# Melt Pharmaceuticals Announces Dosing of Last Patient in Phase 2 Pivotal Efficacy and Safety Study for MELT-300

October 27, 2022

**Top-Line Results Expected by Year-End**

NASHVILLE, Tenn.--(BUSINESS WIRE)--Oct. 27, 2022-- Melt Pharmaceuticals, Inc., a clinical-stage pharmaceutical company developing novel approaches for procedural sedation and analgesia, today announced the dosing of the last patient in 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 and analgesia during cataract surgery. Top-line results from this study are expected before the end of the year.

MELT-300 combines fixed doses of midazolam (3mg) and ketamine (50mg) in one dissolvable tablet that is administered sublingually for procedural sedation and analgesia during cataract surgery. This product candidate utilizes Catalent'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 extraction with lens replacement (CELR). The trial compared MELT-300 against (i) placebo alone, (ii) sublingually delivered midazolam alone, and (iii) sublingually delivered ketamine alone, with the primary efficacy endpoints of appropriate sedation during the cataract surgery and management of intraoperative pain during the surgery. The study was conducted at nine sites and enrolled over 330 subjects.

"With the dosing of the last patient in our MELT-300 Phase 2 study, we anticipate reporting top-line results by the end of 2022, representing a significant step forward towards the achievement of our mission to provide procedural sedation and analgesia that is needle- and opioid-free, enhancing the patient experience and their clinical outcome," said Larry Dillaha, M.D., CEO of Melt Pharmaceuticals. "We are grateful to the investigators and patients who have participated in this pivotal efficacy and safety study, which, to our knowledge, is the first serious attempt to advance the standard of anesthesia care for the nearly 5 million Americans each year who undergo cataract surgery. We are excited to learn and share the findings of the MELT-300 study, and, if the study is successful, we look forward to discussing with the U.S. Food and Drug Administration (FDA) the study results and next steps in the continued development of MELT-300 and its components as a needle- and opioid-free option for sedation and analgesia."

**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 hospital, outpatient and in-office settings. Melt intends to seek regulatory approval through the FDA's 505(b)(2) regulatory pathway for these proprietary, patented small-molecule product candidates, where possible. The core IP that Melt owns is a patented series of combination non-opioid sedation drug formulations that Melt believes has multiple clinical applications for potential indications of use. Melt Pharmaceuticals, Inc. is a former subsidiary of Harrow Health, 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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