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Penwest Announces Initiation of Phase IIa Clinical Trial of A0001 in Patients with Friedreich's Ataxia

Patterson, NY, January 11, 2010 – Penwest Pharmaceuticals Co. (Nasdaq: PPCO) today announced that it initiated a Phase IIa clinical trial for A0001 in December and that the screening of patients is underway. The study is being conducted at The Children's Hospital of Philadelphia in patients with Friedreich's Ataxia (FA).

The primary objective of this study is to investigate whether treatment with A0001 has a discernible impact on various functional, biochemical and subject/clinician-rated scales relevant in the treatment of FA. The Phase IIa clinical trial is a double-blind, randomized, placebo-controlled trial that includes a high and low dose of A0001 and a placebo. Penwest plans to enroll approximately 42 patients with a 2:1 randomization of drug to placebo. The patients will be dosed for 28 days. The Company expects data from this trial in the third quarter of this year.

The Friedreich's Ataxia Research Alliance (FARA) is helping to enroll patients for this study by utilizing its patient registry. Ronald J. Bartek, FARA's President and Co-Founder, said, "The Friedreich's ataxia community is excited that A0001 is ready to be dosed in our patients. We believe the science behind the molecule is very interesting and that A0001 could be an important therapy for FA patients. FARA has been helping support the development of A0001 for a number of years and is continuing to assist its development partners at Penwest by working with the patient community to ensure the trial enrolls rapidly."

Jennifer L. Good, Penwest's President and CEO, said, "We are very pleased to be advancing A0001 into a proof of concept trial in patients. There is a significant unmet medical need in Friedreich's ataxia and we are hopeful that A0001 can provide an important treatment option for these patients."

About A0001

A0001, or alpha-tocopherol quinone, is a coenzyme Q₁₀ analog demonstrated to improve mitochondrial function in-vitro. Penwest believes that impairment of mitochondrial function is a key component of the diseases that it plans to target with A0001, and that enhancing mitochondrial function may provide substantial clinical benefit to patients. The Company exclusively licensed A0001 from Edison Pharmaceuticals, a privately-held biopharmaceutical company headquartered in San Jose, CA.

About Friedreich's Ataxia

Friedreich's Ataxia (FA) is a debilitating, life-shortening, degenerative neuro-muscular disorder. About one in 50,000 people in the United States have FA. Onset of symptoms can vary from childhood to adulthood. FA patients have gene mutations that limit the production of a protein called frataxin. Frataxin is known to be an important protein that functions in the mitochondria



(the energy producing factories) of the cell. Frataxin helps to move iron and is involved with the formation of iron-sulfur clusters, which are necessary components in the function of the mitochondria and thus energy production. It is also known that specific nerve cells (neurons) degenerate in people with FA, and this is directly manifested in the symptoms of the disease.

The signs and symptoms of FA include: loss of coordination (ataxia) in the arms and legs, fatigue, energy deprivation, muscle loss, vision impairment, hearing loss, slurred speech, aggressive scoliosis (curvature of the spine), diabetes mellitus, and a serious heart condition (enlarged heart - hypertrophic cardiomyopathy).

About Penwest Pharmaceuticals

Penwest is a drug development company focused on identifying and developing products that address unmet medical needs, primarily for rare disorders of the nervous system. Penwest is currently developing A0001, or alpha tocopherol quinone, a coenzyme Q10 analog demonstrated to improve mitochondrial function in-vitro. Penwest is also applying its drug delivery technologies and drug formulation expertise to the formulation of our collaborators' product candidates under licensing collaborations.

Penwest Forward-Looking Statements

The matters discussed herein contain forward-looking statements for purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties, which may cause the actual results in future periods to be materially different from any future performance suggested herein. For this purpose, any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words, "believes," "anticipates," "plans," "expects," "intends," "potential," "appears," "estimates," "projects," "targets," "may," "could," and similar expressions are intended to identify forward-looking statements. Important factors that could cause results to differ materially include the following: risks relating to the commercial success of Opana ER, including our reliance on Endo Pharmaceuticals Inc. for the commercial success of Opana ER and risks of generic competition; the need for capital; regulatory risks relating to drugs in development, including the timing and outcome of regulatory submissions and regulatory actions with respect to A0001; uncertainty of success of collaborations; the timing of clinical trials, such as the Phase IIa clinical trial referenced above; whether the results of clinical trials will be indicative of the results of future clinical trials and will warrant further clinical trials, warrant submission of an application for regulatory approval of, or warrant the regulatory approval of, the product that is the subject of the trial; whether the patents and patent applications owned by us will protect the Company's products and technology; actual and potential competition; and other risks as set forth under the caption Risk Factors in Penwest's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 9, 2009, which risk factors are incorporated herein by reference.

The forward-looking statements contained in this press release speak only as of the date of the statements made. Penwest disclaims any intention or obligation to update any forward-looking statements, and these statements should not be relied upon as representing the Company's estimates or views as of any date subsequent to the date of this release.



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