Clinical Trials Update – Jan 16, 2014

VP20629 – Safety and Pharmacology Study of VP 20629 in Adults With FA

This study is actively enrolling and looking for volunteers at all sites (UCLA to open soon).

This is a Phase 1 study which means it is designed to evaluate dosage and safety. It is designed in two arms. The first arm is four groups of 8 individuals (32 individuals needed for the first arm) in which each individual gets a single dose of the drug and is monitored for 3 days. The first cohort of 8 has been completed, and they are now enrolling the second cohort of 8 individuals.

After the first arm is completed, there will be a second arm of three groups of 8 subjects (24 individuals needed for the second arm) in which individuals will receive multiple doses of VP 20629 (300 mg, 600 mg, or 900 mg total daily dose) or placebo. VP 20629 or placebo will be administered every 8 hours for 7 days with a single morning dose on Day 8.

Participation in this study requires both outpatient and inpatient visits. Subjects in the first arm need to stay at the hospital for 3 days, and subjects in the second arm need to stay for 10 days. Subjects who participate in arm 1 may be eligible to participate in arm 2.

Specific information on inclusion and exclusion criteria is available at the study's clinicaltrials.gov site: www.clinicaltrials.gov/ct2/show/NCT01898884.

Please call or email a coordinator below to get more information about the study.

OPEN FOR ENROLLMENT

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CHOP study ad - www.curefa.org/_pdf/VP20629ClinicalTrial.pdf

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Emory study ad – www.curefa.org/_pdf/EmoryTrialVP20629.pdf

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ENROLLMENT ANTICIPATED SOON

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