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PHARMACOKINETICS AND TOLERABILITY OF TRANSDERMAL
CONTRACEPTIVE DELIVERY SYSTEMS (TCDS) CONTAINING
ETHINYL ESTRADIOL (EE) AND LEVONORGESTREL (LNG)

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Pharmacokinetic profile and tolerability of TCDS were evaluated in 2 open label randomized trials. In a Phase 1, 2-period crossover trial AG200 and AG200LE were given to 39 women and compared to a 150 µg LNG/30 µg EE oral contraceptive (OC), Levlen[®]. In a Phase 2 multi-center, 3-cycle study, 123 women used AG200LE, AG200, or a higher-dose formulation, AG200-15. In study 1, mean steady state levels (pg/ml) for the TCDS groups ranged from 17.5 to 26.4 (EE) and from 1303 to 1757 (LNG). The steady state and maximum concentration levels were significantly lower than those reported for Levlen[®]. In study 2, EE and LNG levels in all groups were well within ranges of low-dose OCs. The cycle control parameters of TCDS were also similar to low-dose OCs. In study 1, no TCDS fell off; 91% of subjects showed no skin irritation. In study 2, incidence of patch fall-off was <1% in cycle 3; mild skin irritation occurred after application of 2% of patches. Study 2 demonstrated substantially less EE exposure and EE-related adverse events with AG200-15 than with a currently marketed patch. Ovulation suppression data from the second study were reported earlier. AG200-15 is in phase 3 clinical trials.