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

- On October 16, 2018, Allergan and Medicines360 announced the FDA approval of Liletta (levonorgestrel-releasing intrauterine system), for prevention of pregnancy for up to 5 years.
    - Previously, Liletta was approved for prevention of pregnancy for up to 4 years.
    - Liletta should be replaced after 5 years if continued use is desired.
- The approval of the expanded indication was based on a review of additional efficacy and safety data from an ongoing study with 1,751 women receiving Liletta. The pregnancy rate calculated as the Pearl Index (PI) was the primary efficacy endpoint used to assess contraceptive reliability.
    - Year 5 PI was 0.20 (95% CI: 0.01 to 1.13).
    - The cumulative 5-year pregnancy rate was 0.92 (95% CI: 0.46 to 1.82).
- Liletta should be inserted by a trained healthcare provider using strict aseptic technique. Refer to the prescribing information for specific insertion instructions.
    - The initial release rate of levonorgestrel is approximately 20 mcg/day and declines progressively to about 50% after 5 years.
    - Liletta can be removed at any time but must be removed by the end of the fifth year.