

FOR IMMEDIATE RELEASE

For More Information:
Mark Leonard
mleonard@tersera.com
847-651-9682

TERSERA® ANNOUNCES ADDITION OF CETIRIZINE AS AN ADJUNCTIVE TREATMENT TO INTERIM CDC GUIDELINES FOR MANAGING ADVERSE REACTIONS AFTER COVID-19 VACCINATION

- **CDC Guidelines recommend H1 antihistamines to be available at all COVID-19 vaccination locations and further caution the use of oral H1 antihistamines in persons with impending airway obstruction**
- **QUZYTIR® (cetirizine hydrochloride injection) is the first and only injectable second-generation H1 antihistamine to be approved by the FDA¹**
- **QUZYTIR is indicated for the treatment of acute urticaria in adults and children 6 months of age and older¹**

DEERFIELD, IL — February 23, 2021 — TerSera Therapeutics LLC announced today that cetirizine has been added by the Centers for Disease Control and Prevention (CDC) as an adjunctive therapy to its guidelines titled, "[Interim considerations: preparing for the potential management of anaphylaxis after COVID-19 vaccination.](#)" This is in addition to the CDC's guidelines titled, "[General Best Practice Guidelines for Immunization,](#)" which recommend the use of cetirizine 10 mg IV as an adjunctive therapy in the emergency management of anaphylaxis following immunization in adults. Both sets of guidelines were adopted by the CDC's Advisory Committee on Immunization Practices (ACIP).

In the interim considerations guidance, the CDC recommends that all COVID-19 vaccination locations screen recipients for contraindications and precautions to vaccination, have the necessary supplies available to acutely treat anaphylaxis (epinephrine) and implement recommended post-vaccination observation periods. The CDC also recommends that an H1 antihistamine, blood pressure monitor, and a pulse-timing device be available at all locations to assess and manage potential anaphylaxis. The guidelines specify that an H1 antihistamine, such as cetirizine, may be given as an adjunctive treatment but should not be used as an initial or sole treatment for anaphylaxis. The guidelines further caution the use of oral H1 antihistamines in persons with impending airway obstruction.

QUZYTIR is the first and only injectable second-generation H1 antihistamine to be approved by the U.S. Food and Drug Administration (FDA).¹ QUZYTIR is indicated for the treatment of acute urticaria in adults and children 6 months of age and older.

QUZYTIR is not FDA-approved for the treatment of anaphylaxis.¹ QUZYTIR works by blocking histamine, a substance in the body that causes allergic symptoms.¹ Urticaria is one of the most common symptoms of acute allergic reactions, including anaphylaxis, which is seen in many health care settings such as hospitals, urgent care centers, and clinics.²

“We are very pleased to learn that cetirizine products, such as QUZYTIR, have been added to the CDC guidelines for management of severe allergic reactions following immunization, including COVID-19 vaccine immunizations,” said Nancy Joseph-Ridge, M.D., Executive Vice President of Research and Development and Chief Medical Officer of TerSera Therapeutics.

Click [here](#) to learn more about QUZYTIR.

Click to view the QUZYTIR [product photo](#).

Important Safety Information about QUZYTIR:

INDICATIONS AND USAGE

QUZYTIR is indicated for the treatment of acute urticaria in adults and children 6 months of age and older.

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

Contraindications: Known hypersensitivity to QUZYTIR 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 QUZYTIR 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 QUZYTIR 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.

Patients and healthcare professionals with questions about QUZYTTIR should contact 1-866-QUZYTTIR (866-789-9884) or visit www.QUZYTTIR.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.

1. QUZYTTIR (cetirizine hydrochloride injection) [package insert]. Lake Forest, IL: TerSera Therapeutics LLC; 2020.
2. Shaker MS, Wallace DV, Golden DC, et al. Anaphylaxis – a 2020 practice parameter update, systematic review and GRADE analysis. *J Allergy Clin Immunol*. 2020. pii: S0091-6749(20)30105-6.

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