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JDP Receives U.S. FDA Clearance for Phase 3 Clinical Trial of JDP-205 in Patients with Acute Urticaria Associated with an Acute Allergic Reaction

BLUE BELL, PENNSYLVANIA, March 12, 2014 – JDP Therapeutics Inc., a privately held specialty pharmaceutical company, is pleased to announce that the Company’s Investigational New Drug (IND) to conduct an initial Phase 3 clinical trial of JDP-205 in patients with acute urticaria associated with an acute allergic reaction has been cleared by the U.S. Food and Drug Administration (FDA).

“We are very pleased with the outcome of our interactions with the FDA and Health Canada on the design of our initial phase 3 clinical trial for JDP-205. The IND clearance represents the achievement of an important milestone for the Company. JDP-205 has been tested extensively in several clinical trials to study its pharmacokinetics, tolerability, and safety. This pilot phase 3 clinical is a multi-sites, randomized, double-blind study designed to evaluate the efficacy and safety of JDP-205 in patients with acute urticaria associated with an acute allergic reaction (“Acute Urticaria”). To optimize the study process, we are focusing on emergency departments as the enrollment sites.” said Dr. Jie Du, President and CEO of the Company. “The outcome measure of the study will be to confirm the efficacy as measured by the Acute Urticaria symptom reduction scores and to confirm its safety parameters. We look forward to continuously working with the FDA on the required program to enable a successful future filing of an NDA.”

About JDP-205

JDP-205 is a proprietary injectable product being developed for the treatment of acute allergic reactions for the hospital market. A market QUANT study surveyed 110 physicians, and revealed that 86% of responding doctors had indicated readiness to use JDP-205 in place of the current therapy when the product is approved by the FDA. A second independent market research study with in-depth clinician interviews confirmed the findings.

Acute allergic reaction is a serious condition, potentially life-threatening, and has been growing at concerning rates with very limited selections of medications for treatment. JDP-205 will offer an alternative and superior treatment to the current therapy for the first time in nearly 60 years.

About JDP Therapeutics Inc.

JDP Therapeutics Inc. is a privately held, clinical stage specialty pharmaceutical company focused on developing small molecule therapeutics to treat life threatening diseases with significant unmet medical needs, primarily for use of acute care in the hospital setting.

JDP Therapeutics pursues unfulfilled opportunities in existing molecules from which it develops unique dosage forms, novel formulations, and new indications to achieve 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, 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.