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FURTHER ANALYSES FROM THE REDUCE PROSTATE CANCER RISK REDUCTION TRIAL

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INTRODUCTION AND OBJECTIVE: The REDUCE study was initiated to examine the hypothesis that, in men at elevated risk of developing prostate cancer, dual 5 α -reductase inhibition with dutasteride will alter the natural history of the disease, delaying the formation of new tumors or slowing the rate of progression of clinically undetectable cancers, resulting in a reduced rate of detection on biopsy.

METHODS: REDUCE was a 4-year, international, multicenter, randomized, double-blind, placebo-controlled, parallel-group study evaluating the efficacy and safety of oral, once-daily dutasteride 0.5 mg in men at increased risk of developing prostate cancer. Eligible subjects were men aged 50-75 years, with a PSA 2.5-10 ng/ml (men aged 50-60 years) or 3.0-10 ng/ml (>60 years) at the initial screening visit, and who had a single, negative prostate biopsy (6-12 cores) within 6 months prior to enrollment. Principal exclusion criteria were more than one prior negative prostate biopsy, a previous diagnosis of prostate cancer, or evidence of high-grade prostatic intraepithelial neoplasia (HG-PIN) or atypical small acinar proliferation (ASAP) on the pre-entry prostate biopsy. After screening, eligible subjects completed a 4-week placebo run-in period and were then randomized to either dutasteride or matched placebo. There were scheduled assessments (including PSA measurements) every 6 months post-randomization. Subjects underwent a 10-core transrectal ultrasound (TRUS)-guided biopsy at 2 and 4 years; biopsies could however be performed at any time if clinically indicated. Those biopsies conducted between months 19-24 and 43-48 were considered "protocol-mandated"; those conducted between months 1-18 and 25-42 were considered "protocol-independent".

RESULTS: Data will be presented for the primary study endpoint: biopsy-detectable prostate cancer after 4 years of treatment in the efficacy population (all randomized subjects with a negative entry prostate biopsy as determined by the central pathology laboratory and who received ≥ 1 dose of study treatment). The distribution of Gleason scores for subjects diagnosed with prostate cancer, as well as the occurrence of adverse events in the safety population (all subjects randomized to study drug), will also be reported.

CONCLUSIONS: The results of the REDUCE study will help to determine the value of dual 5 α -reductase inhibition with dutasteride in reducing the risk of biopsy-detectable prostate cancer in men at elevated risk of developing the disease.

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