Melt Pharmaceuticals Reports Positive Phase 3 Topline Efficacy Results for MELT-300, Its Lead Product Candidate for Opioid-Free, Sublingual Procedural Sedation in Patients Undergoing Cataract Surgery

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MELT-300 Demonstrates Statistically Superior Compared to Both Sublingual Midazolam (P=0.009) and Placebo (P<0.001) for Providing Successful Procedural Sedation

Proportion of Patients Requiring Rescue Sedation Was Nearly Two-Fold Higher for Sublingual Midazolam Compared with MELT-300 (P=0.003)

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

NASHVILLE, Tenn.--(BUSINESS WIRE)--Nov. 20, 2024-- Melt Pharmaceuticals, Inc. ("Melt"), a clinical-stage pharmaceutical company developing novel approaches for procedural sedation, today announced positive topline results of its pivotal Phase 3 study evaluating the safety and efficacy of its lead product candidate, MELT-300, a non-IV, non-opioid tablet for procedural sedation during cataract surgery. Based on a Special Protocol Assessment agreement reached with the U.S. Food and Drug Administration ("FDA") earlier this year, this study design and these positive results support the necessary objectives required for a regulatory submission.

MELT-300 uniquely combines a fixed dose of midazolam (3mg) and ketamine (50mg) in one tablet that is administered sublingually using Catalent's proprietary Zydis® delivery technology which dissolves in as little as 3 seconds allowing absorption of the active ingredients across the sublingual mucosa.

The MELT-300 Phase 3 clinical trial was a randomized, double-blind, three-arm study comparing, at a 4:1:1 ratio, MELT-300, sublingual midazolam, and sublingual placebo, respectively, for procedural sedation in patients undergoing cataract surgery. The study was conducted at 13 clinical sites in the United States and enrolled over 530 patients.

In commenting on the topline results, Dr. Larry Dillaha, Chief Executive Officer of Melt, said, "We are extremely excited with this robust topline data from our pivotal Phase 3 study. These overwhelmingly positive results support our belief that MELT-300, if approved by the FDA, would be a safe and effective non-IV, non-opioid alternative to current IV-based cataract surgery sedation protocols, which generally involve the administration of opioids. With the number of cataract surgeries performed each year in the U.S. expected to exceed 5 million in the coming years, we believe offering patients and physicians the ability to achieve an adequate sedation level without the need to start an IV or administer opioids is a very attractive proposition."

MELT-300 co-inventor, Melt Pharmaceuticals board member, and board-certified ophthalmologist John Berdahl, M.D., commented, "A proprietary compounded combination of midazolam and ketamine, which was the inspiration for the development of the MELT-300 product candidate, has been used by hundreds of ophthalmologists, including myself – in hundreds of thousands of cataract surgeries. I am thrilled at the prospect of the FDA approving MELT-300, which I believe would greatly enhance the confidence of healthcare professionals in considering the adoption of this groundbreaking sedation method."

George Magrath, M.D., a board-certified ophthalmologist and a MELT-300 Phase 3 study principal investigator, commented, "These Phase 3 data show the superiority of the combination of midazolam and ketamine compared with midazolam alone. If approved, I believe MELT-300 will be a safe and effective alternative to current sedation methods used for cataract surgery. As an ophthalmologist, I am excited about the prospect of using MELT-300 to enhance the overall experience for my cataract surgery patients."

Dr. Dillaha continued, "In addition to supporting a regulatory submission, these MELT-300 Phase 3 data should further strengthen our already strong patent portfolio, both domestically and internationally. Further, with these data now confirming and complementing our robust Phase 2 efficacy and safety results, we believe we are well positioned to elevate the procedural sedation standard of care for cataract surgery and, through lifecycle management, eventually expand the potential use of MELT-300 to over 100 million annual procedures in various medical specialties, including dermatology, plastic surgery, dentistry, gastroenterology, and emergency care.

"Melt Pharmaceuticals is profoundly grateful to the Phase 3 MELT-300 study participants, whose involvement has been invaluable. This includes the ophthalmologists, optometrists, anesthesiologists, certified registered nurse anesthetists, staff, and patients at the 13 U.S. clinical sites."

About Melt Pharmaceuticals

Melt Pharmaceuticals, Inc. is a clinical-stage pharmaceutical company focused on developing proprietary non-IV, non-opioid, 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. is a former subsidiary of Harrow, Inc. (Nasdaq: HROW) and was carved out as a separately managed business in 2019. To learn more about Melt, please visit their website, www.meltpharma.com.

Forward-Looking Statements

This press release contains forward-looking statements, which are all statements other than those statements of historical facts. No representation or warranty is made as to such statements, all of which involve substantial risks and uncertainties. Actual results could vary materially.

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