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For more information:
Mark Leonard
mleonard@tersera.com
847-651-9682

TERSERA® PRESENTS DATA ON CETIRIZINE HCL INJECTION (QUZYTTIR®) IN THE PREVENTION OF HYPERSENSITIVITY INFUSION REACTIONS IN PATIENTS WITH BREAST CANCER AND OTHER MALIGNANCIES

- **TERSERA® Phase II intravenous cetirizine data presented during the 38th Annual Miami Breast Cancer Conference**

- **First randomized, double-blind, controlled trial evaluating IV cetirizine versus IV diphenhydramine in the prevention of hypersensitivity infusion reactions**

DEERFIELD, IL — March 05, 2021 — TerSera Therapeutics LLC announced today the presentation of data from their Phase 2 study of intravenous (IV) cetirizine versus IV diphenhydramine in the prevention of hypersensitivity infusion reactions in patients with breast cancer and other malignancies. The data were presented in virtual poster sessions during the **38th Annual Miami Breast Cancer Conference on March 4-7, 2021**.[1]

The Phase 2 exploratory study was a randomized, double-blind, study evaluating the prevention of infusion reactions with cetirizine hydrochloride injection 10mg/mL for IV use versus IV diphenhydramine 50 mg in 34 patients receiving paclitaxel or an anti-CD20 Ab (rituximab, its biosimilar or obinutuzumab). In the IV cetirizine group compared to the IV diphenhydramine group, the number of patients with infusion reactions were 2/17 (11.8%) versus 3/17 (17.6%); sedation scores (range 0 - 4) at 1 hour, 2 hours, and discharge were 0.5, 0.6, and 0.1 versus 1.3, 0.9, and 0.4. Time for discharge was 24 minutes less with IV cetirizine versus IV diphenhydramine. The number of treatment-related adverse events were 3 events with IV cetirizine and 6 events with IV diphenhydramine.

"We are pleased with the results of this Phase 2 study," said Nancy Joseph- Ridge, M.D., Executive Vice President of Research and Development and Chief Medical Officer of TerSera Therapeutics. "This is the first study of IV cetirizine compared to IV diphenhydramine for the prevention of infusion reactions, an investigational use of IV cetirizine."

QUZYTTIR is the first and only injectable second-generation H1 antihistamine to be approved by the U.S. Food and Drug Administration (FDA).[2] QUZYTTIR is indicated for the treatment of acute urticaria in adults and children 6 months of age and older. QUZYTTIR is not approved for the prevention of infusion reactions.

Important Safety Information about QUZYTTIR:

INDICATIONS AND USAGE
QUZYTTIR is indicated for the treatment of acute urticaria in adults and children 6 months of age and older.

Limitations of Use: QUZYTTIR is not recommended in pediatric patients <6 years of age with impaired renal or hepatic function.

Contraindications: Known hypersensitivity to QUZYTTIR or any of its ingredients, to levocetirizine, or hydroxyzine.

Additional Warnings and Precautions: The occurrence of somnolence/sedation has been reported in some patients. Advise patients to exercise due caution when driving or operating potentially dangerous machinery. Avoid concurrent use of QUZYTTIR with alcohol or other CNS depressants because additional reduction in alertness and additional impairment of CNS performance may occur.

Adverse Reactions: The most common adverse reactions (incidence <1%) with QUZYTTIR are dysgeusia, headache, paresthesia, presyncope, dyspepsia, feeling hot, and hyperhidrosis.

The most common adverse reactions (incidence ≥2%) with chronic dosing of oral cetirizine hydrochloride in adults are somnolence, fatigue, dry mouth, pharyngitis and dizziness. Adverse reactions observed in pediatric patients with chronic use of oral cetirizine hydrochloride are headache, pharyngitis, abdominal pain, coughing, somnolence, diarrhea, epistaxis, bronchospasm, nausea, and vomiting.

For more information, please see the full Prescribing Information for QUZYTTIR.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit **www.fda.gov/medwatch**, or call 1-800-FDA-1088. You can also contact TerSera Therapeutics at 1-844-334-4035 or **medicalinformation@tersera.com**.

About TerSera Therapeutics
TerSera Therapeutics acquires, develops, and markets specialty pharmaceutical products with a focus on oncology and non-opioid pain. Its mission is to provide products which truly make a difference for patients. For more information about TerSera Therapeutics, please visit www.tersera.com.

References:

1. Physicians' Education Resource (PER®). 38th Annual Miami Breast Cancer Conference®. Available at: https://www.gotoper.com/conferences/mbcc/meetings/38th-annual-miami-breast-cancer-conference. Accessed March 1, 2021.
2. QUZYTTIR (cetirizine hydrochloride injection) [package insert]. Deerfield, IL: TerSera Therapeutics LLC; 2020.