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

- On October 28, 2019, Medicines360 announced the FDA approval of Liletta (levonorgestrel-releasing intrauterine system), for prevention of pregnancy for up to 6 years.
    - Liletta was previously approved for prevention of pregnancy for up to 5 years.
- The approval was based on a review of additional efficacy and safety data from the ongoing ACCESS IUS study, a randomized, open-label trial in 1,751 healthy women aged 16 to 45 years. The pregnancy rate calculated as the Pearl Index (PI) in women aged 16 to 35 years, inclusive, was the primary efficacy endpoint used to assess contraceptive reliability.
    - The table below shows the annual PI for each of the six years and the calculated cumulative life table pregnancy rates through years 1, 2, 3, 4, 5, and 6.

	Number of 28-day cycles of exposure by year	Year-by-year PI pregnancy rate (95% CI)	Cumulative 28-day cycles of exposure	Cumulative year life table pregnancy rate (95% CI)
Year 1	17,175	0.15 (0.02, 0.55)	17,175	0.14 (0.04, 0.57)
Year 2	14,205	0.37 (0.10, 0.94)	31,380	0.49 (0.22, 1.09)
Year 3	11,760	0.11 (0.00, 0.62)	43,140	0.59 (0.28, 1.25)
Year 4	9,891	0.13 (0.00, 0.73)	53,031	0.72 (0.36, 1.45)
Year 5	8,335	0.16 (0.00, 0.87)	61,366	0.87 (0.44, 1.70)
Year 6	5,091	0.00 (0.00, 0.94)	66,457	0.87 (0.44, 1.70)

- Liletta is inserted into the uterine cavity with the provided inserter by a trained healthcare professional. The initial release rate of levonorgestrel (LNG) is approximately 20 mcg/day and declines progressively to approximately 8.6 mcg/day after 6 years.
    - Liletta can be removed at any time but must be removed by the end of the sixth year.
    - Patients should be re-examined and evaluated 4 to 6 weeks after insertion and once a year thereafter, or more frequently if clinically indicated.