DUAVIVE DEMONSTRATED:

Significant reduction in the number and severity of average daily moderate to severe hot flushes (from baseline to Week 12, n=122) vs. placebo (n=63)†.

Mean change from baseline was -7.63 vs. -4.92 and -0.87 vs. -0.26 for severity, p<0.001 for both

Incidence of breast pain and change in breast density shown not to be significantly different from placebo

Incidence of breast pain at Weeks 9–12: 9% vs. 6%, respectively‡. Mean percentage change in breast density from baseline after 1 year of treatment: -0.49 vs. -0.51, respectively

Low incidence of endometrial hyperplasia†

In clinical studies up to 2 years’ duration, 1% incidence of endometrial hyperplasia or malignancies observed (0% and 0.30% at year 1 and 0.68% at year 2.

Cumulative amenorrhea rates similar to placebo‡

In SMART 1, cumulative amenorrhea at Year 1 was 83% in women treated with DUAVIVE, similar to placebo (85%) at 48-57T, cumulative amenorrhoea at Year 1 (Cycle 1 to 13th), was 88% with DUAVIVE, similar to placebo (84%).

Improved sleep adequacy and menopause-specific quality of life total score vs. placebo (secondary endpoints)§

Adjusted mean change from baseline in sleep adequacy score at Week 12: 16.53 vs. 1.07, respectively, p<0.001

The parameters of sleep quantity, somnolence, snoring and shortness of breath were not significantly different from placebo$.

Mean change from baseline in MENSOL total score at Week 12: -1.6 vs. -1.0, respectively, DUAVIVE demonstrated p<0.001

TIP 2

ASSOCIATED WITH MENOPAUSE

TO SEVERE VASOMOTOR SYMPTOMS

FOR THE TREATMENT OF MODERATE

FOR WOMEN WITH A UTERUS*

PROGESTIN-FREE HORMONE THERAPY

FOR MENOPAUSE

ASSOCIATED WITH MENOPAUSE

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