Pfizer Withdraws Application to Switch Viagra to Non-Prescription Status in Europe

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(BUSINESS WIRE)--Pfizer announced today that it has withdrawn its application to switch the legal status of the 50 mg tablet strength of Viagra from ‘prescription only’ to ‘non-prescription’ in the European Union (EU).

Viagra is a well established oral medication for the treatment of erectile dysfunction (ED) and all current doses of Viagra will continue to be available to patients by prescription from their doctor.

Pfizer believes that Viagra 50 mg is a suitable candidate for non-prescription supply through pharmacists in the EU and meets the criteria set out by the European Commission guideline for changing the classification of a medicinal product to non-prescription. However, in a letter to the European Medicines Agency (EMEA), Pfizer said that it has decided to withdraw the application in order to fully consider comments from the EMEA’s Committee for Medicinal Products for Human Use (CHMP), recognizing that there were some concerns regarding the proposed supply of Viagra 50 mg tablets without a prescription in the EU. The CHMP noted that when Viagra is used in accordance with the currently approved prescribing information, its safety profile remains favorable. The withdrawal of the application will enable evaluation of further information and additional data that may be required to allow any future assessments under the centralized procedure.

Pfizer believes that access to Viagra 50 mg without a prescription in a pharmacy setting in the EU would provide valuable benefits to male patients suffering from ED. Millions of men in Europe are currently circumventing the healthcare system when seeking ED medicines, exposing themselves to unnecessary risks of medicines from uncontrolled sources and the missed opportunity to get important health information from a

healthcare professional.

Since its introduction over a decade ago, Viagra has been used by more than 35 million men worldwide. “Viagra has a proven safety profile that has been well established in extensive post-marketing studies and in more than 120 clinical trials,” said Rory O’Connor, Pfizer vice president of Medical and Regulatory Affairs. “We will continue to work with regulators in Europe to improve the availability of our medicines to patients and physicians and the benefits they get from our therapies.”

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Pfizer IncMedia:Lisa O’Neill, + 44 7967 756924Lisa.O’Neill@pfizer.comorOliver Stohlmann, + 43 664-335-0485Oliver.stohlmann@pfizer.comorInvestors:Suzanne Harnett, 212-733-8009