NOTICE OF OPPORTUNITY FOR CLINICAL TRIAL COLLABORATION

UTILIZATION OF AN ALPHA-ADRENERGIC BLOCKING DRUG IN A NIH SPONSORED MULTI-CENTER CLINICAL TRIAL IN MEN WITH CHRONIC PROSTATITIS/CHRONIC PELVIC PAIN SYNDROME

The National Institute of Diabetes and Digestive and Kidney Diseases of the National Institutes of Health (NIH) of the Public Health Service (PHS) of the Department of Health and Human Services (DHHS) seeks collaboration with industry to provide an alpha-adrenergic blocking drug and matching placebo for use in a National Institutes of Health sponsored multi-center clinical trial in men with chronic prostatitis/chronic pelvic pain syndrome.

INTRODUCTION: The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is planning to conduct a randomized controlled clinical trial to evaluate if treatment with an alpha-adrenergic blocking drug will substantially reduce urinary symptoms in men with chronic prostatitis/chronic pelvic pain (CP/CPPS). The trial will be conducted by investigators participating in the Chronic Prostatitis Collaborative Research Network (CPCRN). The two-arm trial will enroll approximately 270 men and randomize them to either drug or placebo. Treatment will be administered in a double-blind fashion. The target population is men with CP/CPPS who have had recent onset of symptoms and are treatment naïve to alpha-adrenergic blocking drugs. Enrollment, expected to take approximately three years, will be performed at the following participating clinical centers: Northwestern University, the University of California at Los Angeles, the University of Washington, the University of Maryland, Temple University, Massachusetts General Hospital, Cleveland Clinic Foundation (Weston, FL), the University of Mississippi, Queen's University (Kingston, Ontario, Canada), Stanford University and the VA Puget Sound Health Care System. Central data collection and analysis will be performed by the NIDDK funded Data Coordinating Center at the University of Pennsylvania.

STUDY GOALS: The aim of this randomized clinical trial is to determine if treatment with an alpha-adrenergic blocking drug for a period of 12 weeks will significantly reduce urinary symptoms associated with CP/CPPS compared to placebo. The primary outcome is a change (reduction) in symptoms as assessed by the National Institutes of Health Chronic Prostatitis Symptom Index (NIH-CPSI). The Global Response Assessment (GRA) as well as other clinical and laboratory measures will be examined.

SUPPLEMENTAL INFORMATION: In 2003, the NIDDK established the second 5-year phase of the Chronic Prostatitis Collaborative Research Network. The purpose of the CPCRN is to conduct high quality randomized controlled clinical trials in men with CP/CPPS. In the first 5-year segment of this program investigators conducted a randomized double-blind placebo controlled clinical trial of an alpha-adrenergic blocking drug and an antibiotic in heavily pre-treated men with longstanding symptoms characteristic of CP/CPPS. The outline of a protocol for a second trial to evaluate an

alpha-adrenergic blocking drug has been recently approved by an independent NIDDK appointed Data and Safety Monitoring Board. It is anticipated that patient recruitment will begin in the summer 2004. However, the Collaborator will have the opportunity to comment on the study protocol prior to implementation. The Collaborator providing the alpha-adrenergic blocking drug will be expected to provide drug without charge for the 12-week drug treatment period for approximately 270 study participants. The Collaborator will also provide sufficient matching placebo without charge.

CAPABILITY STATEMENTS: A Selection Committee will utilize the information provided in the "Collaborator Capability Statements" to help in their deliberations. It is the intention of the NIDDK that qualified applicants will have the opportunity to provide information to the Selection Committee through their Capability Statements. Capability Statements related to treatment with an alpha-adrenergic blocking drug for substantially reducing urinary symptoms in men with chronic prostatitis/chronic pelvic pain (CP/CPPS) and should address the following criteria: time line for ability to provide drug and placebo after selection of Collaborator is determined, approved daily dose of drug, previous studies of efficacy of drug in treating men with lower urinary tract symptoms and known side-effects of drug. Capability Statements may not exceed 10 pages.

TERMS: The Collaborator will be expected to execute a Clinical Trial Agreement, an example of which can be found at http://techdev.niddk.nih.gov/forms.htm No funding from the Government is available.

SUBMISSION DATES: A written statement of interest must be submitted by May 20, 2004 and all Collaborator Capability Statements must be submitted by June 2, 2004.

CONTACT INFORMATION: Submit statements of interest and Capability Statements to:

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