



August 28, 2017

Aquinox Statement on FDA Advisory Committee Meeting to Discuss Interstitial Cystitis/Bladder Pain Syndrome

- Meeting to be Held December 7, 2017 -

VANCOUVER, British Columbia, Aug. 28, 2017 (GLOBE NEWSWIRE) -- [Aquinox Pharmaceuticals, Inc. \("Aquinox"\)](#) (NASDAQ:AQXP), a clinical-stage pharmaceutical company discovering and developing targeted therapeutics in disease areas of inflammation and immuno-oncology issued today the following statement regarding the announcement by the United States Food and Drug Administration (FDA) Division of Bone, Reproductive and Urology Products (DBRUP) that it will hold an Advisory Committee meeting to discuss Interstitial Cystitis and Bladder Pain Syndrome (IC/BPS).

"The FDA had indicated to us previously and confidentially the possibility of this meeting and we welcome the opportunity of a public forum, with input from patients, clinicians, regulators and sponsors, to incorporate current thinking around therapeutic development in IC/BPS," said David Main, President & CEO of Aquinox. "With the diagnosis and treatment of IC/BPS having evolved since the last oral drug for IC/BPS was approved in the US more than 20 years ago, we regard this meeting as recognition of the persisting high unmet need for new, effective therapies and of the debilitating impact of this disease on millions of patients. We believe the meeting will add important context in advance of our reporting of results from our LEADERSHIP 301 trial and greater clarity for the design of future clinical trials with rosiptor in IC/BPS."

The advisory committee meeting is scheduled to be held December 7, 2017 from 8:00 AM to 5:00 PM EST at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD. Notice of the meeting and a proposed agenda can be found on the Federal Register at <https://federalregister.gov/d/2017-18131>.

About [Rosiptor \(AQX-1125\)](#)

Rosiptor, Aquinox's lead drug candidate, is a small molecule activator of SHIP1, which is a regulating component of the PI3K cellular signaling pathway. By increasing SHIP1 activity, rosiptor accelerates a natural mechanism that has evolved to maintain homeostasis of the immune system and reduce immune cell activation and migration to sites of inflammation. Rosiptor has demonstrated preliminary safety and favorable drug properties for once daily oral administration in multiple preclinical studies and eight completed clinical trials.

About Interstitial Cystitis/Bladder Pain Syndrome (IC/BPS)

IC/BPS is a chronic inflammatory bladder disease characterized by pelvic pain and increased urinary frequency and/or urgency. For many sufferers, these symptoms are severe and adversely affect all major aspects of their lives, including overall physical and emotional health, employment, social and intimate relationships, and leisure activities. While the cause of the disease remains largely unknown, erosion of the bladder lining is thought to be a significant contributor. IC/BPS is estimated to affect millions of people in the United States and around the world. Most IC/BPS patients continue to suffer this debilitating condition, despite treatment with existing therapies. Most current therapies and those in development are focused solely on symptomatic relief of IC/BPS. Aquinox believes new and innovative therapies that target the underlying disease to reduce the chronic pain and urinary symptoms are needed.

About the LEADERSHIP 301 Trial

The LEADERSHIP 301 trial, which commenced enrollment in September 2016, is a three-arm, multicenter, randomized, double-blind, placebo-controlled Phase 3 clinical trial investigating the ability of 200 mg and 100 mg oral, once daily rosiptor (AQX-1125) to reduce bladder pain in patients with IC/BPS. The primary endpoint of the LEADERSHIP 301 trial is the difference in the change from baseline in the maximum daily bladder pain score based on an 11-point numeric rating scale (NRS) at twelve weeks recorded by electronic diary. Additional endpoints include urinary symptoms, including frequency and nighttime awakenings to void, as well as measures of quality of life. The LEADERSHIP 301 trial also has an additional 52-week extension period, affording all participating patients the opportunity for treatment with rosiptor. An anticipated minimum of 300 female patients, up to a maximum of 600 patients including males, are currently being enrolled at clinical research

centers in the United States, Canada and Europe. Top-line data from the LEADERSHIP 301 trial are anticipated in third quarter of 2018.

About [Aquinox Pharmaceuticals, Inc.](#)

Aquinox Pharmaceuticals, Inc. is a late clinical-stage pharmaceutical company discovering and developing targeted therapeutics in disease areas of inflammation and immuno-oncology. Our primary focus is anti-inflammatory product candidates targeting SH2-containing inositol-5'-phosphatase 1, or SHIP1, which is a key regulator of an important cellular signaling pathway in immune cells, known as the PI3K pathway. Aquinox's lead drug candidate, rosiptor (AQX-1125), is a small molecule activator of SHIP1 suitable for oral, once daily dosing. In September 2016, we began enrolling patients in a Phase 3 clinical trial of rosiptor in our lead indication, Interstitial Cystitis/Bladder Pain Syndrome (IC/BPS). Other indications are under consideration for future investigation. Aquinox has a broad intellectual property portfolio and pipeline of preclinical drug candidates that activate SHIP1. For more information, please visit www.aqxpharma.com.

Cautionary Note on Forward-looking Statements

Certain of the statements made in this press release are forward looking, such as those, among others, relating to: the scheduled DBRUP Advisory Committee meeting to discuss IC/BPS, development of rosiptor (AQX-1125), LEADERSHIP 301, availability of top-line data, and initiation of clinical trials. These statements are subject to risks and uncertainties that could cause actual results and events to differ materially from those anticipated, including, but not limited to, risks and uncertainties related to: our ability to enroll patients in our clinical trials at the pace that we project; as an organization, we have never conducted a pivotal clinical trial before; the size and growth of the potential markets for rosiptor or any future product candidates and our ability to serve those markets; our ability to obtain and maintain regulatory approval of rosiptor or any future product candidates; reaching agreement on design of pivotal trials with regulatory authorities and our expectations regarding the potential safety, efficacy or clinical utility of rosiptor or any future product candidates. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. More information about the risks and uncertainties faced by Aquinox is contained in the company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2017 filed with the Securities and Exchange Commission. Aquinox disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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