Melt Pharmaceuticals Provides Corporate Update

January 3, 2024

NASHVILLE, Tenn.--(BUSINESS WIRE)--Jan. 3, 2024-- Melt Pharmaceuticals, Inc. (“Melt”), a clinical -stage pharmaceutical company developing novel approaches for procedural sedation, today provided a corporate update. The Company previously announced that MELT-300 achieved the primary sedation endpoint in its Phase 2 Pivotal Efficacy and Safety Study in subjects undergoing cataract surgery. MELT-300, a non-IV, non-opioid tablet that combines fixed doses of midazolam (3mg) and ketamine (50mg), is administered sublingually using Catalent Inc.’s proprietary fast-dissolving Zydis® delivery technology to rapidly dissolve the tablet for absorption across the very thin sublingual mucosa.

Melt Pharmaceuticals recently received a written response from the U.S. Food and Drug Administration (FDA) regarding its planned MELT-300 Phase 3 program. Based on the FDA’s response, Melt Pharmaceuticals expects to begin Phase 3 program activities, which will consist of a single pivotal study comparing MELT-300 to sublingual midazolam and placebo in subjects undergoing cataract surgery, in the first quarter of 2024.

Additionally, Melt has now reached an agreement with and paid in full all the outstanding principal and accrued and unpaid interest under its loan facility with Harrow, Inc. (Nasdaq: HROW), Melt’s largest shareholder, through the issuance of shares of Melt’s Series B and Series B-1 Preferred Stock. Following this transaction, in addition to certain royalty rights, Harrow’s equity ownership percentage of Melt is approximately 47%.

“We are very pleased to have received a response from the FDA that supports the investment we are making in our proposed MELT -300 Phase 3 program,” said Dr. Dillaha. “This was the last step needed to finalize our program design, paving the way for the commencement of Phase 3 program activities in early 2024. Following the debt settlement with Harrow and our successful efforts to date to secure sufficient funding to commence the Phase 3 program, we can now focus on the advancement of our non-IV, non-opioid MELT-300 product candidate, which we believe has the potential to revolutionize short-duration procedural sedation for more than 100 million U.S. medical procedures, enhancing the surgical patient experience by providing greater comfort and reducing reliance on opioids.”

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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