



Allay Therapeutics Announces Development and Commercialization Agreement with Maruishi Pharmaceutical for Ultra-Sustained Pain Therapeutics in Japan

SAN JOSE, CA & OSAKA, JAPAN, December 18, 2023 — Allay Therapeutics, Inc. (Allay) today announced that they have entered into a license agreement with Maruishi Pharmaceutical Co., Ltd. (Maruishi), providing Maruishi with exclusive rights to develop and commercialize Allay’s lead investigational drug candidate, ATX101, and other ultra-sustained analgesic implantable drug candidates for acute pain in Japan. ATX101 is a non-opioid, bupivacaine-based drug product designed to deliver continual, localized pain relief for weeks following total knee arthroplasty (replacement), or TKA, a common orthopedic surgery.

Under the terms of the agreement, Allay will receive an upfront payment and an equity investment, and is eligible to receive future milestone payments related to pre-defined clinical and regulatory events in the U.S. and Japan as well as commercial milestones and royalties on sales in Japan. Allay retains the right to develop and commercialize ATX101 in all territories outside of Japan.

“Maruishi is one of the leading specialty pharmaceutical companies in perioperative care and anesthetic settings, with strong development and commercial capabilities within the acute post-operative pain management arena,” said Adam Gridley, Chief Executive Officer of Allay. “We’re especially excited to partner with Maruishi given their similar mission to improve quality of life and ease post-surgical recovery. We believe that their internal expertise and long history with local anesthetic product R&D and strong relationships with key opinion leaders provide a natural fit to help accelerate the development of ATX101 and potentially deliver better pain management solutions for patients in Japan.”

“We are pleased to initiate this development and commercialization collaboration with Allay. Their leadership and long history in Asia and the U.S. provide the opportunity to rapidly develop ATX101 and other platform products in their ultra-sustained delivery pipeline,” said Katsuhito Inoue, President and Representative Director of Maruishi. “We believe the ATX programs will complement our existing local anesthetic products in Japan, and provide our doctors and patients an attractive alternative to the existing therapies with longer pain relief and better recoveries from surgery.”

TKA surgery represents an estimated potential \$1 billion market, which combined with the multi-billion dollar economic burden of opioid abuse underscores the critical need to reimagine the pain management paradigm. An open-label Phase 1b/2a study completed by Allay demonstrated ATX101’s potential to transform post-surgical pain management, with

data supporting the potential for a strong safety profile and sustained pain relief lasting two weeks after administration. Allay is currently evaluating ATX101 in a randomized controlled Phase 2b study. The parties plan to advance ATX101 into the requisite registration studies in the US and Japan.

Renexes LLC served as an advisor to Allay in connection with the transaction. Cooley LLP acted as legal counsel to Allay for the transaction.

About ATX101

ATX101 is a novel configuration of an approved, well-characterized, validated intracellular sodium ion channel blocker, bupivacaine, and a biopolymer that has been designed to provide weeks of pain relief following TKA. ATX101 has a high density of drug within its small footprint to allow for ultra-sustained analgesia. It is placed at the end of standard surgery, in minutes, to deliver its analgesic effect over weeks before dissolving into water and carbon dioxide over a longer period. On a Phase 1b/2a study, ATX101 demonstrated compelling delivery of drug over several weeks with a reduction in pain and opioid usage, and was generally well tolerated.

About Allay Therapeutics, Inc.

Allay is pioneering a new category of ultra-sustained pain therapeutics to transform post-surgical pain management and recuperation for patients and physicians. Allay's proprietary technology platform combines validated non-opioid analgesics and biopolymers to create dissolvable therapeutics to deliver pain relief within a targeted site over weeks—an order of magnitude greater than the longest-lasting pain treatments currently available. The company's lead investigational product candidate, ATX101, is currently being evaluated in a Phase 2 clinical study in TKA surgeries. Allay unites a dynamic, global team of entrepreneurs, scientists, clinicians and innovators in the San Francisco Bay Area and Singapore. Learn more at allaytx.com.

About Maruishi Pharmaceutical Co., Ltd.

Maruishi, an Osaka-based company which commenced operations in 1888, has a strong presence in the Japanese market as a specialty pharma developing, manufacturing, and marketing perioperative and infection control products, and as a leading producer of Japanese Pharmacopoeia drugs. Making use of the technology, knowledge, and know-how that have been cultivated over 130 years of history, Maruishi continues to contribute to the healthcare and improvement of QOL of the patients. For further details, please visit <https://www.maruishi-pharm.co.jp/english/>.

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