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### **Prostate Study Shows BOTOX May Be Safe, Effective Method for Managing Benign Prostatic Hyperplasia**

AURORA, Colo. (April 27, 2009) – Phase II data presented today at the annual meeting of the American Urology Association (AUA) indicate that men suffering from an enlarged prostate may benefit from BOTOX injections.

The two-stage, multi-center, double-blind, randomized study showed that two different dose levels of Botulinum Neurotoxin Type A (BOTOX®) injected into the prostate was both safe and efficacious for the management of benign prostatic hyperplasia (BPH), a common noncancerous enlargement of the prostate that can cause difficulty in urination.

“People often underestimate the significant impact BPH can have on a man’s quality of life,” said Dr. E. David Crawford, one of the principal investigators of the study and head of the Urologic Oncology Department at the University of Colorado Health Sciences Center. “These data indicate that BOTOX is an effective, fast acting treatment option that does not require daily dosage. We are excited to see what the long-term data will show us.”

A renowned urologist and clinician, Dr. Crawford is a lead investigator on 18 abstracts presented at the AUA regarding both BPH and prostate cancer screening, including the prostate arm of the Prostate, Lung, Colorectal, and Ovarian (PLCO) study.

Study results included data from 125 men with BPH, aged 50 years and older, and treatment success was defined in terms of efficacy and safety over a 12 week timeframe. Patients were assigned to receive either 100 units or 300 units of BOTOX. Seventy-three percent of patients taking 100 units and 81 percent taking 300 units passed the cut offs for efficacy, defined as 30 percent or more improvement from baseline. Both doses also passed the safety criteria. Specifically, there was no grade four or five toxicity events observed in either dose, and only 17 percent in the 100 dose and 18 percent in the 300 dose reported grade two or three events.

“A condition that effects more than half of men in their sixties and nearly 90 percent of those over the age of seventy, new treatment options and greater awareness are needed to help support men suffering from this condition,” said Wendy Poage, president of the Prostate Conditions Education Council. “We applaud Dr. Crawford and his colleagues for their research of innovative new treatment options for the thousands of men with BPH.”

BPH occurs commonly in men over the age of 60. While experts do not know what causes BPH, many believe that the condition may be related to hormone changes that occur during the aging process. BPH is not life threatening, but can cause bothersome urinary symptoms, including difficulty urinating, the need to urinate quite frequently, or awaking during the night to urinate.

### **About the Prostate Conditions Education Council**

A national organization committed to men's health, the Prostate Conditions Education Council (PCEC) – formally the Prostate Cancer Education Council – is the nation's leading resource for information on prostate health. The PCEC is dedicated to saving lives through awareness and the education of men, the women in their lives, as well as the medical community about prostate cancer prevalence, the importance of early detection, and available treatment options, as well as other men's health issues. The Council – comprised of a consortium of leading physicians, health educators, scientists and prostate cancer advocates – aims to conduct nation wide screenings for men and perform research that will aid in the detection and treatment of prostate conditions. More information is available at [www.prostateconditions.org](http://www.prostateconditions.org).

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