Safety results from large real-world safety study in Zoely published

- The real world PRO-E2 safety study of over 101,000 women in 12 countries for up to 2 years has confirmed that the risk of venous thromboembolism (VTE)* is at least as low with Zoely▼® (NOMAC-E2) as with levonorgestrel-containing combined oral contraceptives (COC-LNG)[1]
- The study also demonstrated a statistically significant lower risk of unintended pregnancy compared with commonly prescribed COC-LNGs [2]
- NOMAC-E2 is the only monophasic combined oral contraceptive (COC) to contain estrogen with an identical structure to the one naturally produced by women[3,4]

Consilient Health Ireland has announced that the safety results from the PRO-E2 real-world safety study for Zoely® (NOMAC-E2) have been published in The European Journal of Contraception and Reproductive Health Care (EJCRH).[1]

The post-authorisation safety study (PASS), known as PRO-E2, was a large, prospective, non-interventional controlled cohort study of over 101,000 women. PRO-E2 compared the risks of using NOMAC-E2 versus COCs containing levonorgestrel (COC-LNG), a commonly prescribed contraceptive.[1]

The primary objective of the real-world study was to assess and compare the risk of cardiovascular events* in NOMAC-E2 users with COC-LNG users. For the main clinical outcome, the risk of VTE† was as least as low with NOMAC-E2 as with COC-LNG, consistent with findings of previous studies (0.59 Hazard Ratio [HR]† 95% confidence interval [CI], 0.25-1.35).[1]

*Specifically deep venous thrombosis of the lower extremities and pulmonary embolism

†HR adjusted for age, body mass index, current duration of hormonal contraceptive use, family history of VTE

PRO-E2 also demonstrated that contraceptive failure (the risk of unintended pregnancy), a key secondary outcome, was statistically significantly lower with NOMAC-E2 compared with COC-LNG (0.45 HR†, 95% CI, 0.34-0.60, [p<0.0001]). Further analyses showed that the lower rate of unintended pregnancy with NOMAC-E2 was even more pronounced in women under 35 years of age.[2] The shorter hormone-free interval with NOMAC-E2, its longer half-life, and monophasic regimen may all contribute to fewer unintended pregnancies.[5,6,7] These results will be published in the EJCRH later this month.

All 14 secondary outcomes of the study were met, with the risk of severe adverse events and depressive disorders or changes in weight or acne score with NOMAC-E2 comparable to COC-LNG.[2]

The safety and efficacy publications were accepted by the EJCRH in September. The publication on safety results is available online: https://www.tandfonline.com/doi/10.1080/13625187.2021.1987410

The efficacy publication will be available online later this month. Both publications will be available in the printed journal in December.

Results have also been submitted to the European Medicines Agency (EMA) and will be presented at the European Society of Gynecology congress in November this year.

References available on request.

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