Developing and Introducing a Dual Prevention Pill

Oral PrEP & oral contraceptive for HIV and pregnancy prevention

September 2021

Background

A coalition of partners is developing a novel Dual Prevention Pill (DPP) for prevention of pregnancy and HIV acquisition in high-need countries. In East and Southern Africa — where the DPP is initially planned for introduction — 65 percent of new HIV infections are amongst women aged 15 and over, and 16 percent of women of reproductive age have an unmet need for contraception.1 As the “youth bulge” results in millions of young people entering their reproductive years,2 it will impact efforts to end the HIV epidemic and reduce unintended pregnancies. It is critical to ensure all women have access to both contraception and HIV prevention.

The results of the Evidence for Contraceptive Options in HIV Outcomes (ECHO) Trial, released in June 2019, found that HIV incidence rates were alarming among women using widely available forms of contraception who were receiving a comprehensive HIV prevention package.3 The findings underscore the urgent need to optimize access to HIV prevention and contraception for African women.

Contraceptive multipurpose prevention technologies (MPTs) have the potential to overcome adherence and uptake challenges seen with oral pre-exposure prophylaxis (PrEP) and stigma associated with HIV service delivery. A DPP, an MPT comprising oral PrEP and an oral contraceptive, will offer significant advantages. It will be highly effective at preventing both HIV and pregnancy when used daily, feasible to deliver in various settings, with the potential to deliver public health impact by expanding choice and method mix. Adding an MPT to the available method mix could empower users with choices that better fit their needs and lives.

In the near-term, a DPP could increase the uptake of PrEP — decreasing new infections among women in high-burden settings — and reduce the number of unintended pregnancies. A DPP could also lay the groundwork for the development and rollout of other MPTs currently in the research pipeline, such as vaginal rings, injectables, implants and films.

3 ECHO Trial Consortium, HIV incidence among women using intramuscular depot medroxyprogesterone acetate. 
5 UNAIDS 2020 data.
### Key Milestones for Dual Prevention Pill Development

#### Product Development
- A single co-formulated tablet containing Truvada and combined oral contraceptive (COC) active pharmaceutical ingredients (APIs) is under development.
- Conduct bioequivalence study to compare bioavailability of co-formulated tablet to Truvada and COC separately.
- File dossier with stringent regulatory authority (SRA) for regulatory approval.

#### End-User Research
- To shape product development and demand creation strategies, conduct human-centered design research in South Africa and Zimbabwe on perceptions, barriers, and motivators of end users, providers and influencers as they relate to the DPP.
- To inform clinical cross-over acceptability studies, conduct formative research to understand perspectives on the DPP among women, health care providers, community members and key opinion leaders.
- Conduct clinical cross-over acceptability studies with over-encapsulated tablets of two pills in South Africa and Zimbabwe to compare women’s experiences using a DPP to two separate Truvada and COC pills.

#### Market Preparation
- Establish Advisory Board with leading research entities, normative agencies, donors, implementers and advocates working on HIV and SRHR to plan for and coordinate introduction of the DPP in parallel with product development activities.
- Engage with policymakers, regulators, civil society and key opinion leaders in HIV and SRH to generate buy-in, shape introduction plans, understand potential market size and inform regulatory strategies for DPP introduction.
- Develop a comprehensive Go-To-Market Strategy with global and national stakeholders.

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<tr>
<th>2021</th>
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<th>2024</th>
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<tbody>
<tr>
<td>Go-To-Market Strategy developed</td>
<td>Clinical crossover acceptability studies begin</td>
<td>SRA dossier filing expected</td>
<td>US FDA regulatory decision expected</td>
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<tr>
<td>Human-centered design and formative research conducted</td>
<td>Bioequivalence results expected</td>
<td>Clinical crossover acceptability study results available</td>
<td>National Medicines Regulatory Authority regulatory review expected</td>
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<td>Implementation research designed</td>
<td>Implementation research conducted</td>
<td>Targeted introduction for prioritized countries</td>
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<td>Initial cost-effectiveness modeling completed</td>
<td>Country introduction plans developed and costed</td>
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<td>Marketing strategy developed</td>
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* Timelines are subject to modification given funding, government buy-in, development feasibility, and regulatory requirements.

For inquiries, updates and resources on the development of the DPP, please visit prepwatch.org/dpp.