IPM Receives €10 Million Award from German Government to Accelerate Promising HIV Prevention Technologies for Women

Funding will support IPM product development and regulatory submission processes

SILVER SPRING, Md. (Dec. 8, 2016) — The nonprofit International Partnership for Microbicides (IPM) announced today that it has received a €10 million award over five years from the German Federal Ministry of Education and Research through the KfW Development Bank to advance safe and effective microbicides designed to prevent HIV among women in developing countries most affected by the epidemic.

The competitive award will support the regulatory submission process for IPM products, including its monthly dapivirine vaginal ring, shown in clinical trials this year to safely help prevent HIV. IPM is currently compiling the comprehensive dossier of data on the dapivirine ring required for regulatory review. The ring slowly releases the antiretroviral drug (ARV) dapivirine over the course of one month, and is the first long-acting and self-initiated prevention method to confirm efficacy in two clinical trials.

The new award will also help finance the development of other promising microbicides that would build on IPM's recent progress and potentially advance them along the regulatory pathway to help meet women's need for a range of new prevention options.

"Germany is a leader in promoting innovative solutions to overcoming the most pressing development challenges, and we applaud its investment in women's health and well-being," said Dr. Zeda Rosenberg, Founder and Chief Executive Officer of IPM. "Today's announcement is timely as IPM will soon take the critical next step of seeking regulatory approval for the monthly dapivirine ring, and will strengthen the pipeline of next-generation HIV prevention products that could give women new discreet tools they urgently need."

According to UNAIDS, current prevention methods are not slowing the rate of new infections quickly enough to end the HIV/AIDS epidemic. Women continue to be infected with HIV at alarmingly high rates, especially in sub-Saharan Africa, where young women are at least twice as likely to have HIV as young men.

IPM's dapivirine ring serves as a platform technology for new options that could increase convenience and efficacy. The German government's award will help IPM advance next-generation technologies that are longer-acting and could combine different types of ARVs.

"We have the opportunity to make significant progress for women's health with promising new methods like the dapivirine ring," said Renate Bähr, Executive Director of DSW Germany. "This award highlights the potential for public and

private sectors to unite resources and expertise to help ensure that women are healthy and HIV-free."

Among the new products the funding will support are a three-month version of the dapivirine ring, which is expected to enter initial clinical trials in 2017, and three-monthly vaginal rings now in development that would combine dapivirine with other potent ARVs in IPM's portfolio such as DS003 and darunavir. Products that contain multiple ARVs with different mechanisms of action may offer greater protection against HIV than a single drug alone and could help reduce the chance of acquiring drug-resistant HIV.

"This is welcome news for women everywhere," said Heidemarie Wieczorek-Zeul, who serves on the Boards of Directors for IPM and for Friends of the Global Fund Europe (Friends Europe), where she is also the vice-chair in charge of Germany. "We cannot slow down our efforts to equip women with HIV prevention methods they can and want to use if we are to bring the epidemic to an end. Germany has reinforced its commitment to achieve this vision."

Today's news builds on the German government's history of supporting research and development for women's HIV prevention products. IPM previously received funding from the Ministry for Economic Cooperation and Development to support microbicide acceptability studies, outreach and access planning.

As a product development partnership, IPM holds an exclusive worldwide license for one ARV and five royalty-free licenses for eight other ARVs through landmark collaborations with five major pharmaceutical companies. These licenses help ensure that women in low-resource settings have affordable access to potentially effective microbicides.

IPM's work is also generously supported by the Bill & Melinda Gates Foundation, the Ministry of Foreign Affairs of Denmark, Flanders Department of Foreign Affairs, Irish Aid, the Ministry of Foreign Affairs of the Netherlands through the Netherlands Enterprise Agency, the Norwegian Agency for Development Cooperation (Norad), the United Kingdom Department for International Development (DFID), and the American people through the United States Agency for International Development (USAID) through the US President's Emergency Plan for AIDS Relief (PEPFAR).

See the German Federal Ministry of Education and Research's <u>announcement</u> (German only) and the KfW Development Bank's announcement in <u>German</u> and <u>English</u>.

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About dapivirine: Dapivirine is a non-nucleoside reverse transcriptase inhibitor that blocks 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 DS003: DS003 is a gp120 entry inhibitor that acts early in the HIV life cycle and targets the virus directly. IPM holds a royalty-free license for DS003 from Bristol-Myers Squibb.

About darunavir: Darunavir is a protease inhibitor that blocks HIV's ability to produce viable new virus, and is currently marketed as PREZISTA® for HIV treatment. IPM holds an exclusive royalty-free license for darunavir from Janssen.

About IPM: IPM is a nonprofit organization that developed the monthly dapivirine ring, and is dedicated to developing other new HIV prevention tools and sexual and reproductive health technologies for women, and making them available in developing countries. Our partnerships with public, private and civil society bring scientific ingenuity, political will and financial resources to bear on developing and delivering products designed to have significant public health impact. IPM has offices in South Africa and the United States. Please visit www.IPMglobal.org.

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