Melt Pharmaceuticals' MELT-300 (Midazolam 3mg and Ketamine 50mg Sublingual Tablet) Achieves Primary Sedation Endpoint in Phase 2 Pivotal Efficacy and Safety Study

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MELT-300 Statistically Superior for Procedural Sedation Compared to All Comparator Treatment Arms, Including Midazolam 3mg (P=0.0129) and Ketamine 50mg (P=0.0096)

MELT-300 Treatment Arm 50% Less Likely to Require Rescue Sedation Compared to Midazolam (P=0.0198)

MELT-300 Treatment Arm 66% Less Likely to Require Rescue Sedation Pre-Operatively Compared to the Midazolam Treatment Arm

MELT-300 Had a Favorable Safety Profile That Was Generally Comparable to Placebo

NASHVILLE, Tenn.--(BUSINESS WIRE)--Dec. 21, 2022-- Melt Pharmaceuticals, Inc., a clinical-stage pharmaceutical company developing novel approaches for procedural sedation, today announced top-line results of its Phase 2 pivotal efficacy and safety study for its lead product candidate, MELT-300, a sublingual, needle- and opioid-free patented formulation for procedural sedation during cataract surgery. Based on the outcome of the MELT-300 data, the company intends to request a meeting with the U.S. Food and Drug Administration (FDA) to discuss the results of this study and the continued clinical development of MELT-300.

MELT-300 combines fixed doses of midazolam (3mg) and ketamine (50mg) in one rapidly dissolving tablet (RDT) that is administered sublingually for procedural sedation during cataract surgery. MELT-300 utilizes Catalent Inc.'s proprietary fast-dissolving Zydis ® delivery technology to rapidly dissolve the tablet for absorption across the very thin sublingual mucosa.

The factorial-designed, randomized, double-blind, placebo-controlled, parallel-cohort Phase 2 study was designed to evaluate the efficacy and safety of MELT-300 and the contribution of midazolam and ketamine components to sedation and intraoperative ocular analgesia in subjects undergoing cataract surgery. The trial compared MELT-300 against (i) placebo alone, (ii) sublingually delivered midazolam alone, and (iii) sublingually delivered ketamine alone, with two independent primary efficacy endpoints: (a) appropriate cataract surgery sedation using a validated sedation scale (Ramsay Sedation Scale), or (b) the management of intraoperative pain during the cataract surgery. The study was conducted at nine sites and enrolled over 300 subjects.

"We are extremely pleased with the robust sedation efficacy from our pivotal Phase 2 study of MELT-300," said Larry Dillaha, M.D., CEO of Melt Pharmaceuticals. "The clear, critical, and positive findings for our procedural sedation primary endpoint allow us to confidently proceed with the development of this non-IV option for cataract surgery. We believe the commercial appeal for offering patients and physicians the ability to achieve adequate sedation without the need to start an IV is an extremely attractive option for the nearly 5 million cataract surgeries performed every year in the U.S. and the more than 20 million cataract surgeries performed around the world each year."

MELT-300 co-inventor, Melt Pharmaceuticals board member, and ophthalmologist John Berdahl, M.D., commented, "The MELT-300 data for procedural sedation is extraordinary and promises to catalyze a shift in the sedation paradigm for cataract surgery in the United States and around the world. In particular, the data demonstrating that pre-operative sublingual administration of MELT-300 was superior to midazolam has important implications for the daily workflow of the surgical team and most importantly the patient experience. I am excited beyond measure to see MELT-300 advance and, in time, become a candidate for FDA approval."

Dr. Dillaha continued, "We intend to leverage the demonstrable synergy between the components of MELT-300 to fortify an already strong domestic and international patent portfolio so that in the future, we can develop, consistent with our vision, procedural sedation solutions for the approximately 100+ million annual procedures our technology may impact."

About Melt Pharmaceuticals

Melt Pharmaceuticals, Inc. is a clinical-stage pharmaceutical company focused on the development and commercialization of proprietary non-opioid, non-IV, sedation, and analgesia therapeutics for human medical procedures in the hospital, outpatient, and in-office settings. Melt intends to seek regulatory approval through the FDA's 505(b)(2) regulatory pathway for its proprietary, patented small-molecule product candidates, where possible. Melt's core intellectual property is the subject of multiple granted patents in North America, Europe, Asia, and the Middle East. Melt Pharmaceuticals, Inc. was founded in 2019 by Harrow Health, Inc. (Nasdaq: HROW), which currently owns 46% of Melt, along with a 5% royalty on the MELT-300 drug candidate. To learn more about Melt, please visit their website, www.meltpharma.com.

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