Pfizer’s Sayana® Press Becomes First Injectable Contraceptive In The United Kingdom Available For Administration By Self-Injection

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Builds on Current Momentum Towards Broadening Access to This Contraceptive Option for Women Across the Globe

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Pfizer Inc. announced today that the company’s injectable contraceptive, Sayana®Press (medroxyprogesterone acetate), is now available to women in the United Kingdom (UK) for administration by self-injection. This follows the recent approval from the UK Medicines and Healthcare Products Regulatory Agency (MHRA) of an update to the Sayana® Press label, adding the option for self-injection by women when considered appropriate by a healthcare professional (HCP).

Sayana® Press is the first injectable contraceptive in the UK available for administration via self-injectioni,ii. This new method of administration is also approved or pending local approval in additional European Union (EU) markets (Austria, Belgium, Hungary, Ireland, Netherlands). Pfizer will continue its efforts to help bring this updated label to more countries across the globe, with an initial focus on those in the developing world – such as in Burkina Faso, Senegal and Uganda – where data show unmet neediii and demand for injectable contraceptivesiv. Sayana® Press is not yet approved for self- injection outside of the EU.

“With this revised label, following consent from a healthcare professional and with proper training, UK women will now have the opportunity to administer Sayana® Press outside of a clinical setting,” said Dr. Salomon Azoulay, senior vice president and chief medical officer, Pfizer Global Established Pharma Business. “This is an exciting milestone for women in the United Kingdom, and, potentially, in countries around the world, who might prefer this method of contraception and mode of administration.”

Sayana® Press combines a long-acting, reversible, contraceptive with an all-in-one prefilled, single-use, non-reusable Uniject™ injection system, eliminating the need to prepare a needle and syringe. Approved for use by the MHRA in 2011, the contraceptive is indicated for the prevention of pregnancy. Each subcutaneous injection prevents ovulation and provides contraception for at least 13 weeks (+/- one week). Sayana® Press professional and patient information, including the risk of bone mineral density loss and other warnings and precautions for use, can be found here.

Injectable contraceptives are a widely-used family planning method, particularly among women in developing countriesv. They are discreetvi, eliminate the need for a daily pill regimenvii and, for some women living in remote areas, they can alleviate the deterrent of having to frequently travel long distances to get to a clinicviii. Accordingly, experts have identified the need for a contraceptive method that can be administered in low-resource, non-clinic settings.ix

In November 2014, Pfizer Inc., the Bill & Melinda Gates Foundation and the Children’s Investment Fund Foundation (CIFF) entered into a partnership to help broaden access to Sayana® Press for women most in need in 69 of the world’s poorest countriesx. Through this collaboration, Sayana® Press is being sold for US $1 per dose to qualified purchasers, who help enable the poorest women in these countries to have access to the contraceptive at reduced or no cost. The agreement is supported by a consortium of private sector donors and aid organizations, which include PATH, United Kingdom’s Department for International Development (DFID), the United Nations Population Fund (UNFPA) and the United States Agency for International Development (USAID).

“Helping to broaden access to Sayana® Press is a key priority for Pfizer,” said John Young, president, Pfizer Global Established Pharma Business. “Through the tremendous efforts and ongoing collaboration with our Partners, we have already made great progress in bringing Sayana® Press to thousands of women living in sub-Saharan Africa. We hope to continue the great momentum achieved, enabling us to further help address the specific family planning needs of women in the developing world.”

In July 2014, this same consortium of public and private organizations piloted efforts to help make Sayana® Press available for the first time in four countries in sub-Saharan Africa. Through June 2015, more than 170,600 Sayana® Press units have been distributed to health facilities across Burkina Faso, Niger, Senegal and Uganda. In addition, over 6,000 health care providers were trained on Sayana® Press administration xi.

Sayana® Press is approved by regulatory authorities in the European Union and in a number of countries across the globe, including Bangladesh, Burkina Faso, Kenya, Niger, Nigeria, Senegal and Uganda. Additional regulatory submissions are being pursued.

Important Safety Information

SAYANA® PRESS should not be used in women with known or suspected malignancy of the breast or genital organs, metabolic bone disease, active thromboembolic disease and in women with current or past history of cerebrovascular disease.

Use of SAYANA® PRESS is associated with significant loss of bone mineral density (BMD). This loss of BMD is of particular concern during adolescence and early adulthood, a critical period of bone accretion. Decrease in BMD during treatment appears to be substantially reversible after depot medroxyprogesterone acetate (DMPA) injection is discontinued.

Re-evaluation of the risks and benefits of treatment should be carried out in all women who wish to continue use for more than 2 years.

Most women using DMPA SC experience a change in menstrual bleeding patterns. Bleeding may be heavy.

No information is available that would support the safety of DMPA SC use in women with a history of thromboembolic disease.

Women may gain weight on DMPA. MPA may cause some degree of fluid retention.

There is a potential for delay in return to ovulation following use of DMPA SC, regardless of the duration of use.

Monitor patients with a history of clinical depression or diabetes mellitus.

DMPA SC does not protect against HIV infection (AIDS) or other sexually transmitted diseases.

Injection site reactions such as injection site pain, injection site tenderness, injection site nodules, injection site atrophy (persistent) and lipoatrophy of the injection site have been reported with DMPA SC 104 mg/0.65 mL suspension for injection (pre-filled syringe).

The most common adverse events in phase 3 clinical trials of DMPA-SC included amenorrhea, heavy intermenstrual bleeding, weight gain and headache.

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DISCLOSURE NOTICE: The information contained in this release is as of September 24, 2015. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information related to the roll-out of Sayana Press and the potential benefits of Sayana Press that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development; whether and when any applications for Sayana Press or label updates for Sayana Press may be filed with regulatory authorities in any other jurisdictions; whether and when regulatory authorities may approve such applications and any other applications that are pending for Sayana Press, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of Sayana Press; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2014, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 10-Q and Form 8-K, all of which are filed with the SEC and available at www.sec.gov and www.pfizer.com.

_____ i National Health Service. The Contraceptive Injection. Available at: http://www.nhs.uk/conditions/contraception-guide/pages/contraceptive-injection.aspx. Accessed: September 8, 2015. ii Electronic Medicines Compendium. Noristerat SPC. Available at: http://www.medicines.org.uk/emc/medicine/1835. Accessed: September 8, 2015. iii FP 2020 Progress Report: 2013-2014. Figures 4.14, AX. 12 and AX. 12. Available at:http://progress.familyplanning2020.org/downloads. Accessed: July 27, 2015. iv FP 2020 Progress Report: 2013-2014. Figures 4.12, AX. 4 and AX. 18. Available at:http://progress.familyplanning2020.org/downloads. Accessed: July 27, 2015. v United Nations. World Contraceptive Patterns 2013. Available at:www.un.org/en/development/desa/population/publications/pdf/family/worldContraceptivePatt Accessed: November 4, 2014. vi Family Planning 2020. FP2020: Partnership in Progress 2013-2014. Available at:progress.familyplanning2020.org/uploads/ckfinder/files/FP2020_Progress_Report_2013-2014_Digital_View_lores.pdf. vii Family Planning 2020. FP2020: Partnership in Progress 2013-2014. Available at:progress.familyplanning2020.org/uploads/ckfinder/files/FP2020_Progress_Report_2013-2014_Digital_View_lores.pdf. viii World Health Organization. Family Planning Fact Sheet. Available at:http://www.who.int/mediacentre/factsheets/fs351/en/. ix UNFPA. Adding it Up: Costs and Benefits of Contraceptive Services. Estimates for 2012. Available at:https://www.unfpa.org/webdav/site/global/shared/documents/publications/2012/AIU%20Paper%20Estimates%20for%202012%20final.pdf. Accessed: November 7, 2014. x Family Planning 2020. Available at: http://www.familyplanning2020.org/countries/all-countries. Accessed: November 5, 2014. xi PATH data on file.

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