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JDP Initiates Pivotal Phase 3 Clinical Trial of JDP-205 for Acute Urticaria

BLUE BELL, PENNSYLVANIA, May 30, 2017 – JDP Therapeutics Inc., a privately held specialty pharmaceutical company focused on developing and commercializing proprietary product candidates principally for use in the hospital and urgent care settings, announced today that it has initiated its pivotal phase 3 clinical trial, ETTAU-03, to evaluate the efficacy and safety of JDP-205 (IV cetirizine) for the treatment of acute urticaria, the most common symptom of acute allergic reactions.

JDP-205 is an intravenous injection of cetirizine (aka "IV Cetirizine") for the indication of acute urticaria. The oral cetirizine 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 pivotal phase 3 clinical trial, referred to as ETTAU-03, is the last trial as part of JDP's clinical program to evaluate the efficacy and safety of IV cetirizine injection for the treatment of acute urticaria.

The ETTAU-03 study is a randomized, double-blind, active controlled study. It will enroll a total of 256 patients who will be treated with either IV cetirizine injection or the active control IV diphenhydramine injection in patients with a diagnosis of acute urticaria who need treatment with antihistamine to alleviate their allergic symptoms.

The primary endpoint of the trial is to establish the non-inferiority of IV cetirizine injection compared to IV diphenhydramine injection in reducing a key symptom score two hours after treatment. Other endpoints include reduced time of Emergency Department (ED) discharge, reduced ED return rate and reduced adverse events, etc. of IV cetirizine as compared to the current standard of care (i.e. IV diphenhydramine).

The trial is being conducted at approximately 22 sites throughout the United States and Canada. Due to the acute nature of the disease being treated in the trial, all participating sites are emergency departments and urgent care centers.

"JDP's pivotal Phase 3 trial of IV cetirizine in acute urticaria signals the advancement of this exciting product into the very last stage of the clinical program required for marketing registration in the United States and Canada," said Jie Du, Ph.D., president of the company. Dr. Du added: "There is a significant unmet need among patients with acute urticaria (acute allergic reaction) requiring treatment with antihistamine injections. Treatment options

currently available involve a significant amount of unwanted and well-known side effects. Our objective for JDP's clinical program is to validate the capacity of IV cetirizine to fulfill this important unmet need."

JDP expects to submit a 505(b)(2) new drug application (NDA) to the U.S. Food and Drug Administration in the first half of 2018 requesting marketing approval of IV cetirizine for acute urticaria in adults and children. This NDA will include data from both JDP's own clinical development program and reference data available globally from currently marketed oral products containing the cetirizine molecule. Similar filings and regulatory registrations will be pursued for Canada, Europe and rest of the world.

About JDP-205 (IV Cetirizine)

JDP-205 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.

A market QUANT study surveyed 110 physicians and revealed that 86% of responding doctors had indicated readiness to use JDP-205 (IV Cetirizine) in place of the current therapy (diphenhydramine injection). Physicians sited JDP-205's lack of side effects as compared to those associated with diphenhydramine as the most compelling reason underlying their support for the JDP-205 treatment.

Two additional independent market research studies with in-depth clinician interviews confirmed the findings that IV Cetirizine 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. JDP-205 (IV Cetirizine) will offer a superior treatment to the current therapy for the first time in the last 60+ years.

About JDP Therapeutics Inc.

JDP Therapeutics Inc., a privately held specialty pharmaceutical company focused on developing and commercializing proprietary product candidates principally for use in the hospital and urgent care settings. Its lead product candidate is now at the last stage of phase 3 development for acute urticaria (acute allergic reactions) for the hospital, urgent care center and clinic markets.

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.