verse modes of access to phytotherapy (prescription vs. OTC) in the various countries.

POD-06.02

The effects of dutasteride, tamsulosin, and combination therapy on lower urinary tract symptoms and Qmax in men with BPH and prostatic enlargement: Two-year results from the Combination of Avodart® and Tamsulosin (CombAT) study

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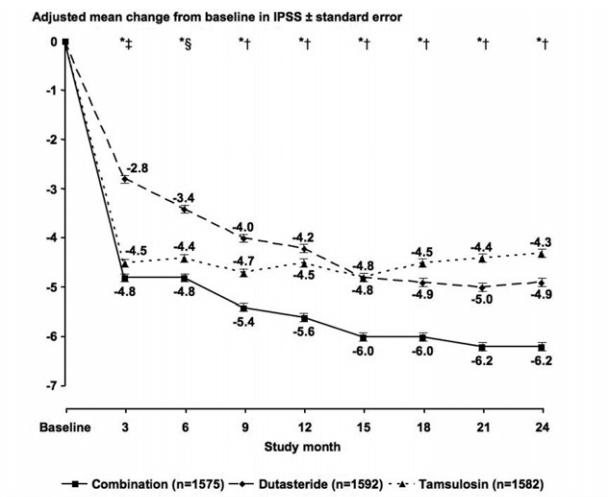
Objectives: The ongoing CombAT study is investigating whether combination therapy with dutasteride and tamsulosin is more effective than either monotherapy alone for improvement of symptoms and long-term clinical outcomes of AUR and BPH-related prostatic surgery in a population of men aged ≥50 years with moderate-to-severe BPH symptoms and prostatic enlargement. This abstract reports pre-planned 2-year analyses of IPSS and Qmax findings.

Materials and Methods: The CombAT study is a multicenter, randomised, double-blind, parallel-group study. Men aged ≥50 years with a clinical diagnosis of BPH, an IPSS ≥12 points, prostate volume ≥30 cc, total serum PSA 1.5–10 ng/mL, and Qmax >5 and ≤15 mL/sec with a minimum voided volume ≥125 mL were randomised to dutasteride 0.5 mg, tamsulosin 0.4 mg or the combination once daily for 4 years. Urinary symptoms were assessed at screening, baseline and every 3 months using the self-administered IPSS questionnaire; Qmax was assessed at screening, baseline and every 6 months. The primary endpoint at 2 years was change in IPSS from baseline. Superiority for combination *versus* monotherapies was based on a two-sided p-value ≤0.01.

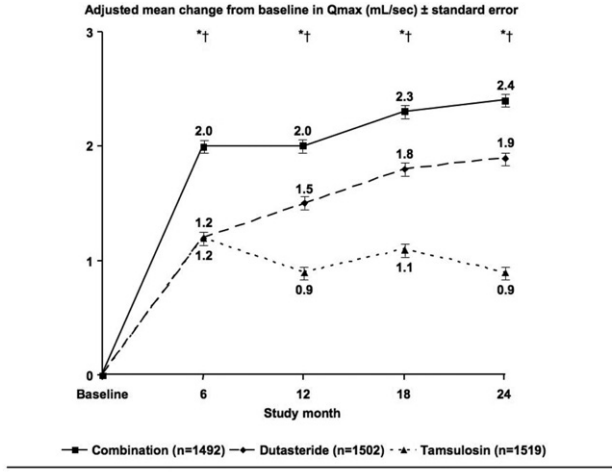
Results: Combination therapy resulted in a significantly greater improvement in symptoms *versus* dutasteride from Month 3 and tamsulosin from Month 9 (Figure). A significantly greater improvement from baseline in Qmax was observed for combination therapy *versus* dutasteride and tamsulosin monotherapies from Month 6.

Conclusions: In men with enlarged prostates (≥30 cc) and moderate-to-severe BPH symptoms, treatment with combination therapy provided continuous symptom and Qmax improvement over 24 months, with a significantly greater degree of improvement compared with either monotherapy alone. CombAT is the first study to demonstrate benefit in BPH symptom improvement for combination therapy over monotherapies in the first 12 months of treatment.



ITT population; LOCF. Randomised: combination n=1610; dutasteride n=1623; tamsulosin n=1611. Baseline IPSS was 16.6 (combination); 16.4 (dutasteride, tamsulosin).
*p<0.001 for combination *versus* dutasteride; †p<0.001 for combination *versus* tamsulosin; ‡p=0.18 for combination *versus* tamsulosin; §p=0.032 for combination *versus* tamsulosin.

Figure 1. POD-06.02



ITT population; LOCF. Randomised: combination n=1610; dutasteride n=1623; tamsulosin n=1611. Baseline Qmax was 10.9 mL/sec (combination), 10.6 mL/sec (dutasteride) and 10.7 mL/sec (tamsulosin). *p≤0.006 for combination *versus* dutasteride and tamsulosin.

Abstract Withdrawn

POD-06.03

Long-term treatment with finasteride results in a clinically significant reduction in total prostate volume compared to placebo over a wide range of baseline prostate size: data from MTOPS and PLESS

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Introduction: Previously, in a predefined exploratory analysis of the MTOPS study, we demonstrated that the combination of doxazosin and finas-