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Mylan and Aspen Announce Launch of Generic Busulfex® Injection

HERTFORDSHIRE, England, PITTSBURGH and DURBAN, South Africa, Dec. 4, 2017 /PRNewswire/ -- [Mylan N.V.](#) (NASDAQ, TASE: MYL) and its partner, Aspen (JSE: APN), today announced the U.S. launch of Myleran (busulfan) Injection, 60 mg/10 mL (6 mg/mL) Single-dose Vial, a generic version of Otsuka Pharmaceutical's Busulfex® Injection. Aspen received final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for this product, which is indicated for use in combination with cyclophosphamide as a conditioning regimen prior to allogeneic hematopoietic progenitor cell transplantation for chronic myelogenous leukemia. (1)

As part of its partnership with Aspen, Mylan will commercialize Busulfan Injection, 60 mg/10 mL (6 mg/mL) Single-dose Vial in the U.S. [Mylan](#) has one of the largest injectable portfolios in the industry and is also one of the largest suppliers of cancer medicines by volume in the U.S.

U.S. sales for Busulfan Injection, 60 mg/10 mL (6 mg/mL) Single-dose Vial were approximately \$97 million for the 12 months ending Sept. 30, 2017, 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 more than 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](#).

About Aspen

Aspen is a leading global player in specialty, branded and generic pharmaceuticals with an extensive basket of products that provide treatment for a broad spectrum of acute and chronic conditions experienced through all stages of life.

With a presence of nearly two decades in the pharmaceutical sector, Aspen is committed to sustaining life and promoting healthcare through increasing access to high quality, affordable medicines and products, with its core focus being in the Thrombosis, Anaesthetic, High Potency & Cytotoxic and Nutritional therapeutic categories.

Aspen has a strong presence in both emerging and developed countries. Its emerging market footprint includes SubSaharan Africa, Latin America, China, South East Asia, Eastern Europe and the Commonwealth of Independent States, comprising Russia and the former Soviet Republics. It is also a leading pharmaceutical company in developed countries including Australia and most notably, countries throughout Western Europe.

Aspen operates with an established business presence in approximately 50 countries spanning 6 continents and employs more than 10,000 people. The Group operates 25 manufacturing facilities across 18 sites. Aspen holds international manufacturing approvals from some of the most stringent global regulatory agencies including the FDA, TGA and EMA.

Aspen's manufacturing capabilities are scalable to demand and cover a wide variety of product types including oral solid dose, liquids, semi-solids, steriles, biologicals, APIs and infant nutritionals.

With a market capitalisation of approximately \$10 billion, Aspen is the largest pharmaceutical company listed on the JSE Limited (share code: APN) and ranks amongst the top 20 listed companies on this exchange. For more information visit: <http://www.aspenpharma.com/>

(1) Generic Busulfex® for Injection causes severe and prolonged myelosuppression. Hematopoietic progenitor cell transplantation is required to prevent potentially fatal complications of the prolonged myelosuppression.



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