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# JDP Therapeutics Announces Positive Results from Pivotal Phase 3 Trial of QZYTIR™ for Acute Urticaria

**Study Achieves Primary Endpoint and Key Secondary Endpoints**

**BLUE BELL, PENNSYLVANIA, June 25, 2018** – JDP Therapeutics Inc., a privately held specialty pharmaceutical company focused on developing and commercializing proprietary product candidates for use in the hospital and urgent care settings, announced today that its pivotal Phase 3 clinical trial, ETTAU-03, evaluating QZYTIR™ (IV cetirizine) to treat acute urticaria, met primary and key secondary endpoints.

Following approval by U.S. Food and Drug Administration (FDA), QZYTIR™ may be the only product indicated for acute urticaria, which is the most common symptom of acute allergic reactions. Cetirizine oral tablet has been marketed by Pfizer as Zyrtec® for allergic rhinitis and chronic urticaria since 1995, and later by McNeil as an OTC product since 2008.

The ETTAU-03 study is a randomized, double-blind, active controlled study evaluating the efficacy and safety of QZYTIR™ (IV cetirizine) for the treatment of acute urticaria. The trial enrolled a total of 262 patients from 22 treatment centers across U.S. and Canada who had a diagnosis of acute urticaria and needed treatment with antihistamine injections to alleviate their acute allergic reaction symptoms. The patients were treated with either QZYTIR™ 10 mg/mL or the active control diphenhydramine injection 50 mg/mL, which is the current standard of care.

The primary endpoint of ETTAU-03 established statistical non-inferiority of QZYTIR™ compared to diphenhydramine injection in reducing a key symptom pruritus score two hours after treatment. Key secondary endpoints, including reduced 2nd visit return rate to treatment center and time spent in treatment center, demonstrated QZYTIR™'s statistical superiority to the comparator, diphenhydramine injection. Other secondary endpoints, such as less adverse events, less sedation, reduced rescue drug usage, and reduced symptom recurrence, further indicated statistical superiority of QZYTIR™ compared to diphenhydramine injection. Detailed trial results will be submitted for presentation at a future scientific conference or for publication in a journal.

"JDP's pivotal Phase 3 trial of QZYTIR™ in acute urticaria signals the completion of development for this exciting product and advancement to the regulatory NDA stage for marketing registration in the United States, Canada, and other countries," said Jie Du, Ph.D., president of the company. Dr. Du added, "There is a significant unmet need among patients with acute urticaria requiring treatment with antihistamine injections. Treatment options are very limited with no innovation in the last ~65 years. The only available antihistamine injection is the 1st generation H1 antagonist diphenhydramine injection involving a significant amount of unwanted and well-known side effects. JDP's clinical program (ETTAU-02 and ETTAU-03) validated the capacity of QZYTIR™ (IV cetirizine) to fulfill this important unmet need."

Dr. Bill Berger (Former President, American College of Allergy, Asthma and Immunology) further added, "It should not be that in life-threatening situations, we are still using older medications – there is a gaping need. Diphenhydramine injection also causes anticholinergic effects; if you drive with diphenhydramine injection after discharge, that can be a DUI charge due to sedation; it affects your judgement. QZYTIR™ gives patients the ability to recover from acute symptoms while not causing a whole new set of problems. This is long overdue."

JDP anticipates filing an NDA with FDA for marketing approval of QZYTIR™ for acute urticaria in adults and children in Q3 2018. Similar filings and regulatory registrations will be pursued for Canada, Europe and rest of the world.

**About QZYTIR™ (IV cetirizine)**

QZYTIR™ is a proprietary injectable product of cetirizine (IV cetirizine) being developed for the treatment of acute urticaria, the most common symptom of acute allergic reactions, for the hospital, urgent care, and clinic markets. Due to the acute nature of this disease, an injectable product is needed to provide an immediate onset of action. When approved, it may be the only product to be indicated for acute urticaria.

A market QUANT study surveyed 110 physicians and revealed that 86% of responding doctors had indicated readiness to use QZYTIR™ (IV cetirizine) in place of the current therapy, diphenhydramine injection. Physicians cited QZYTIR™'s lack of side effects as compared to those associated with diphenhydramine as the most compelling reason underlying their support for the QZYTIR™ treatment.

Two additional independent market research studies with in-depth clinician interviews confirmed the findings that QZYTIR™ will be able to fulfill the unmet need of the current therapy.

Acute urticaria is the most common symptom of acute allergic reaction, a serious and potentially life-threatening condition which has been growing at concerning rates with very limited options for treatment. QZYTIR™ (IV cetirizine) will offer a superior treatment to the current therapy for the first time in the last ~65 years.

**About JDP Therapeutics Inc.**

JDP Therapeutics Inc., a privately held specialty pharmaceutical company, is focused on developing and commercializing proprietary product candidates principally for use in the hospital and urgent care settings. Its lead product candidate QZYTIR™ has successfully completed the pivotal Phase 3 clinical trial for the treatment of acute urticaria, the most common symptom of acute allergic reactions, for use in hospitals and clinics.

JDP Therapeutics focuses on developing small molecule therapeutics to treat life threatening diseases with significant unmet medical needs, primarily for use in the hospital and clinical setting. The company develops unique dosage forms, novel formulations, and new indications for proven chemical entities to achieve their full therapeutic and market potential. This approach mitigates risk, shortens the development cycle, leads to a well-defined regulatory pathway, and fully characterizes clinical needs for each product opportunity.

For further information about JDP, please email: info@jdptherapeutics.com

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*Safe Harbor Statement Regarding Forward-looking Statements*
*The statements in this release and oral statements made by representatives of JDP relating to matters that are not historical fact, including without limitation those regarding the timing or potential outcomes of research or clinical trials, any market that might develop for any of JDP's product candidates are forward-looking statements that involve risks and uncertainties, including, but not limited to, the likelihood that future research will prove successful, the likelihood that any product in the research pipeline will receive regulatory approval in the United States or abroad, the ability of JDP and/or its partners to develop, manufacture and commercialize, JDP's ability to fund such efforts with or without partners, and other risks.*