



Allay Therapeutics Announces First Patients Dosed in Pivotal Phase 2b Registration Trial of ATX101 for Post-Surgical Pain Management After Knee Replacement Surgery

- *ATX101 is designed to provide extended pain relief after surgery, reducing the need for opioids and improving patient recovery*
- *Phase 2b registration trial is assessing the efficacy and safety of ATX101 for post-surgical pain management in total knee replacement patients and is currently enrolling across U.S. clinical sites*
- *Maruishi Pharmaceutical, Allay's partner in Japan also has enrolled first several patients in Phase I/II open-label study*

SAN JOSE, CA, February 18, 2024 (BUSINESSWIRE) – Allay Therapeutics, a clinical-stage biotechnology company pioneering ultra-sustained analgesic products to transform post-surgical pain management and recuperation, today announced that the first patient has been dosed in its Phase 2b registration trial evaluating ATX101 for the treatment of post-surgical pain following total knee replacement (TKA) surgery. ATX101 is a novel investigational analgesic that provides extended pain relief after surgery, reducing the need for opioids and improving patient recovery.

“We’re thrilled to achieve this important milestone with the patients dosed in our Phase 2b registration trial of ATX101,” said David Hewitt, Chief Medical Officer at Allay Therapeutics. “This trial is a significant step forward on our path to changing the paradigm of postoperative pain management by providing a simplified locally targeted solution that provides sustained analgesia in the weeks following surgeries. Building on promising data from our earlier dose-ranging studies, we are excited to see how ATX101 can help improve patient outcomes, reduce opioid use and improve function more rapidly than currently available therapies.”

The Phase 2b registration trial of 200 participants undergoing total knee arthroplasty (replacement, or TKA surgery) is being conducted at multiple U.S. sites and is a three-arm, randomized, controlled study evaluating treatment with ATX101 1,500 mg versus placebo and bupivacaine active comparator. A prior dose-ranging Phase 2b trial achieved clinically meaningful durable treatment effects with ATX101 versus standard-of-care bupivacaine based on pain intensity out to four weeks, with less use of opioids and meaningful improvement in functional activities up to 60 days following surgery.

Allay Therapeutics’ Japanese partner Maruishi Pharmaceutical has also dosed the first patient in January in a Phase I/II multi-center open-label safety study of ATX101 in Japan. Initial clinical data from both studies is expected to be shared in the second half of 2025.

About ATX101

ATX101 is a novel investigational 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 total knee arthroplasty (TKA, or replacement), a common orthopedic surgery. ATX101 has a high density of drug within its small footprint to allow for ultra-sustained analgesia. It is placed in minutes at the end of standard surgery to deliver its analgesic effect over weeks before eventually dissolving into water and carbon dioxide. The simple procedure does not require specialized training and is intended to replace the existing complex mix of analgesic products used for shorter-term pain management in the post-surgical setting. ATX101 is an investigational product that has not been approved by the U.S. Food and Drug Administration.

About Allay Therapeutics

Allay Therapeutics is pioneering ultra-sustained analgesic products to transform post-surgical pain management and recuperation for patients and physicians. Our proprietary technology platform combines validated non-opioid analgesics and biopolymers to create dissolvable candidates to deliver pain relief within a targeted site over weeks: an order of magnitude greater than the longest-lasting pain treatments currently available. Our platform and vision were shaped by The Foundry incubator and Lightstone Venture's Singapore Fund. 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.

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