

Advocates Welcome the Launch of Merck’s Phase 3 EXPrESSIVE Program and the Potential of a Monthly Pill for HIV Prevention
A Milestone Toward Expanding HIV Prevention Choices

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HIV prevention advocates from around the world welcome the launch of the EXPrESSIVE program, which will evaluate the safety and efficacy of Merck’s monthly oral pill for PrEP, MK-8527.

[Announced at the International AIDS Society Conference in Kigali](#) on 14 July, the EXPrESSIVE trials represent a bold new program to expand the toolbox for HIV prevention with a monthly option that could fill a critical gap alongside daily pills, a monthly vaginal ring and periodic injections. The undersigned advocates from around the world commend Merck and its research partners for this important investment in innovation, equity, and choice.

The [MK-8527 pill](#) is now entering two major efficacy trials in sites throughout the world. [EXPrESSIVE-10](#) will enroll approximately 4,580 cisgender women and adolescent girls and young women (AGYW) aged 16–30 in Kenya, South Africa, and Uganda. [EXPrESSIVE-11](#) will enroll approximately 4,390 men who have sex with men (MSM), gender non-binary individuals, and transgender individuals in 16 countries in the Americas, Africa, Asia and Europe. [This graphic shows where these trials are taking place.](#)

“This is not just another trial; it’s a signal that the needs of young women and other key groups most affected by HIV really matter,” said Chilufya Kasanda Hampongo, Chair of the Young Women’s HIV Prevention Council (YWHPC). *“A monthly pill will offer a new kind of freedom – something discreet, something manageable, something we can own on our terms.”*

With ongoing challenges to access products for HIV prevention across many settings, and with recent advances such as twice-yearly injectable lenacapavir (LEN), every-other-month injectable cabotegravir (CAB-LA), and the monthly dapivirine vaginal ring (DVR), the EXPrESSIVE trials emerge at a time of both progress and urgency. A monthly PrEP pill could transform the field, expanding the use of HIV prevention, especially to young women, key populations, and those navigating stigma, clinic fatigue, or other barriers to health services.

“Choice is the superpower in HIV prevention. Even with injectable CAB and LEN, we still have gaps, and a monthly pill will add a vital option. We need ongoing research to fill these gaps in prevention; not everyone wants or will be able to access an injection, and daily pills don’t work for many people in need. It’s about options and access,” said Nandisile Sikwana, AVAC’s Regional Stakeholder Engagement Manager based in South Africa and a member of the EXPrESSIVE-10 Global Community Accountability Group (GCAG)

Advocates are also encouraged by the community-centered design of the EXPrESSIVE program, which was shaped by extensive stakeholder engagement from the earliest stages.

The EXPrESSIVE trials build on lessons from earlier programs, including [IMPOWER-022](#), the [PURPOSE](#) program and the MATRIX consortium, where community engagement helped maintain trust, clarify expectations, and ensure dignity in the face of clinical holds and

programmatic shifts. The EXPrESSIVE program's foundation in Good Participatory Practice ([GPP](#)) helps ensure that the voices of those most affected by HIV are included in every step, from design to access planning.

“As the Global Community Advisory Group for EXPrESSIVE-10, we are committed to ensuring that this trial is both scientifically sound and deeply rooted in the actual realities of the African communities it aims to serve. As a GCAG, we will strive to uphold the Good Participatory Practices from the initial design to results dissemination, as well as amplify community voices, and advocate for timely, equitable access if MK-8527 is shown to be effective. Our responsibility is to ensure that research protects communities, and that innovation is matched with real-world impact.” Simon Odiwuor Ondiek, Former Chair, EXPrESSIVE-10 GCAG

Advocates acknowledge the complexity of conducting HIV prevention research at a time when policies and funding are unpredictable both globally and in countries where the EXPrESSIVE trials will take place. As PEPFAR funding faces uncertainty and previously active HIV prevention research programs – such as [MATRIX](#) and [CATALYST](#)– have been halted mid-way, the stakes are high for sustaining new and ongoing research and maintaining trust with communities. Addressing the need for access to existing and newly proven HIV prevention for communities where trials take place is of particular importance. The EXPrESSIVE trials must navigate these challenges with clear communication, community input, and ethical safeguards.

“Access to existing and new products is not optional; it's a fundamental right. HIV prevention will only achieve impact if everyone who needs it can access it. Populations who contribute their time and their bodies to research -- gay, bisexual, MSM, trans, non-binary, AGYW – must benefit first. Access cannot wait until a trial ends; it must be built into every step, from research to delivery,” said Rena Janamnuysook, a leading HIV prevention advocate based at the Institute of HIV Research and Innovation (IHRI) in Bangkok, Thailand, where EXPrESSIVE-11 will take place.

Finally, Merck and the trial teams' commitment to community and civil society engagement thus far in the development of the EXPrESSIVE program deserves enthusiastic support. Advocates and civil society have and will continue to hold them to their commitment to ensure the potential monthly PrEP pill, if proven effective, is accessible with speed, scale and equity.

Community Expectations and Calls to Action for the EXPrESSIVE Program

- **Honor Good Participatory Practice (GPP):** GPP is not only about engaging communities in trial design, but it is about ensuring ongoing durable partnerships throughout the research, development and delivery journey.
- **Deliver more than a trial result:** The EXPrESSIVE trials will deliver important efficacy results, hopefully in the most clear, efficient way possible. Advocates will look to Merck for speedy and transparent next steps following the trials' conclusion, whether that be toward introduction of the monthly pill, additional research, or both.
- **Make civil society partners in access planning:** Advocates are encouraged by Merck's clear plans for post-trial access for trial participants, but this alone is not enough. Global access planning should happen in parallel with efficacy trials. Merck should commit to

ongoing, formal engagement with civil society partners as it makes global access plans through the course of the efficacy program; key issues include licensing, generic manufacturing, procurement, regulatory timelines, and country planning. Civil society can help navigate and push for change around obstacles and challenges that have slowed introduction of other new prevention interventions.

HIV prevention advocates can be both watchdogs and champions for these trials, and others still to come. Together, in partnership with Merck and other key stakeholders, we can ensure research and development speed the expansion of HIV prevention to everyone who needs it.

Signatories:

- African Women Prevention Community Accountability Board (AWPCAB)
- Advocacy for Prevention of HIV and AIDS (APHA)
- Ascend Futures Foundation
- AVAC
- Civil Society Caucus of the Coalition to Accelerate Access to Long-Acting PrEP
- Coalition for Health Promotion and Social Development (HEPS Uganda)
- European AIDS Treatment Group
- EXPrESSIVE-10 GCAG
- Global Black Gay Men Connect (GBGMC)
- Greater Women Initiative for Health and Right Nigeria
- Institute of HIV Research and Innovation
- International Community of Women living with HIV Eastern Africa (ICWEA)
- Pangaea Zimbabwe
- Root to Rise
- Treatment Action Group (TAG)
- Young Women's HIV Prevention Council (YWHPC)
- Dawn Averitt, Individual Advocate, USA
- Brian Minalga, Individual Advocate, USA
- Julie Patterson, individual Advocate, USA
- Veriano Terto Jr., Individual Advocate, Brazil