# Melt Pharmaceuticals Announces Exclusive Development and License Agreement with Catalent for Its Zydis® Fast-Dissolve Technology for Use in MELT-300 for Needle- and Opioid-Free Procedural Sedation

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NASHVILLE, Tenn.--(BUSINESS WIRE)--Sep. 26, 2023-- Melt Pharmaceuticals, Inc., a clinical-stage pharmaceutical company developing novel approaches for procedural sedation, today announced it recently entered into an exclusive development and license agreement with Catalent, the global leader in enabling the development and supply of better treatments across multiple modalities.

Under the terms of the agreement, Melt Pharmaceuticals will utilize Catalent's proprietary Zydis® orally disintegrating tablet (ODT) fast-dissolve technology with MELT-300, a sublingual, needle- and opioid-free patented formulation for procedural sedation during cataract surgery in the U.S. and any other countries mutually agreed upon by both parties. MELT-300, which combines fixed doses of midazolam (3mg) and ketamine (50mg), is administered sublingually for procedural sedation during cataract surgery and utilizes Zydis® ODT technology to rapidly dissolve the tablet for absorption across the very thin sublingual mucosa. Catalent's Zydis® ODT technology is currently used in over 35 FDA-approved and U.S.-marketed products.

"This exclusive license with Catalent is a key milestone for the continued development of MELT-300," said Larry Dillaha, M.D., CEO of Melt Pharmaceuticals. "We chose Catalent's Zydis® delivery technology because it is a proven fast-dissolving technology, and with the Zydis technology, our product candidate dissolves in a matter of seconds and begins to be absorbed across the sublingual mucosa. We believe this technology could eliminate the need for painful needle sticks in many procedures in the future."

"Zydis technology offers many advantages in formulation design, and this program has the potential to replace IV-administered sedation with an easily administered sublingual, fast-dissolving tablet," commented Tom Hawkeswood, President, Division Head of Pharma Product Delivery, Catalent. "We are excited to continue partnering with Melt Pharmaceuticals on its MELT-300 development program that potentially can help to improve the treatment experience for patients undergoing cataract surgeries and together, deliver better treatments to market."

Dr. Dillaha continued, "We look forward to continuing to build our partnership with Catalent on MELT -300 through this exclusive license, which fortifies an already strong domestic and international patent portfolio. This agreement allows us, going forward, to develop, consistent with our vision, procedural sedation solutions for the approximately $100^{+}$ million annual procedures our technology may impact."

Melt Pharmaceuticals previously announced that MELT-300 achieved the procedural sedation primary endpoint in its Phase 2 efficacy and safety study. Melt Pharmaceuticals is currently in discussions with the FDA (U.S. Food and Drug Administration) on the Phase 3 program, which Melt expects to begin in early 2024.

**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 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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