Novel Agreement Expands Access to Pfizer's Contraceptive, Sayana® Press, for Women Most in Need in the World's Poorest Countries

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Collaboration will help advance progress and support global efforts to increase access to voluntary family planning information, services and contraceptives by 2020

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NEW YORK, N.Y., November 13 – Pfizer Inc., the Bill & Melinda Gates Foundation and the Children's Investment Fund Foundation (CIFF) today announced an agreement that will expand access to Pfizer's injectable contraceptive, Sayana® Press (medroxyprogesterone acetate), for women most in need in 69 of the world's poorest countriesⁱ. Through this collaboration of organizations from the public and private sectors, Sayana® Press will be sold for US \$1 per dose to qualified purchasers, who can help enable the poorest women in these countries to have access to the contraceptive at reduced or no cost.

Sayana® Press combines a long-acting, reversible, contraceptive with an all-in-one prefilled, single-use, non-reusable UnijectTM injection system that eliminates the need to prepare a needle and syringe. The use of this delivery system allows the contraceptive to be administered by health workers to women at home or in other convenient settings. The training required is basic and straightforward. 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 hereⁱⁱ.

"This is a great example of applying innovation to a Pfizer heritage product to help broaden access to family planning," said John Young, President, Pfizer Global Established Pharma Business. "Pfizer saw an opportunity to address the needs of women living in hard-to-reach areas, and specifically enhanced the product's technology with public health in mind. I'm so pleased with the leadership from the Bill & Melinda Gates Foundation, the Children's Investment Fund Foundation and other collaborating organizations that are helping create a sustainable market through an approach that could be a model for other medicines."

More than 200 million women in developing countries want to delay pregnancy or prevent undesired pregnancy but are not using any method of contraceptionⁱⁱⁱ. Since the landmark London Summit on Family Planning in July 2012, the global community has been working together toward an ambitious and achievable goal: to provide an additional 120 million women in the world's 69 poorest countries with access to voluntary family planning information and services by 2020.

On November 3, Family Planning 2020 (FP2020)—the global initiative that carries this commitment forward—released its second progress report, which found that, in 2013, the number of women using modern contraceptives in the 69 focus countries increased by 8.4 million (compared to 2012) to 273 million. The report estimates that overall modern contraceptive use in 2013 helped avert 77 million unintended pregnancies and 125,000 maternal deaths. The collaboration announced today will help contribute to the FP2020 effort by providing more women around the world with contraceptive access and options.

"When women are able to plan their families, they are more likely to survive pregnancy and child birth, to have healthier newborns and children, and to invest more in their families' health and wellbeing," said Dr. Chris Elias, President of Global Development Programs at the Bill & Melinda Gates Foundation. "We are proud to be part of this innovative public-private collaboration that will help more women around the world -- even in remote areas -- plan their lives and their futures."

Injectable contraceptives are a widely-used family planning method among women in developing countries^{vi}, where the lifetime risk for death due to a maternal cause can be as high as one in 15. vii In many developing countries, women must return to a clinic or health post every three months for a new injection from a skilled health worker, limiting access in remote and other hard-to-reach areas. Accordingly, experts have identified the need for a contraceptive method that can be administered in low-resource, non-clinic settings. viii Because of its delivery technology, expanding access to Sayana® Press could help fill this gap.

Sayana® Press is approved by regulatory authorities in the European Union and in a number of FP2020 focus countries. These countries include Bangladesh, Burkina Faso, Kenya, Niger, Nigeria, Senegal and Uganda, as well as additional markets in Latin America and within the Asia Pacific region. Additional regulatory submissions are being pursued. Sayana® Press is not approved or available for use in the United States.

"Far too many women die or are harmed because of unwanted pregnancies," said Michael Anderson, Chief Executive Officer at the Children's Investment Fund Foundation. "This important partnership expands the choice of affordable contraceptives. We believe this will further support CIFF's mission of enabling more women and children to survive and thrive."

The consortium of public- and private-sector donors and aid organizations supporting this collaboration includes PATH, the United Kingdom's Department for International Development (DFID), the United Nations Population Fund (UNFPA), and the United States Agency for International Development (USAID). These organizations play an important role in ensuring that Sayana® Press reaches women in the world's poorest countries. In addition to assisting with procurement, this consortium will support country introductions and the delivery of Sayana® Press to health facilities and community-based distribution networks. At the country level, the organizations will also work with local governments with the goal of including injectable contraceptive methods in reproductive health plans and budgets, coordinate health worker trainings, and raise awareness about the availability of Sayana® Press.

This agreement builds on the momentum of recent efforts undertaken by this same consortium of public and private organizations on an introduction program to help make Sayana® Press available for the first time in five

countries in sub-Saharan Africa (Burkina Faso, Niger, Senegal and Uganda), coordinated by PATH, and in South Asia (Bangladesh).

Since the introduction program launched in Burkina Faso in July 2014, approximately 75,000 Sayana® Press units have been distributed to health facilities in the introduction countries, and approximately 2,500 health care providers have thus far been trained on Sayana® Press administration. In Burkina Faso alone, preliminary data from five out of 23 total districts and two local nongovernmental organization partners involved in the introduction program indicate that approximately 5,729 women are using Sayana® Press, and 1,659 of these women are new users of family planning^{ix}.

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Additional Organization Remarks

"Sayana® Press is now an option for women who have been at the margins of family planning access for way too long. I am hopeful that this new agreement increases sustained availability of Sayana® Press for any woman who chooses to use it." – **Dr. Cathy Ndiaye, Senegal Project Manager, Sayana® Press Introduction, PATH**

"Access to modern, safe and reliable family planning methods is vital in helping women to control their lives and their futures. Without the ability to choose when they have children and how many they have, too often women lose the opportunity to participate fully in their economies and societies." – **Justine Greening, International Development Secretary, DFID**

"USAID has invested in Sayana® Press for many years, and we are thrilled that these efforts have finally come to fruition. This public-private collaboration will now help more women access injectable contraceptives. Expanding contraceptive choice is crucial to helping women plan and space their pregnancies, which we believe contributes to the health and economic wellbeing of families and communities across the globe." – **Dr. Ariel Pablos-Mendez, Assistant Administrator for Global Health, USAID**

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Bill & Melinda Gates Foundation

Guided by the belief that every life has equal value, the Bill & Melinda Gates Foundation works to help all people lead healthy, productive lives. In developing countries, it focuses on improving people's health and giving them the chance to lift themselves out of hunger and extreme poverty. In the United States, it seeks to ensure that all people—especially those with the fewest resources—have access to the opportunities they need to succeed in school and life. Based in Seattle, Washington, the foundation is led by CEO Sue Desmond-Hellmann and Co-Chair William H. Gates Sr., under the direction of Bill and Melinda Gates and Warren Buffett. For further information, please contact media@gatesfoundation.org.

Children's Investment Fund Foundation

The Children's Investment Fund Foundation (CIFF) is an independent philanthropic organisation, headquartered in London with offices in Nairobi and New Delhi. We work to transform the lives of poor and vulnerable children in developing countries. We have a child-focused portfolio of investments, targeting challenges that

need urgent attention. Areas of work include children and mothers' health and nutrition, children's education and welfare, and smart ways to slowdown climate change. CIFF-funded programmes place significant emphasis on quality data and evidence. Before making an investment and during implementation, CIFF works with partners to measure and evaluate progress to achieve large scale and sustainable impact. Every child deserves to survive and thrive. Learn more at ciff.org.

PATH

PATH is the leader in global health innovation. An international nonprofit organization, PATH saves lives and improves health, especially among women and children. Accelerating innovation across five platforms—vaccines, drugs, diagnostics, devices, and system and service innovations—PATH harnesses its entrepreneurial insight, scientific and public health expertise, and passion for health equity. By mobilizing partners around the world, PATH takes innovation to scale, working alongside countries primarily in Africa and Asia to tackle their greatest health needs. With these key partners, PATH delivers measurable results that disrupt the cycle of poor health. Learn more at www.path.org.

Pfizer Inc.: Working together for a healthier world®

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more, please visit us at www.pfizer.com.

UK Department for International Development (DFID)

The Department for International Development (DFID) leads the UK's work to end extreme poverty. DFID is ending the need for aid by creating jobs, unlocking the potential of girls and women and helping to save lives when humanitarian emergencies hit.

U.S. Agency for International Development (USAID)

The U.S. Agency for International Development is leading the US government's efforts to end extreme poverty and promote resilient, democratic societies. Support for voluntary family planning programs is a key component of reducing poverty, ending preventable child and maternal deaths, and achieving an AIDS-free generation. USAID is the largest bilateral donor of international family planning assistance and the largest supporter of the development of safe, effective, and acceptable contraceptive technologies designed specifically for provision and use in low-resource settings. For more information about USAID and its programs, please visit www.usaid.gov.

- [i] Family Planning 2020. Available at: http://www.familyplanning2020.org/countries/all-countries. Accessed: November 5, 2014.
- [ii] http://www.medicines.org.uk/emcmobile/search?searchTerm=Sayana+Press&SearchType=All.
- [iii] PATH.org. *Sayana Press Pilot Introduction Project*. Available at: http://sites.path.org/rh/recent-reproductive-health-projects/sayanapress/. Accessed: October 28, 2014.
- [iv] Family Planning 2020. *Progress Report 2013-2014: Executive Summary*. Available at: http://progress.familyplanning2020.org/executive-summary. Accessed: November 4, 2014.
- [v] Family Planning 2020. *Progress Report 2013-2014: Executive Summary*. Available at: http://progress.familyplanning2020.org/executive-summary. Accessed: November 4, 2014.
- [vi] United Nations. *World Contraceptive Patterns 2013*. Available at: www.un.org/en/development/desa/population/publications/pdf/family/worldContraceptivePatternsWallChart2013.pdf
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[vii] The World Bank. *Data: Over 99 percent of maternal deaths occur in developing countries*. May 4, 2012. Available at: http://http://data.worldbank.org/news/over-99-percent-of-maternal-deaths-occur-in-developing-countries. Accessed: October 29, 2014.

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[ix] PATH data on file. , php

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