SPEAKING NOTES BY THE MINISTER OF HEALTH, DR AARON MOTSOALEDI, DURING LENACAPAVIR ACCESS AND SUSTAINABILITY IN SA ROUNDTABLE

DATE: 14 and 15 OCTOBER 2025

TIME- 09H00 – 17H00

PROTEA HOTEL OR TAMBO, JOHANNESBURG

"Lenacapavir, Access, Affordability and Sustainability in HIV Prevention"

South African National AIDS Council CEO

Civil Society Forum Chairperson

Global Fund representatives

WHO representatives

UNAIDS, UNFPA., UNICEF representatives

Gates Foundation

Developmental Partners

Private Sector, Partners from the pharmaceutical industry,

Research institutions

Esteemed donors

Department of Health teams and entire dedicated health workers.

I'm honoured to speak today at this national roundtable on Lenacapavir Access and Sustainability. Today, we come together at a pivotal moment in South Africa's HIV response. We are here to launch a new chapter in HIV prevention – one that introduces a groundbreaking long-acting preventive therapy and reinforces our broader strategy to finally end the HIV epidemic in our country.

This gathering is about partnership and coordination. The fight against HIV has always demanded collective effort, and the presence of a wide range of stakeholders like in this room. This demonstrates our shared commitment. Our focus is the introduction of Lenacapavir, a novel long-acting HIV prevention option. We will discuss how to ensure its accessibility, affordability, and sustainability for all who need it. I am confident that with the unity of purpose we have here, we can make this innovation a success and bring hope to hundreds of thousands of people at risk.

Progress and Challenges in HIV Prevention

South Africa has made remarkable strides in combating HIV. We continue to carry the highest burden of HIV globally, with an estimated 8 million People Living with HIV (PLHIV) in our country, yet we have not stood idle: our treatment program is the largest in the world, and our prevention efforts have expanded dramatically. Our nation has become a world leader in rolling out pre-exposure prophylaxis (PrEP).

To date, over 2 million people have been initiated on oral PrEP across 98% of public primary healthcare facilities – an extraordinary achievement that covers almost the entire country. So we have given millions of South Africans a tool to protect themselves from HIV. We have also implemented comprehensive education, HIV testing, condom distribution, male medical circumcision and other behavioural interventions as part of a combination prevention approach. All these efforts are paying off: new HIV infections have been steadily declining from their peak in the early 2000s.

However, despite our progress, HIV is still a challenge. Despite all our advances, the truth remains: prevention still eludes us. Approximately 149,000 South Africans acquired HIV in 2023 alone, a number that is far too high. Adolescent Girls and Young Women continue to bear a disproportionate burden of new infections, and the other key populations.

The reality is for many individuals at risk of HIV, our current prevention options are not yielding the results required. For example, Condoms are still not being used as widely as we would like. Whilst, oral PrEP is effective, retention and adherence have been suboptimal, especially among the people who could benefit the most. Many users find it difficult to take a pill every single day due to stigma, pill fatigue, or life circumstances. When people stop taking PrEP regularly, its protective benefit drops, and opportunities to prevent infections are lost.

To reach our goal of ending AIDS as a public health threat and achieve the UNAIDS target of 95% of people at risk having access to prevention options, we must continually improve and expand our prevention toolkit. We need prevention methods that fit into people's lives, that address the gaps left by existing tools. This is where Lenacapavir comes in as a timely and much-needed innovation to help us overcome the persistent challenges in our HIV response. Lenacapavir expands the choices within our combination prevention strategy. It widens the scope of choices for citizens, an empowering option and ensuring that no one is left behind simply because the existing tools did not fit their lives.

Introducing Lenacapavir: A Breakthrough in HIV Prevention

Lenacapavir is a new long-acting antiretroviral drug, specifically, an HIV-1 capsid inhibitor, that is used for HIV prevention (as PrEP). What makes Lenacapavir groundbreaking is its dosing schedule and efficacy. Lenacapavir is delivered via injection only twice a year, offering six months of continuous protection per dose. just two injections a year could protect an individual from HIV, a contrast to the daily pills or the bi-monthly injections we have used so far. Lenacapavir represents a true breakthrough in prevention science and service delivery,

This six-monthly dosing schedule has the potential to overcome many of the barriers we've seen with daily oral PrEP: it offers greater discretion, convenience, and likely much better adherence for users, especially for people who struggle with taking a pill every day or making frequent clinic visits.

Lenacapavir is highly effective. Clinical trials (the PURPOSE 1 and 2 studies) demonstrated outstanding efficacy of Lenacapavir in preventing HIV. In one trial among women, it showed 100% efficacy within the study period – and in another trial amongst men who have sex with men and transgender women, efficacy was around 96%. On the strength of this evidence, the World Health Organization (WHO) this year issued new guidelines recommending Lenacapavir as an additional HIV prevention choice. WHO now strongly recommends offering long-acting injectable Lenacapavir to people at risk of HIV, as part of combination prevention approaches. This global guidance gives us confidence that we are on the right track by introducing Lenacapavir in South Africa.

For individuals at risk, be it a young woman, a pregnant woman, a sex worker, or a seronegative partner in a discordant couple, Lenacapavir can be life-changing. With only two clinic visits per year for injections, someone can maintain protection without the daily reminder or burden of pills. This discretion and ease of use will particularly benefit those who face stigma or privacy concerns, and those who simply find it hard to adhere to daily medication.

Lenacapavir will be empowering for populations that have been underserved by existing prevention options: adolescent girls and young women, men who have sex with men, transgender individuals, sex workers, and pregnant and breastfeeding women, amongst others. Our goal is to integrate Lenacapavir into our prevention programs so

that these groups, and indeed anyone at substantial risk of HIV, have the choice of a long-acting injectable PrEP if it suits their needs.

As excited as we are about Lenacapavir, we are also mindful that the initial supply will be limited and must be managed strategically. South Africa has secured an initial allocation of Lenacapavir through a generous Global Fund grant, but this will only cover a fraction of the total need in the first couple of years. Specifically, the Global Fund's catalytic investment of about US $29 million will provide approximately 456,000 Lenacapavir initiations over two years, translating into 912 000 doses. This is a tremendous start, about half a million people will be able to begin using Lenacapavir thanks to this support, but demand will likely outstrip supply at first. We therefore must prioritize and target our efforts to ensure the greatest impact and equity from day one.

Our approach is firmly data-driven. Modelling analysis by our local experts , Health Economics and Epidemiology (HE2RO) and others) indicates that if we focus the initial rollout on those populations at highest risk of HIV, we can achieve the most infections averted. In particular, the analysis suggests that prioritizing pregnant and breastfeeding women (PBFW), along with adolescent girls and young key populations (AGYW), female sex workers (FSW), and men who have sex with men (MSM), would yield the highest impact in terms of new infections prevented. Geographic targeting is another crucial piece of our strategy.

HIV incidence is not uniform across the country; some districts carry a much heavier burden of new infections. To maximize both impact and fairness, we are adopting a blended geographic and risk-based rollout. In practice, this means we will concentrate on Lenacapavir introduction in selected high-burden districts – specifically, those aligned with the National Department of Health's focus provinces and districts for HIV prevention. We plan to roll out Lenacapavir initially in about 23 high-incidence districts across six provinces, targeting around 360 high-performing public clinics within these areas for Phase 1 implementation.

We're preparing clinics at the selected sites. Early integration of Lenacapavir delivery through the primary health care clinics extending to community-based sites linked to those clinics, which caters for all the at risk population.

Training healthcare providers will be undertaken so that nurses and counsellors are prepared to discuss this new option with clients, manage the administration of the injection, and handle any follow-up needs. Data systems will also be updated to incorporate Lenacapavir indicators into our national monitoring systems.

Finally, as we expand access, we will pay attention to young people, rural communities and marginalized groups. Community-led organizations will be vital in demand creation, helping to raise awareness that Lenacapavir exists and is available, addressing questions or fears, and linking people to services. We will also look at

how to support those who start on Lenacapavir to stay on it for as long as they remain at risk, through reminder systems, community follow-up, and other retention strategies (some of which we'll hear about during this roundtable). By prioritizing smartly and supporting users, we can ensure that this innovation truly reaches those who need it most and achieves the public health impact we know it can.

Introducing Lenacapavir is not just a biomedical or programmatic effort; it also demands financial foresight and a sustainability plan.

We are fortunate that the Global Fund has stepped up with a substantial initial donation of Lenacapavir medication and implementation funding. As mentioned, this US$29 million grant (October 2025 to March 2027) will jump-start our program. It covers the procurement of roughly 973,000 vials, enough to provide protection to nearly half a million persons in Phase 1. For this, we express our deep gratitude to the Global Fund and its Country Coordinating Mechanism here in South Africa. This donation is a game-changer. It means we can start to roll out as early as March to April in 2026.

However, donations alone cannot carry us indefinitely. Sustainability is the name of the game. We must plan now for how Lenacapavir and other long-acting PrEP will be financed and supplied in the long run, once the initial donated stock is utilized. The Ministry of Health is fully committed to integrating Lenacapavir into our domestic financing mechanisms. We are already working to include Lenacapavir in the Essential Medicines List (EML). Inclusion in the EML and positive

guidance from our National Essential Medicines Committee will pave the way for provinces to procure Lenacapavir using the normal budgets via the HIV Conditional Grant. Our vision is that after the first 2 years Lenacapavir will transition to routine funding as we did for oral PrEP. We will be earmarking resources in our Medium-Term Expenditure Framework to ensure that once generic versions become available or prices drop, we can scale up access without interruption.

New Developments

During UNGA, a very successful, innovative and life-changing program was announced by Clinton Health Access Initiative (CHAI), UNITAID, WITS RHI, and Dr Reddy's Laboratories whereby Gilead, the original manufacturer of Lenacapavir, offered voluntary licensing to 6 pharmaceutical companies.

Dr Reddy's laboratories is one off those that have been offered these voluntary licences. Partnering with CHAI, UNITAID and WITS-RHI, Dr Reddy's will use this licence to manufacture a Lenacapavir generic which is extremely affordable. It will cost 40 US dollars per person per year. If you do not understand what this means, let me remind you that Lenacapavir costs 28 000 USD, this is close to half a million rands. As you can see, no country in Africa and most of the global South can afford it.

Another powerful partnership was announced. The Bill and Melinda Gates Foundation has partnered with HETERO (One of the companies that got voluntary licence) also to produce a generic for 40 USD.

As you can see, this agreement means the price of Lenacapavir has been reduced 700 times. This is phenomenal. This is what revolutions are made of.
What is now left is for us, as South Africa, a major consumer of anti-retrovirals, to get our own voluntary licence. One of our pharmaceutical companies here in our country must be offered a voluntary licence for local manufacturing.

Beyond drug cost, sustainability also means securing ongoing support for the programmatic aspects, the training, the community outreach, the monitoring systems.
Government and Public Sector: The National Department of Health, together with provincial health departments, is leading the rollout, ensuring policy alignment, guideline development, training, and integration into public clinics. Our regulators (SAHPRA) are expediting reviews to make sure Lenacapavir is approved with all due standards of quality and safety. Other government agencies, like the Department of Science and Innovation, are helping pave the way for local manufacturing and research. Strong support from our political leadership, from Cabinet to Parliament, fortifies this effort with the needed mandate and oversight.

Civil Society and Communities: Perhaps most importantly, I want to emphasize the role of community engagement. We know from experience that the HIV response succeeds when communities are at the center. So civil society organizations, community health workers, peer educators, youth leaders, and activists all have a seat at the table

in designing and rolling out Lenacapavir services. The WHO guidelines themselves stress that the full participation of communities in designing, implementing, and monitoring programs will enhance the success of Lenacapavir introduction. We're listening. The National AIDS Council (SANAC) and its Civil Society Forum have been involved in planning from the start; indeed, SANAC is co-hosting this roundtable. Community representatives will be crucial in demand creation, helping to educate people about Lenacapavir, dispel myths, and generate trust in the intervention.

We have learned from the rollout of oral PrEP that word of mouth and peer support can drive uptake. I salute the advocates who have already been spreading the message about long-acting PrEP and pushing us in government to move faster on access. Your voices have been heard, and your continued vigilance will keep us accountable to the people we serve.

Partnerships: I want to acknowledge the invaluable contributions of all our partners. The Gates Foundation, ELMA Philanthropies, CIFF, UNITAID, and other donors have been closely involved in planning and are providing technical and financial assistance to complement the Global Fund's investment. We call on these partners (and others who are committed to HIV prevention) to continue and increase their support as we move from pilot phase to scale-up. Private sector partners, too, have a role, whether through corporate social responsibility initiatives or public-private partnerships that expand delivery channels for PrEP. By pooling resources and expertise, we

can ensure that Lenacapavir introduction is not a one-off project but rather a sustainable program that will run for the long term, ultimately becoming self-sustaining under our national health system.

Everyone in this room has a role. Our slogan for this phase could well be “Shared responsibility for a shared solution.” If we each commit to doing our part – government ensuring leadership and resources, donors providing support and flexibility, communities driving demand and keeping us grounded in people’s realities, and the private sector contributing innovation and capacity – we will collectively ensure that Lenacapavir lives up to its promise. Together, we can create a model of public-private-community partnership that not only gets this drug to people but also builds a stronger foundation for future prevention efforts (including other long-acting preventatives or even vaccines, should they emerge).

As we stand on the cusp of introducing Lenacapavir, I feel a sense of historic opportunity. This is more than just the rollout of a new medication; it is the launch of a new era in our fight against HIV. An era where we can finally provide a prevention method that truly fits into people’s lives, where the burden of adherence is lightened, and where our toolbox is more powerful than ever.

We often say that ending the HIV epidemic will require innovation and commitment. Here we have the innovation, a six-monthly injection with the potential to dramatically reduce new infections. And I see the commitment all around me, from each of you present here today. Now

we must translate this into action and impact on the ground. The communities we serve are looking to us with hope: the young woman in KwaZulu-Natal who wants to stay HIV-free through university; the serodiscordant couple hoping to conceive a child safely; the pregnant woman who wants to give birth to a child free from HIV, the sex worker who needs protection that clients cannot negotiate; the health worker who is tired of seeing new infections that could have been prevented. We owe it to them to make Lenacapavir work, to roll it out fast, efficiently, and fairly.

If we do this right, the payoff is immense. **Mathematical modelling shows that if 2 to 4 million people use Lenacapavir over 12 to 24 months, South Africa could reduce new HIV infections to below 0.1% by 2032, achieving epidemic control ten years earlier than the expected 2042. That is the prize we are working towards, a South Africa where HIV is no longer a public health threat.

To reach that goal, Let's move with urgency and unity. In the coming days and weeks, decisions will be made, about funding allocations, about district roll-out plans, and about licensing terms. Let those decisions be bold and in the interest of saving lives. Health workers will need training and support; let’s give it to them, so they feel confident offering this new product. Communities will need information; let’s share it widely, honestly, and with culturally appropriate messaging. If there are obstacles, let us solve them through collaboration and ingenuity, not let them slow us down.

We have an opportunity to create a success story that the world can look to, just as we did with our HIV treatment program.
The journey to end HIV is long, but today we have one more tool and a renewed resolve to walk that journey together. Let's make history, together.

Announcement

Ladies and gentlemen, I have an announcement to make. We were in agony, the beginning of this year when PEPFAR pulled out of our shores. We started pointing fingers at each other. We nearly became each other's enemies. This should not be. PEPFAR pulled out of the funding that was coming through USAID because USAID has been totally closed down, even in the United States of America. Now, what we were left with was funding that was coming through the CDC.

Unfortunately, it also expired at the end of September. Some three months back, we had a visit of American delegation led by Charge'de Affairs, who told us that Washington is changing its approach to PEPFAR. The new approach is that countries will be taken through a transitional period before PEPFAR completely pulls out. There will be three categories, some countries will go through a transition of one year, others three years and the last group five before PEPPFAR completely pulls out. That plan is still being hatched and it is not ready.

My announcement is: We received a letter from Washington that, in the meantime, we will receive R2,008 billion to carry us until the end of March. We ought to be happy about this because it could have been worse.

Thank you