



Mylan Expands Oncology Portfolio with Launch of Generic Tarceva® Tablets

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Erlotinib Hydrochloride Tablets treat metastatic non-small cell lung and pancreatic cancers

HERTFORDSHIRE, England, and PITTSBURGH, May 10, 2019 /PRNewswire/ -- Global pharmaceutical company [Mylan N.V.](#) (NASDAQ: MYL) today announced the U.S. launch of Erlotinib Hydrochloride Tablets, 25 mg, 100 mg and 150 mg, a generic version of Genentech's Tarceva®. Mylan Pharmaceuticals received final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for this product.

Erlotinib Hydrochloride Tablets is indicated for the treatment of patients with metastatic non-small cell lung cancer whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test receiving first-line, maintenance, or second or greater line treatment after progression following at least one prior chemotherapy regimen. The safety and efficacy of erlotinib has not been established in patients with NSCLC whose tumors have other EGFR mutations. It is also indicated as a first-line treatment for patients with locally advanced, unresectable or metastatic pancreatic cancer, in combination with gemcitabine. Erlotinib is not recommended for use in combination with other platinum-based chemotherapy.

U.S. sales for Erlotinib Hydrochloride Tablets, 25 mg, 100 mg and 150 mg were approximately \$212 million for the 12 months ending March 31, 2019, according to IQVIA.

Currently, Mylan has 165 ANDAs pending FDA approval representing approximately \$82.2 billion in annual brand sales, according to IQVIA. Forty-six of these pending ANDAs are potential first-to-file opportunities, representing \$56.4 billion in annual brand sales, for the 12 months ending December 31, 2018, according to IQVIA.

About Mylan

Mylan is a global pharmaceutical company committed to setting new standards in healthcare. Working together around the world to provide 7 billion people access to high quality medicine, we innovate to satisfy unmet needs; make reliability and service excellence a habit; do what's right, not what's easy; and impact the future through passionate global leadership. We offer a growing portfolio of more than 7,500 marketed products around the world, including antiretroviral therapies on which more than 40% of people being treated for HIV/AIDS globally depend. We market our products in more than 165 countries and territories. We are one of the world's largest producers of active pharmaceutical ingredients. Every member of our approximately 35,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at [Mylan.com](#). We routinely post information that may be important to investors on our website at [investor.mylan.com](#).



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