Melt Pharmaceuticals Announces MELT-210 Top-Line Results of Phase 1 Pharmacokinetics (PK) Study for Procedural Sedation

May 4, 2022

Bioavailability of MELT-210 Compares Favorably to Reference Drug

NASHVILLE, Tenn.--(BUSINESS WIRE)--May 4, 2022-- Melt Pharmaceuticals, Inc., a clinical-stage pharmaceutical company developing novel approaches for procedural sedation and analgesia, today announced top-line results of its phase 1 pharmacokinetics (PK) study of MELT-210. MELT-210 is a fixed dose of 3 mg of midazolam formulated in a proprietary rapidly dissolving sublingual tablet technology for procedural sedation.

The study was conducted in 23 patients and compared 3 mg and 6 mg MELT-210 sublingual midazolam tablets against an IV-administered comparator of midazolam. The top-line data demonstrated that concentration comparisons between MELT-210 and the reference drug met the goals of the study.

“We are pleased with the data that we are seeing from our PK study of MELT-210,” said Larry Dillaha, M.D., CEO of Melt Pharmaceuticals. “We view this as another important milestone in our goal to provide patients and their doctors with an IV-free option for procedural sedation. Our next step is meeting with the U.S. Food and Drug Administration (FDA) to discuss the results from this study and our continued clinical development of MELT-210.”

MELT-210 is administered in a rapidly dissolving, sublingual tablet developed in partnership with Catalent, using its proprietary Zydis® orally disintegrating tablet (ODT) technology to create a tablet that dissolves quickly when placed under the tongue. This technology has been used in over 35 NDA-approved products, spanning almost three decades. Because of the uniqueness of Catalent’s technology, no therapeutically equivalent product has been approved by the FDA for any of the previously NDA-approved products using Zydis®.

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 medical procedures in outpatient and in-office settings. Melt’s core technology is a series of non-opioid sedation drug formulations that may replace or supplement current sedation and/or analgesia 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20220503006359/en/

Investor Contact:
Larry Dillaha, M.D.
Chief Executive Officer
ldillaha@meltpharma.com

Source: Melt Pharmaceuticals, Inc.