Title

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Abstract Title: Phase 3 Clinical Trial Results of a New Combined Oral Contraceptive with Estetrol 15mg and Drospirenone 3mg

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Text:

OBJECTIVE: To assess the contraceptive efficacy and safety of estetrol, a native estrogen, with drospirenone in a 24/4-day oral regimen in U.S. and Canadian women.

METHODS: This multicenter, open-label, phase 3 trial enrolled healthy women 16-50 years with regular cycles and BMI ≤35 kg/m^2 at 94 sites to receive estetrol 15mg/drospirenone 3mg for up to 13 cycles. Follow-up visits occurred during cycles 2, 4, 7, 10 and after treatment completion. We evaluated primary outcomes of contraceptive efficacy in women 16-35 years at screening using the Pearl Index (PI), method-failure PI in at-risk cycles (at least one act of intercourse and no other contraceptive use) and 13-cycle life-table pregnancy rate. We assessed secondary outcomes of cycle control and safety.

RESULT: Of 2,148 enrolled subjects, 1,864 started study treatment and 1,016 (54.5%) completed 13 cycles. The primary efficacy population included 1,524 women with 12,763 at-risk cycles. Twenty-six on-treatment pregnancies occurred of which 14 were method failure, resulting in an overall PI of 2.65 (95%CI 1.73-3.88), method-failure PI of 1.43 (95%CI 0.78-2.39), and cumulative 13-cycle pregnancy rate of 2.06% (95%CI 1.40-3.04%). Withdrawal bleeding lasted ≤5 days (median) per cycle and <20% of women had unscheduled bleeding from Cycle 5 onwards. The most common adverse events were headache (94; 5.0%) and metrorrhagia (86; 4.6%); however, these events resulted in discontinuation in only 6 (0.3%) and 16 (0.9%) women, respectively. Overall, 132 (7.1%) subjects discontinued for treatment-related adverse events. No thromboembolic events occurred.

CONCLUSION: Estetrol 15mg/drospirenone 3mg met planned primary and secondary outcomes for efficacy, cycle control and safety.