NEWS RELEASE

Merck Announces Initial Access Plans for Alimatravir, an Investigational Once-Monthly Oral HIV Pre-Exposure Prophylaxis in Phase 3 Development

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Multi-faceted strategy aims to enable rapid, broad and sustainable access to alimatravir (MK-8527), if approved, in low- and middle-income countries

Voluntary licensing agreements cover 129 countries in regions which account for the substantial majority of new HIV diagnoses globally

As Phase 3 trials continue, Merck is committed to advancing access plans, working in close collaboration with the HIV community and global health stakeholders

RAHWAY, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside of the United States and Canada, today announced early components of a **multi-faceted strategy** to provide rapid, broad and sustainable access in low- and middle-income countries (LMICs) to alimatravir (MK-8527), an investigational, novel, once-monthly oral pill as pre-exposure prophylaxis (PrEP) for the prevention of HIV-1, following regulatory approval. Initial access plans as part of Merck's broader strategy include establishing early generic licensing covering 129 LMICs; supporting targeted, regional manufacturing capabilities in Africa and Latin America; and investing early in product manufacturing to enable timely access and availability in regions of high unmet need. The first steps of this strategy are being announced in the lead up to the 26th International AIDS Conference in Rio de Janeiro, Brazil.

Key Highlights:

- Planning early for rapid, broad and sustainable access in LMICs: By initiating a multi-faceted access strategy while Phase 3 trials are ongoing and before enrollment is complete, Merck aims to make alimatravir available in LMICs as broadly and as quickly as possible, if approved.
- Community-guided access strategy: Merck's access plans have been shaped by years of engagement with the HIV community, advocates and global health stakeholders, and that collaboration will continue as Phase 3 trials progress.
- A potential new oral PrEP option: If approved, alimatravir would provide an important new option, with the potential to offer one month of protection from HIV-1 in one pill, predicted to be protective starting within one hour after dosing.

Globally, 1.2 million people acquired HIV in 2025, approximately 3,300 each day. Today, multiple HIV prevention options are available, including daily oral PrEP, long-acting injectable PrEP, and other evidence-based prevention tools. Yet, according to the 2024 UNAIDS report, only 3.5 million people were using oral PrEP in 2023, demonstrating the urgent need to expand access and uptake to reach the global goal of 20 million people receiving PrEP by 2030. New access programs should enable rapid, broad and sustainable scale-up, and focus on the persistent barriers that may be limiting PrEP use, including stigma and affordability.

"Scientific innovation only has impact when it reaches those who need it most," said Robert M. Davis, chairman and chief executive officer, Merck. "Merck has a deep legacy in HIV and a longstanding commitment to public health. Recognizing the urgent, unmet needs in HIV prevention, we are acting early to enable rapid, broad and sustainable access to alimatravir, an investigational once-monthly oral PrEP option, in low- and middle-income countries. These important first steps reflect years of engagement with advocates and global health stakeholders. As Phase 3 trials progress, we remain committed to advancing our efforts in partnership with the HIV community to help maximize the public health impact of alimatravir, if approved."

Establishing early voluntary licensing agreements

Merck has signed seven non-exclusive **voluntary licensing agreements*** with generic manufacturers, including three in sub-Saharan Africa (Aspen Pharmacare Holdings, Ltd (Aspen), Quality Chemical Industries Limited (Qcil) and UCL Kenya) and four in India (Aurobindo, Cipla, Emcure and Viatris). The royalty-free agreements with these companies cover both the public and private sectors and will enable supply of generic alimatravir in 129 LMICs that account for a substantial majority of new HIV diagnoses globally.

Entering into licensing agreements before Phase 3 trial enrollment is complete represents a first in HIV prevention. This early action should help stakeholders across the HIV response begin planning for ambitious scale-up. It will also facilitate the acceleration of developmental and regulatory activities by the licensed generic manufacturers to help them bring generic alimatravir that meets internationally recognized standards to market in licensed territories, if approved.

“Merck's early and proactive efforts to enable quick access to its new PrEP option, if approved, are important to help protect the communities most affected by HIV,” said Mark Suzman, chief executive officer of the Gates Foundation, which aims to end or significantly reduce preventable infectious diseases, including HIV, in the next two decades. “We look forward to continuing to work with Merck and other partners who will help advance these plans and expand access to HIV prevention options.”

Supporting targeted, regional manufacturing

Sustainable access for HIV prevention requires reliable supply chains, strong local partnerships and country ownership and prioritization. The voluntary licensing strategy for alimatravir is designed to help support sustainable access across Africa and other high-burden geographies by enabling regional manufacturing, strengthening supply resilience and supporting long-term availability following approval.

Africa has the highest burden of HIV worldwide. With this announcement, for the first time in HIV, generic manufacturers in sub-Saharan Africa have been included in the initial voluntary licenses granted, alongside generic manufacturers in India, enabling planning for introduction and scale-up by local manufacturers.

“People across Africa need more options to prevent HIV. A once-monthly pill could provide a different choice for people in how to protect themselves, subject to successful trials and regulatory approval,” said Jean Kaseya, Director General of the Africa Centres for Disease Control and Prevention. “We welcome this decision to engage African manufacturers early. Africa must continue to expand its role across the health innovation value chain, from supporting research ecosystems and clinical trial capacity to manufacturing and access. This is how we strengthen health sovereignty and bring new HIV prevention options closer to our people.”

HIV incidence remains a pressing public health challenge in Latin America, and specifically in Brazil, where approximately 55,000 people acquired HIV in 2024. In recognition of this significant unmet need, Merck is in active discussions with organizations, including Fiocruz, with a goal to enable rapid availability and broad supply of alimatravir in the region.

Investing early in product manufacturing

To reduce the time between potential regulatory approval of alimatravir and its availability in LMICs, Merck is investing early in its product manufacturing capacity as Phase 3 trials continue. These efforts are intended to help ensure that sufficient product supply is made available, if approved, in areas of high unmet need following the anticipated U.S. approval to enable early program implementation and ambitious scale-up.

Merck expects to provide initial supply and continue supplying product as needed while licensed generic manufacturers complete development, obtain the necessary regulatory approvals and prepare to provide supply in

the licensed territories. The goal is to help avoid delays in access by providing an initial supply pathway until generic manufacturing capacity is established and brought online.

These actions represent important early steps to help support the future availability and supply of alimatravir in countries with a high burden of HIV, subject to applicable regulatory approvals and requirements. Merck is committed to continuing to advance its access plans, working in close collaboration with communities and global health stakeholders, as Phase 3 trials continue.

About alimatravir (MK-8527)

Alimatravir (MK-8527) is being evaluated as a potential once-monthly oral prevention option for HIV-1. Alimatravir inhibits reverse transcriptase through multiple mechanisms, including:

- inhibition of reverse transcriptase translocation, resulting in immediate chain termination, and
- induction of structural changes in the viral DNA (delayed chain termination).

Alimatravir is currently being evaluated in two ongoing Phase 3 clinical trials. With financial support from the Gates Foundation, the Phase 3 EXPrESSIVE-10 trial (MK-8527-010, **NCT07071623**) is evaluating the safety and efficacy of alimatravir in adolescent girls and young women in Kenya, South Africa and Uganda. The Phase 3 EXPrESSIVE-11 trial (MK-8527-011, **NCT07044297**) is evaluating the safety and efficacy of alimatravir among people with greater likelihood of HIV-1 exposure in 16 countries. Both trials are now enrolling.

The initiation of the Phase 3 clinical trial program was supported by results of a double-blind, multicenter, Phase 2 trial (MK-8527-007, **NCT06045507**) examining the safety and pharmacokinetics of alimatravir. The study enrolled 350 participants, 18–65 years of age, with low likelihood of HIV-1 exposure, who were randomized 2:2:2:1 to receive alimatravir (3, 6 or 12 mg) or placebo once monthly for six months. In the trial, the rates of adverse events were similar among those in the alimatravir arms and those in the placebo arm, and no clinically meaningful changes were seen in laboratory tests, including total lymphocyte and CD4 T-cell counts. The pharmacokinetics of alimatravir and alimatravir-triphosphate, the active form of alimatravir, support the continued development of alimatravir as an oral, once-monthly option for PrEP.

Merck is committed to ensuring that the people who are participating in the EXPrESSIVE Phase 3 trials have access to alimatravir after the trials conclude, pending regulatory approval.

Merck’s Commitment to HIV

For more than 40 years, Merck has been committed to research and discovery in HIV leading to scientific breakthroughs that have helped change HIV treatment. Our work has helped pioneer the development of new options across multiple drug classes to help those impacted by HIV. Today, we are developing a series of antiviral

options for both HIV treatment and prevention. We're inspired by the lived experiences of the HIV community as we advance research with real life in mind. Our work focuses on potentially transformative innovations, collaborations with others in the global HIV community and access initiatives to help end the HIV epidemic.

For an overview of Merck's HIV treatment and prevention clinical development program, please click **here**.

About Merck

At Merck, known as MSD outside of the United States and Canada, we are unified around our purpose: We use the power of leading-edge science to save and improve lives around the world. For more than 130 years, we have brought hope to humanity through the development of important medicines and vaccines. We aspire to be the premier research-intensive biopharmaceutical company in the world – and today, we are at the forefront of research to deliver innovative health solutions that advance the prevention and treatment of diseases in people and animals. We foster a diverse and inclusive global workforce and operate responsibly every day to enable a safe, sustainable and healthy future for all people and communities. For more information, visit **www.merck.com** and connect with us on **X (formerly Twitter)**, **Facebook**, **Instagram**, **YouTube** and **LinkedIn**.

Forward-Looking Statement of Merck & Co., Inc., Rahway, N.J., USA

This news release of Merck & Co., Inc., Rahway, N.J., USA (the "company") includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company's management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline candidates that the candidates will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's Annual Report on Form 10-K for

the year ended December 31, 2025 and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (**www.sec.gov**).

*Template before negotiations and execution with the generic manufacturers.

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