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

October 10, 2024

Topline Readout Expected in Q4 2024

FDA Agrees to a MELT-300 Phase 3 Special Protocol Assessment

NASHVILLE, Tenn.--(BUSINESS WIRE)--Oct. 10, 2024-- Melt Pharmaceuticals, Inc. (“Melt”), a clinical-stage pharmaceutical company developing novel approaches for procedural sedation, today announced the dosing of the last patient in 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.

MELT-300 combines fixed doses of midazolam (3mg) and ketamine (50mg) in one tablet that is administered sublingually using Catalent’s proprietary Zydis® delivery technology to dissolve and absorb the active ingredients across the sublingual mucosa rapidly. 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, respectively, for procedural sedation. The study was conducted at 13 clinical sites and enrolled over 525 patients. The topline readout from this study is expected before the end of 2024.

Additionally, Melt today announced that it had reached an agreement with the U.S. Food and Drug Administration (“FDA”) on a Special Protocol Assessment (“SPA”) for the MELT-300 Phase 3 study. FDA agreed the study would “adequately address the objectives necessary to support a regulatory submission.” The SPA agreement establishes a binding agreement on key elements to support a future marketing application. Further, based on its review of results from a recently completed cardiac safety study evaluating the potential risk for a serious drug-induced irregular heart rhythm, the FDA agreed that MELT-300 did not alter normal heart rhythm. A final decision regarding marketing approval will be based on the FDA’s review of the full MELT-300 submission package.

Melt previously announced its MELT-300 Phase 2 clinical trial results in patients undergoing cataract surgery, which 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, “Completing the enrollment in our Phase 3 study and receiving the FDA’s agreement on our SPA are key milestones in the development of MELT-300 as we pursue our mission to provide needle- and opioid-free procedural sedation. We are extremely grateful to the investigators and patients who participated in this pivotal study and are excited to learn and share the findings of the Phase 3 study in the coming weeks.”

Dr. Dillaha added, “To our knowledge, this is the first constructive attempt to advance the standard of care of procedural sedation for cataract surgery patients, affecting the more than 5 million patients estimated to undergo this procedure annually in the U.S. in the coming years. Additionally, we believe success in the MELT-300 Phase 3 study should fuel further development and label expansion, with the potential of allowing MELT-300 to be utilized for procedural sedation 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-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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