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Mylan expands oncology portfolio with launch of Generic Faslodex Injection

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"Mylan's launch of Fulvestrant Injection represents an important addition to our growing oncology portfolio and, more importantly, expands the available treatment options for women who are facing advanced or metastatic stages of breast cancer."

Mylan N.V. has announced the U.S. launch of Fulvestrant Injection, 250 mg/5 mL (50 mg/mL) per single-dose prefilled syringe, a generic version of AstraZeneca's Faslodex® Injection. Mylan received final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for this product, which is used to treat certain types of advanced breast cancer in women who have experienced menopause as monotherapy and in advanced or metastatic breast cancer in combination with other products.

"Mylan's launch of Fulvestrant Injection represents an important addition to our growing oncology portfolio and, more importantly, expands the available treatment options for women who are facing advanced or metastatic stages of breast cancer," said Mylan President Rajiv Malik. "The launch also reinforces our scientific expertise in bringing to market complex products, like injectables, which further enhances our institutional business and exemplifies our continued commitment to expanding access to medicine."

Mylan is dedicated to supporting patients at every stage of cancer care with more than 50 oncology supportive care, therapeutic and diagnostic products in the U.S.

Fulvestrant Injection, 250 mg/5 mL (50 mg/mL) per single-dose prefilled syringe, had U.S. sales of approximately $550 million for the 12 months ending June 30, 2019, according to IQVIA.

Currently, Mylan has 151 ANDAs pending FDA approval representing approximately $88.4 billion in annual brand sales, according to IQVIA. Forty-four of these pending ANDAs are potential first-to-file opportunities, representing $59.2 billion in annual brand sales, for the 12 months ending June 30, 2019, according to IQVIA.

Fulvestrant Injection is a prescription medicine used to treat women with:

- Hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer or breast cancer that has spread to other parts of the body (metastatic), who have gone through menopause, in combination with ribociclib as their first endocrine therapy or after their cancer has progressed while on prior endocrine

therapy

- HR-positive, HER2-negative advanced breast cancer, who have gone through menopause and have not been previously treated with endocrine therapy
- HR-positive advanced breast cancer, who have gone through menopause and whose disease has progressed after endocrine therapy
- HR-positive, HER2-negative advanced or metastatic breast cancer in combination with palbociclib or abemaciclib whose disease has progressed after endocrine therapy