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FOR IMMEDIATE RELEASE

IPM's New Drug Application for Dapivirine Vaginal Ring to Reduce HIV Risk in Women Accepted for Filing by US Food and Drug Administration

SILVER SPRING, Md. (March 3, 2021)—The nonprofit International Partnership for Microbicides (IPM) announced today that the US Food and Drug Administration (FDA) has accepted for review a New Drug Application (NDA) for the monthly dapivirine vaginal ring, designed to reduce the risk of HIV-1 infection through vaginal sex.

Made of flexible silicone, the investigational product releases an antiretroviral drug (ARV) called dapivirine over the course of one month. Women can insert and replace the ring themselves. IPM designed the ring to offer women a discreet and long-acting HIV prevention choice that they can control themselves.

“Women need more product choices to help protect their sexual and reproductive health, and the monthly dapivirine ring would be the first long-acting prevention method available specifically for women, if approved,” said Dr. Zeda F. Rosenberg, founder and chief executive officer of IPM. “Today’s news is an important step toward enhancing the HIV prevention package and contributing to improved health for women in the US and around the world.”

The FDA filing is based on data from two Phase III trials in Africa, The Ring Study led by IPM and the ASPIRE study conducted by the US National Institutes of Health-funded Microbicide Trials Network, as well as data from two open-label follow-on trials, 11 supporting clinical trials in the US, Europe and Africa and more than 200 other clinical and non-clinical studies. IPM expects a decision from the FDA at the end of 2021.

Women bear a disproportionate burden of the global HIV/AIDS epidemic. In the US, nearly one in every five new infections among adults and adolescents ages 15 and older are among women, primarily through heterosexual sex; of these, over 60% are among Black women. Expanding women’s options so that they can choose the method that best meets their needs is essential to achieving the US government’s objectives to reduce new HIV infections by 90% by 2030.

IPM received the rights to develop dapivirine as a vaginal microbicide from the Janssen Pharmaceutical Companies of Johnson & Johnson, which is also partnering closely with IPM to plan for the ring’s introduction, pending approvals. The license is designed to ensure that women in low-resource settings have affordable access to any dapivirine-based vaginal HIV prevention method.

The dapivirine ring received a [positive opinion](#) from the European Medicines Agency under Article 58 in July 2020 and [prequalification](#) by the World Health Organization (WHO) in November 2020. The dapivirine ring also received a [recommendation](#) from the WHO in January 2021 as an additional HIV prevention option for women at substantial HIV risk as part of combination prevention approaches. IPM is currently seeking regulatory approvals for the ring’s use in countries in sub-Saharan Africa, where women’s need is urgent, including Kenya, Malawi, Rwanda, South Africa, Tanzania, Uganda, Zambia and

Zimbabwe. IPM will also seek to make the ring available in Eswatini and Lesotho through national import license processes. In countries where the dapivirine ring has not been approved, including the US, the ring is an investigational product.

IPM is also developing longer-acting vaginal rings, including one that could offer simultaneous HIV prevention and contraception, to further expand women's sexual and reproductive health choices.

IPM receives generous support from the Danish Ministry of Foreign Affairs, the German Federal Ministry of Education and Research (BMBF) through the KfW Development Bank, Irish Aid, the Ministry of Foreign Affairs of the Netherlands, UK aid from the UK Government's Foreign, Commonwealth & Development Office, the American people through the US President's Emergency Plan for AIDS Relief (PEPFAR) in partnership with the United States Agency for International Development (USAID), and the Bill & Melinda Gates Foundation.

About dapivirine: Dapivirine is a non-nucleoside reverse transcriptase inhibitor that acts by blocking HIV's ability to replicate itself inside a healthy cell. IPM holds an exclusive worldwide license for dapivirine from Janssen Sciences Ireland UC, one of the Janssen Pharmaceutical Companies of Johnson & Johnson.

About IPM: IPM is a nonprofit organization dedicated to developing new HIV prevention tools like the [dapivirine ring](#) and other sexual and reproductive health technologies for women, and making them available in developing countries and low-resource settings. IPM has offices in the United States, South Africa and Belgium. Please visit www.IPMglobal.org.