1. Following the results from the PURPOSE 1 and PURPOSE 2 trials, Gilead's press release stated it will be applying for regulatory approval for lenacapavir as an every-six-month injection for HIV PrEP. Where will Gilead be applying for regulatory approval and what is the possible timeline for approval and subsequent production that is being looked at?

- *Gilead will begin a series of global regulatory filings by the end of 2024. In discussions with the FDA, we expect the initial filing for LEN for PrEP to include the results from both the PURPOSE 1 and PURPOSE 2 trials to ensure LEN for PrEP reaches multiple populations and communities most in need of additional HIV prevention options.*

- *As part of our global access strategy, Gilead is prioritizing speed to enable the most efficient path for the regulatory approval of long-acting PrEP in countries that account for most of the global disease burden. We are exploring frameworks intended to facilitate faster access in target populations and countries such as the EMA's EU Medicines for All (EUM4All), and WHO's collaborative review and prequalification procedures. We believe these frameworks could enable Gilead to secure approvals in key high-incidence, resource-limited countries as quickly as possible in relation to an EU approval.*

- *Updates on regulatory filings for LEN for PrEP will be shared as discussions with regulatory bodies progress.*

2. Gilead announced its agreement with 6 generic companies for the production of generic lenacapavir for every six-month injection last week, based on this are there any potential timelines for when access to the generics for lenacapavir might become available?

- *LEN for PrEP remains an investigational drug until approved by regulatory authorities. The availability of generic versions of the medication that will be developed under our recent licensing agreements will depend on how long it takes our partners to develop the generic medicines and how long it takes to secure regulatory approval in selected countries.*

3. Gilead has committed to selling lenacapavir at a "not for profit" price, is there any estimate yet on what the amount that is being referred to here? If not, when might we expect a price to be announced?

- *While Gilead prepares for global regulatory filings, it is too early to disclose the price of lenacapavir for HIV prevention. Our pledge is to price our medicines to reflect the value they deliver to people, patients, healthcare systems and society. For Gilead-branded lenacapavir, we do plan to price it at no profit to Gilead in 18 select high-incidence, resource-limited countries until generic manufacturers are able to fully support demand.*

4. Advocates and several international organizations have criticized Gilead's decision to exclude several countries, like Brazil and Peru from the generic access to lenacapavir in the licensing agreement, firstly is this an accurate statement? And how does Gilead respond?

- *Gilead's access policy includes tailored approaches to enable rapid and broad access. Gilead objectively considered the countries where a partnership with voluntary licensees would provide the most benefit. Gilead's voluntary license primarily covers countries based on economic need and HIV burden, which are primarily low- and lower-middle income countries. The voluntary license also covers certain middle-income countries with limited access to healthcare.*

- *We recognize that some middle-income countries also have a high burden of HIV. For these countries, we are exploring several innovative strategies to support access to LEN for PrEP (if approved), including tiered pricing, and are working with payors to establish fast, efficient pathways to help reach people who need or want PrEP. Those include:*
    - *Prioritizing timely registration*
    - *Planning for manufacturing at volumes that will meet demand*
    - *Leveraging partnerships for the long-term that will build and sustain access – understanding that these partnerships are critical for any drug impact*

- *Ensuring access in middle-income and upper-middle income countries, including those in Latin America, is a priority for Gilead. Planning for these countries, incorporating input from advocates and global health organizations, is ongoing and updates will be shared as discussions progress.*

5. And the following on from that, why are some of the countries that took part in the research studies for PURPOSE 2 not included in the generic licensing agreement?

- *To support our access strategy, Gilead is prioritizing speed to enable the most efficient path for the regulatory approval of long-acting PrEP in countries that account for most of the global disease burden, economic need, and limited access to healthcare. As stated above, we are exploring several innovative strategies to support access to LEN for PrEP, including tiered pricing, and are working to establish fast, efficient pathways to reach people who need or want PrEP. We are also working closely with governments and other payors to help health systems maximize the reach of our medicines and to understand economic constraints.*

- *Additionally, Gilead is committed to ensuring that individuals who participated in the PURPOSE studies have been offered and will be able to stay on open-label lenacapavir until it is available in their country.*

6. Is there a possibility that Gilead will amend or extend its generic licensing agreement?

- *As we do with all our voluntary licensing programs, we will assess demand and capacity to supply over time to determine if more partners are needed in the future.*