage pharmaceutical company focusing on the development and commercialization of products for disorders of the ear, nose, and throat (ENT), today announced that the two companies, together with the shareholders of Otic Pharma, have entered into a definitive share purchase agreement under which the shareholders of Otic Pharma will become the majority owners of Tokai.

The transaction will result in a NASDAQ-listed company focused on the development and commercialization of products for ENT disorders, including Otic Pharma's lead candidate which is a nasally-administered, combination drug product (OP-02) intended to address the underlying cause of otitis media and Eustachian tube dysfunction (OM/ETD), a condition that affects more than 700 million people around the world every year. The company will operate under the name OticPharma, Inc., and will be led by Gregory J. Flesher, current Chief Executive Office of Otic Pharma Ltd. Current President and Chief Executive Officer of Tokai, Jodie Morrison, will remain as a member of the board of directors.

"Over the last several months, Tokai has conducted an extensive review of strategic alternatives aimed at maximizing value for our shareholders over the long-term," said Jodie Morrison, President and CEO of Tokai Pharmaceuticals. "We believe the proposed transaction with Otic Pharma, a company that has both a promising pipeline and an experienced leadership team with a track record of creating significant shareholder value in public pharmaceutical companies, advances this goal."

"Our lead program in otitis media, OP-02, has significant potential," said Gregory J. Flesher, Chief Executive Officer of Otic Pharma. "OP-02 is an investigational drug product designed to break the cycle of recurrent and chronic otitis media which affect millions of people around the world. We expect to have phase 1 clinical pharmacodynamic data in the first half of 2017 and, with this transaction, to have the capital needed to be able to move directly into phase 2 development to explore the product's ability to prevent otitis media in children."

#### **Share Purchase Agreement Details**

Under the terms of the agreement, the shareholders of Otic Pharma will receive a total of 32,172,209 shares of newly issued Tokai common stock, while outstanding Otic Pharma options and convertible securities will be assumed by Tokai. Upon the exchange, it is expected that existing Tokai stockholders will own approximately 40% of the combined company, with existing Otic Pharma shareholders owning approximately 60%. The transaction has been unanimously approved by the boards of directors of both companies and shareholders of Otic Pharma. Tokai's largest stockholder, Apple Tree Partners, who holds approximately 35% of Tokai's common stock has entered into an agreement in support of the proposed transaction. The transaction is expected to close during the first quarter of 2017, subject to customary closing conditions, including approval by shareholders of Tokai.

Wedbush PacGrow advised Tokai Pharmaceuticals and Piper Jaffray & Co. advised Otic Pharma in the proposed transaction. Wilmer Cutler Pickering Hale and Dorr LLP and Gross, Kleinhendler, Hodak, Halevy, Greenberg & Co. served as legal counsel to Tokai and Gibson, Dunn & Crutcher LLP and Yigal Arnon & Co. served as legal counsel to Otic Pharma.

## **Management and Organization**

Upon the close of the proposed transaction, the board of directors of the combined company will consist of seven

members, three to be designated by Tokai and four to be designated by Otic Pharma. Officers of the new company will be Gregory J. Flesher, President and Chief Executive Officer; Christine G. Ocampo, Chief Financial and Compliance Officer; and Dr. Catherine C. Turkel, Chief Development Officer.

### **Additional Funding**

An Otic Pharma investor syndicate, including current shareholders and members of the management team, has committed to invest \$7 million of additional capital in connection with the share purchase agreement.

# **Conference Call Information**

Tokai and Otic Pharma will host a conference call in early January to discuss the proposed transaction. Call in information will be provided in a future press release.

## **About Otic Pharma**

Otic Pharma is a clinical-stage pharmaceutical company focusing on the development and commercialization of products for disorders of the ear, nose, and throat (ENT). The company has two platform technologies, each of which has the potential to be developed for multiple ENT indications. The company is currently developing a nasally-administered, combination drug product (OP-02) intended to address the underlying cause of otitis media and Eustachian tube dysfunction (OM/ETD), a condition that affects more than 700 million people around the world every year. Otitis media is one of the most common disease seen in pediatric practice and the most frequent reason children consume antibiotics or undergo surgery. The company also has a foam-based drug delivery technology platform (OP-01) that can be used to deliver drugs into the ear, nose, and sinus cavities. The company is currently developing OP-01 as an improved treatment option for acute otitis externa ("swimmers ear"). For more information on the company, please visit www.oticpharma.com.

### **About Tokai Pharmaceuticals**

Tokai Pharmaceuticals is a biopharmaceutical company previously focused on developing and commercializing innovative therapies for prostate cancer and other hormonally driven diseases. The ARMOR2 and ARMOR3-SV clinical trials of Tokai's drug candidate, galeterone, for the treatment of metastatic castration-resistant prostate cancer (mCRPC) have been closed, with only patients in ARMOR2 long-term extension continuing treatment at this time. Plans remain in effect to present data from the ARMOR3-SV trial in a scientific forum once fully available and analyzed. Assessment of plans for galeterone, the ARDA platform and Tokai's AR-V7 assay work are underway at this time.

#### Safe Harbor

# Additional Information about the Proposed Transaction and Where to Find It

In connection with the proposed transaction, Tokai intends to file with the Securities and Exchange Commission (the "SEC") a proxy statement in connection with the proposed transaction with Otic Pharma and furnish or file other materials with the SEC in connection with the proposed transaction. The definitive proxy statement will be sent or given to the stockholders of Tokai and will contain important information about the proposed transaction and related matters. BEFORE MAKING ANY VOTING DECISION, TOKAI'S STOCKHOLDERS ARE URGED TO READ THE PROXY STATEMENT AND THOSE OTHER MATERIALS (INCLUDING ANY AMENDMENTS OR SUPPLEMENTS THERETO) CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION AND THE PARTIES TO THE PROPOSED TRANSACTION. The proxy statement and other relevant materials (when they become available), and any other documents filed by Tokai with the SEC, may be obtained free of charge at the SEC's website at <a href="https://www.sec.gov">www.sec.gov</a>. In addition, security holders will be able to obtain free copies of the proxy statement upon request directed to the Corporate Secretary at 255 State Street, Boston MA 02109, or by phone at 617-225-4305.

# Participants in the Solicitation

Tokai, Otic Pharma and each of their respective directors and executive officers may be deemed to be participants in the solicitation of proxies from the stockholders of Tokai in connection with the proposed transaction. Information regarding the interests of these directors and executive officers in the proposed transaction described herein will be included in the proxy statement described above. Additional information regarding the directors and executive officers of Tokai is included in proxy statement for its 2016 Annual Meeting, which was filed with the SEC on April 29, 2016, and is supplemented by other public filings made, and to be made, with the SEC by Tokai.

### **Forward-looking Statements**

Any statements in this press release that are not historical facts, including statements regarding the structure, timing and completion of the proposed transaction; Tokai's continued listing on NASDAQ prior to and after the proposed transaction; expectations regarding the capitalization, cash balances and working capital, resources and ownership structure of the company after the transaction; expectations regarding the sufficiency of the company's resources to fund the advancement of any development program or the completion of any clinical trial; the nature, strategy and focus of the company after the transaction; the safety, efficacy and projected development timeline and commercial potential of any product candidates; the expectations regarding voting by Tokai stockholders: and other statements containing the words "believes," "anticipates," "plans," "expects," "may," 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: risks and uncertainties associated with stockholder approval of and the ability to consummate the proposed transaction; whether the anticipated cash resources will be sufficient to fund operations for the period anticipated and to conduct the anticipated studies; whether the necessary approvals to commence clinical trials of Otic's product candidates can be obtained on a timely basis or at all; and whether the results of clinical trials will warrant submission for regulatory approval, any such submission will receive approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies and, if any of such product candidates obtains such approval, it will be successfully distributed and marketed. Risks and uncertainties facing Tokai are discussed in the "Risk Factors" section of its quarterly report on Form 10-Q for the three months ended September 30, 2016 Any forward-looking statements contained in this press release speak only as of the date hereof and not of any future date, and the companies expressly disclaim any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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#### **Tokai Investors:**

Argot Partners
David Pitts or Maeve Conneighton, 212-600-1902
<a href="mailto:david@argotpartners.com">david@argotpartners.com</a>
<a href="mailto:maeve@argotpartners.com">maeve@argotpartners.com</a>
or

# Otic Pharma Investors:

The Trout Group Gita Ogawa, 646-378-2949 Gogawa@troutgroup.com