Media Contact:
Jonathan Black
JDP THERAPEUTICS, INC.
Email: info@jdptherapeutics.com
www.jdptherapeutics.com

JDP Therapeutics Announces U.S. FDA Filing Acceptance of New Drug Application for QUZYTTIR™ for Indication of Acute Urticaria

BLUE BELL, PENNSYLVANIA, February 18, 2019 – JDP Therapeutics Inc., a privately held specialty pharmaceutical company focused on developing and commercializing proprietary product candidates for use in the hospital and acute care settings, announced it has received notification of acceptance for filing from the U.S. Food and Drug Administration (FDA) for its New Drug Application for its lead product QUZYTTIR™. JDP seeks approval for the use of this product to treat acute urticaria in adults and children.

"We are pleased to announce another significant milestone in the development of QUZYTTIR™ in the advancement of our strategy to build an acute care, hospital & oncology business," said Dr. Jie Du, President of JDP Therapeutics. "The FDA's acceptance of our NDA filing positions us one step closer to launching a long waited antihistamine injection into the U.S. market.

Following approval by the FDA, QUZYTTIR™ may be the only product indicated for acute urticaria, the most common symptom of acute allergic reactions.

Similar filings and regulatory registrations will be pursued for Canada, Europe and rest of the world.

About QUZYTTIR™

QUZYTTIR™ 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, oncology 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 QUZYTTIR™ (IV cetirizine) in place of the current therapy, diphenhydramine injection. Physicians cited QUZYTTIR™'s lack of side effects as compared to those associated with diphenhydramine as the most compelling reason underlying their support for the QUZYTTIR™ treatment.

Two additional independent market research studies with in-depth clinician interviews confirmed the findings that QUZYTTIR™ 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. QUZYTTIR™ 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 acute care settings. Its lead product candidate QUZYTTIR™ 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. QUZYTTIR™ NDA is now under FDA's review.

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.