Melt Pharmaceuticals Announces First Patient Dosed in Pivotal Phase 3 Program of Its Lead Product Candidate, MELT-300, for Needle- and Opioid-Free Sedation in Patients Undergoing Cataract Surgery

June 6, 2024

Topline Readout Expected in Q4 2024

NASHVILLE, Tenn.--(BUSINESS WIRE)--Jun. 6, 2024-- Melt Pharmaceuticals, Inc. (“Melt”), a clinical-stage pharmaceutical company developing novel approaches for procedural sedation, today announced that the first patient has been dosed in its Phase 3 program evaluating the safety and efficacy of its lead product candidate, MELT-300, a non-IV, non-opioid tablet that combines fixed doses of midazolam (3mg) and ketamine (50mg). MELT-300 is administered sublingually using Catalent Inc.’s proprietary fast -dissolving Zydis® delivery technology to rapidly dissolve the tablet for absorption across the sublingual mucosa.

The MELT-300 Phase 3 clinical trial is a randomized, double-blind, three-arm study comparing – at a 4:1:1 ratio – MELT-300, sublingual midazolam, and sublingual placebo for procedural sedation in 528 patients undergoing cataract surgery at 14 participating clinical sites. The topline readout is expected in the fourth quarter of 2024.

Melt previously announced the results from its MELT-300 Phase 2 clinical trial in patients undergoing cataract surgery. The Phase 2 clinical trial compared MELT-300 against (i) sublingual placebo alone, (ii) sublingual midazolam, and (iii) sublingual ketamine in over 300 patients. MELT-300 was statistically superior for procedural sedation compared to all individual comparator arms: (i) sublingual placebo (P <0.0001), (ii) sublingual midazolam (P=0.0129) and (iii) sublingual ketamine (P=0.0096).

In commenting on the announcement, Dr. Larry Dillaha, Chief Executive Officer of Melt, said, “We are very excited to announce the first dosing in our pivotal Phase 3 program. Over the past 20 years, a lack of innovation in outpatient procedural sedation has created a significant unmet need, with IV-administered medications being a procedural mainstay and contributing to an increase in opioid usage. We believe that MELT-300 could revolutionize procedural sedation while enhancing the patient’s experience in all sites of care by offering greater comfort without a needle stick and by reducing exposure to opioids.”

Dr. Dillaha added, “While we are initially targeting sedation during cataract surgery for MELT-300, estimated to be over 5 million annual procedures in the U.S. in the coming years, we believe with further development and label expansion, MELT-300 could be utilized in over 100 million annual procedures in areas such as dermatology, plastics, dental, gastrointestinal, and emergency rooms.”

About Melt Pharmaceuticals

Melt Pharmaceuticals, Inc. is a clinical-stage pharmaceutical company focused on developing 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. 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.

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