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PrEP in Black America (PIBA) Coalition Celebrates FDA Approval of Twice-Yearly Lenacapavir for HIV Prevention

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Groundbreaking Long-Acting PrEP Option Must Be Matched by Equitable Access and Community Trust

The PrEP in Black America (PIBA) Coalition applauds today's historic FDA approval of twiceyearly lenacapavir for pre-exposure prophylaxis (PrEP) - a scientific breakthrough with the potential to transform HIV prevention for Black communities across the U.S.

Lenacapavir, developed by Gilead Sciences, is the first and only long-acting injectable PrEP option requiring just two doses per year. Its approval is grounded in robust evidence from the PURPOSE 1 and PURPOSE 2 clinical trials, which demonstrated exceptional efficacy (100%) in preventing HIV acquisition, particularly among populations most affected by the epidemic: Black adolescent girls and young women; Black gay, bisexual men and other men who have sex with men; and Black transgender individuals.

"This is a moment of scientific achievement. However, we caution that science alone is not enough to prevent new diagnoses in Black communities," said John Meade Jr., a founding member of PIBA. "We must now ensure that lenacapavir is accessible, affordable, and a trusted HIV prevention option among the very communities who need it most."

PIBA emphasizes that despite the promise of lenacapavir, there are persistent social-structural barriers to equitable access. Stigma, medical mistrust and distrust, high medication costs, insurance gaps, and other structural inequalities continue to limit access to PrEP for Black communities. As such, PIBA strongly urges a comprehensive rollout strategy that prioritizes community voices, addresses cost barriers, and invests in culturally responsive education and outreach.

"We are calling on Gilead Sciences to partner directly with community led, centered and focused organizations like PrEP in Black America to ensure equitable, affordable, and widespread access to lenacapavir," said Danielle M Campbell. "This includes transparent pricing, support for safety net providers, and reinvestment in Black-led HIV prevention efforts."

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The coalition underscores that trust-building is just as critical as delivery logistics. New technologies do not automatically translate into uptake, especially in Black communities where anti-Black medical racism and neglect have created deep-seated skepticism toward the healthcare system. Ongoing engagement, education, and partnership with trusted messengers are essential to ensure that lenacapavir fulfills its potential.

"This is not just about innovation—it's about implementation with intention," said Leisha McKinley-Beach, Founding Member of PIBA and Executive Director of Black Public Health Academy. "We cannot repeat past mistakes where Black communities were last to benefit from medical advances. This time, we must lead."

With the current unprecedented threats to HIV prevention and research funding, investing in community-led strategies is more critical than ever to make lenacapavir a success for Black communities. The PrEP in Black America Coalition stands ready to collaborate with public health leaders, providers, policymakers, and industry partners to ensure that twice-yearly lenacapavir becomes a tool of equity—not exclusion.

About PIBA

PrEP in Black America (PIBA) is an intersectionality informed social justice movement comprised of Black advocates, activists, researchers, policy-makers, and people living with and affected by HIV from communities disproportionately affected by HIV in the US. We are organized to: 1) Energize the Black public health workforce to lead the HIV prevention response; 2) Educate Black people in the science and effectiveness of PrEP; and 3) Support a federallyfunded National PrEP program. Follow PIBA on Instagram @prepinblackamerica

About BHPA

Black Public Health Academy seeks to empower Black health leaders and foster positive change. Join us in shaping a healthier tomorrow. For inquiries contact: Leisha@blackpublichealthacademy.com. Follow BHPA on Instagram @blackpublichealthacademy

About BLKHLTH

BLKHLTH is a Black-led non-profit focused on advancing the wellbeing of Black communities across the country through equity-centered education, advocacy, research, and programs. We strive to create a world where racism and other intersecting forms of oppression no longer impact Black health through digital and community-based narrative change, capacity building, and preventive health programming. Follow BLKHLTH on Instagram @blkhlth