Adynxx Announces Payment Date of Special Cash Dividend Previously Announced by Alliqua BioMedical

May 10, 2019

Adynxx announces May 29, 2019 as payment date of previously announced special cash dividend of $1.05 per share to former Alliqua shareholders

Adynxx confirms intent to consummate the previously announced distribution of shares of AquaMed Technologies, Inc., subject to completion of the merger between AquaMed and TO Pharmaceuticals

Adynxx plans to initiate two Phase 2 studies of brivoligide in postoperative pain during 2019 with support from the National Institute on Drug Abuse

SAN FRANCISCO, May 10, 2019 (GLOBE NEWSWIRE) -- Adynxx, Inc., (Nasdaq:ADYX), a clinical-stage biopharmaceutical company leading the development of transcription factor decoy technology and first-in-class therapeutics for the treatment of pain and inflammatory diseases, today announced May 29, 2019 as payment date for the special cash dividend announced by Alliqua Biomedical, Inc. (formerly Nasdaq:ALQA) on April 11, 2019. The special cash dividend entitled each share of Alliqua common stock outstanding as of the close of business on April 22, 2019 to receive $1.05 in cash, subject to the consummation of Alliqua's previously announced merger transaction with Adynxx. The merger was consummated on May 3, 2019, immediately prior to which Alliqua effected a six-for-one reverse stock split. The distribution of the special cash dividend will be made on a pre-split basis.

In addition to payment of the special cash dividend, Adynxx intends to consummate the previously announced distribution of shares of AquaMed Technologies, Inc., now a wholly-owned subsidiary of Adynxx, as soon as practicable following the satisfaction of all conditions to closing of the previously announced merger transaction between AquaMed and TO Pharmaceuticals, LLC. In the event the closing conditions to the merger between AquaMed and TO Pharmaceuticals are satisfied, the stock distribution will be made no later than June 21, 2019.

"With the payment of the special cash dividend, we are excited to deliver value to the former Alliqua shareholders and look forward to rapidly advancing our AYX platform of non-opioid pain therapies to continue to create value for the shareholders of Adynxx," said Rick Orr, Chief Executive Officer. "In light of the ongoing opioid crisis in the United States, we remain dedicated to developing transformative pain therapies with the potential to reduce the need for opioid-based analgesics."

Adynxx plans to initiate two Phase 2 studies this year for the company's lead program, brivoligide for postoperative pain, with data from the first study expected in mid-2020. With a single administration at the time of surgery, brivoligide is intended to reduce both the severity and duration of postoperative pain in a readily-identified group of patients at greater risk of experiencing increased and prolonged pain following surgery, relative insensitivity to analgesics and elevated opioid use as a result. The first study, ADYX-005, will be conducted in subjects undergoing unilateral total knee arthroplasty or TKA. The second study, ADYX-006, will be conducted in subjects undergoing mastectomy with immediate tissue expander or implant placement. Topline data for both Phase 2 studies are expected in 2020.

In December, 2018, Adynxx received a Notice of Award from the National Institute on Drug Abuse (NIDA), part of the National Institutes of Health (NIH), for a grant to provide Adynxx with $5.7 million over a two-year period to complete ADYX-006. Following completion of milestones related to ADYX-006, Adynxx can receive an additional award of up to $9 million for a Phase 3 study of brivoligide.

Adynxx also plans to initiate IND-enabling studies for AYX2 in the second half of 2019. AYX2 is the second product candidate originating from the Adynxx AYX platform and is intended to provide long-term reduction of chronic pain, including both inflammatory and neuropathic pain, with a single or infrequent dosing regimen.

Outside of the AYX platform, the company is collaborating with twoXAR, Inc., an artificial intelligence-driven drug discovery company, utilizing twoXAR's proprietary AI technology to identify a set of medical treatments with the potential to treat and prevent the recurrence of endometriosis and associated symptoms. Adynxx also continues to evaluate partnering opportunities to build a diverse pipeline to address unmet medical needs in pain and inflammation.

About Adynxx

Adynxx is a clinical-stage biopharmaceutical company focused on bringing to market novel therapeutics for the treatment of pain and inflammatory diseases. A leader in transcription factor decoy technology, Adynxx is utilizing its platform of AYX transcription factor decoys to create first-in-class therapies with disease-modifying properties. Transcription factor decoys are short, synthetic double-stranded DNA oligonucleotides that bind to transcription factors and prevent their interaction with the genome, effectively inhibiting a coordinated network of pathologic gene expression. The AYX platform has applications across multiple disease states and has initially been leveraged to create novel, non-opioid therapeutics for the treatment of pain.

About Brivoligide

Clinical studies suggest that a single administration of brivoligide at the time of surgery can safely reduce pain for weeks, accelerate the time to achieve mild pain, and substantially reduce the need for opioid use during recovery specifically in patients at greater risk of experiencing increased and prolonged pain following surgery. Brivoligide (formerly AYX1) is an intrathecally-administered, 23 base-pair, double-stranded DNA transcription factor decoy oligonucleotide. It inhibits the transcription factor EGR1 in the dorsal root ganglia and spinal cord at the time of surgery. EGR1 binds to the promoter regions of many genes associated with nociceptive sensitization and increased pain. EGR1 launches waves of gene regulation at the time of surgery that initiate and maintain neuronal sensitization. This sensitization may lead to increased and prolonged postoperative pain in certain patients who are relatively insensitive to analgesics and may be at high risk for elevated use of rapidly acting opioids, the type most commonly associated with Opioid Use Disorder or OUD.

Forward-Looking Statements

Statements contained in this press release that are not purely historical may be deemed to be forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995 and other federal securities laws. Without limiting the foregoing, the use of words such as “may,” “intends,” “can,” “might,” “will,” “expect,” “plan,” and other similar expressions are intended to identify forward-looking statements. The product candidates discussed are in clinic and not approved and there can be no assurance that the clinical programs will be successful in demonstrating safety and/or efficacy, that Adynxx will not encounter problems or delays in clinical development, or that any product candidate will ever receive regulatory approval or be successfully commercialized. All forward-looking statements are based on estimates and assumptions by Adynxx’s management that, although Adynxx believes to be reasonable, are inherently uncertain. All forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those that Adynxx expected. In addition, Adynxx’s business is subject to additional risks and uncertainties, including among others, the initiation and conduct of preclinical studies and clinical trials; the timing and availability of data from preclinical studies and clinical trials; expectations for regulatory submissions and approvals; potential safety concerns related to, or efficacy of, Adynxx’s product candidates; the availability or commercial potential of product candidates; the ability to maintain continued listing of Adynxx’s common stock on The Nasdaq Stock Market or any national securities exchange; the consummation of the Special Dividend or the Distribution; and Adynxx’s and its partners’ ability to perform under their license, collaboration and manufacturing arrangements. These statements are also subject to a number of material risks and uncertainties that are described in the definitive proxy statement filed by Alliqua BioMedical, Inc. with the Securities and Exchange Commission on January 24, 2019, as updated by Adynxx’s subsequent filings with the Securities and Exchange Commission. Any forward-looking statement speaks only as of the date on which it was made. Adynxx undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required under applicable law.

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Source: Adynxx, Inc.

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