



Melt Pharmaceuticals Submits INDs for MELT-210 and MELT-400 to FDA

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Company Actively Dosing Patients for Phase 2 Pivotal Efficacy Study for MELT-300; Full Enrollment Followed by Readout on Topline Data Expected by End of Second Quarter of 2022

NASHVILLE, Tenn.--(BUSINESS WIRE)--Jan. 4, 2022-- Melt Pharmaceuticals, Inc., a clinical-stage pharmaceutical company developing first-in-class medicines for sedation and analgesia, today announced the filing of two investigational new drug applications (INDs) with the U.S. Food and Drug Administration (FDA) for two sublingual, IV-free, non-opioid formulations – MELT-210 (midazolam) for procedural sedation and MELT-400 (ketamine) for pain. Both formulations have been developed in an exclusive partnership with Catalent (NYSE: CTLT) using its proprietary Zydis® orally disintegrating tablet (ODT) technology, which is currently used in 35 products.

The Company also announced that it is actively dosing patients in its ongoing Phase 2 pivotal efficacy study for MELT-300 and expects full enrollment near the beginning of the second quarter of 2022. In the study, MELT-300 is being compared to sublingual formations of the individual components, MELT-210 and MELT-400, using the same proprietary, rapidly dissolving technology used in MELT-300, as well as a placebo. The MELT program's IV-free and non-opioid approach seeks to replace the current practice of IV-delivered sedation and analgesia medication, including the use of fentanyl intraoperatively and other opioids prescribed for pain. The Company expects to report top-line clinical results of its Phase 2 pivotal efficacy study by the end of the second quarter of 2022.

"We are pleased with the progress we have made in our clinical development program of our lead product, MELT -300, a patented combination of midazolam and ketamine in a rapidly dissolving sublingual tablet," said Dr. Larry Dillaha, CEO of Melt Pharmaceuticals. "The filing of these two INDs for MELT-210 and MELT-400, the individual components contained in MELT-300, and the active dosing of patients in our Phase 2 pivotal efficacy study are important achievements in the overall development and commercialization strategy for our patented MELT Technology. We are very excited about the possibility of bringing the first-ever IV-free and non-opioid option for sedation and analgesia to patients undergoing cataract surgery, which we believe will be a great clinical benefit to both patients and clinicians alike. We also believe MELT-300 has the potential to virtually eliminate the need for using opioids during cataract surgeries, aiding in the fight against the devastating public health effects of the U.S. opioid crisis, which was declared a national public health emergency in 2017."

About MELT-300

MELT-300 is a patented combination of midazolam and ketamine in a rapidly dissolving, sublingual tablet to provide sedation and analgesia for patients undergoing cataract surgery. This needle-free and opioid-free approach seeks to replace the current practice of IV-delivered sedation medication for patients. MELT is being developed in an exclusive partnership with Catalent using its proprietary Zydis® orally disintegrating tablet (ODT) technology to create a freeze-dried tablet that disperses almost instantly in the mouth without water.

MELT-300 is protected by patents issued in the United States, Canada, Japan, South Korea, and Australia, with patents pending in jurisdictions throughout the world.

About Melt Pharmaceuticals

Melt Pharmaceuticals, Inc. is a clinical-stage pharmaceutical company focused on the development and commercialization of patented non-intravenous and non-opioid sedation and analgesia medicines for short-duration medical procedures in outpatient and in-office settings. Melt's core technology is a series of combination non-opioid sedation drug formulations that may replace or supplement current sedation modalities for more than 100 million medical procedures in the United States. Melt Pharmaceuticals, Inc. was carved out of Harrow Health, Inc. (Nasdaq: HROW) in 2019. To learn more about Melt, please visit their website, www.meltpharma.com.

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