Liletta® (levonorgestrel-releasing intrauterine system) – Expanded indication

- On November 14, 2022, Medicines360 announced the FDA approval of Liletta (levonorgestrel-releasing intrauterine system), for prevention of pregnancy for up to 8 years.
    - Liletta was previously approved for this indication for up to 6 years.
- The approval of Liletta for the expanded indication was based on a review of additional efficacy and safety data from ACCESS IUS, a randomized, open-label study in 1,751 U.S. women receiving Liletta. The pregnancy rate calculated as the Pearl Index (PI) in participants 16 to 35 years of age, inclusive, was the primary efficacy endpoint used to assess contraceptive reliability. The PI was calculated based on 28-day equivalent exposure cycles; evaluable cycles excluded those in which back-up contraception was used unless a pregnancy occurred in that cycle.
    - The year-by-year PI in year 7 was 0.49 (95% CI: 0.06, 1.78) and in year 8 it was 0.00 (95% CI: 0.00, 1.31).
- Liletta contains 52 mg of levonorgestrel (LNG). Initially, LNG is released *in vivo* at a rate of approximately 20 mcg/day. This rate decreases progressively to approximately 6.5 mcg/day after 8 years.
    - Liletta can be removed at any time but must be removed by the end of the eighth year. Liletta can be replaced at the time of removal with a new Liletta if continued contraceptive protection is desired.