**Prix Galien 2023 Awards Ceremony Program (the Golden Book)**

**Product abstract for Sunlenca® (lenacapavir)**

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| **Company Name:** *[Correct capitalization, punctuation]* | Gilead Sciences, Inc. | |
| **Indication(s):** | Sunlenca (300 mg tablet and 463.5 mg/1.5 mL injection) is a first-in-class, long-acting human immunodeficiency virus type 1 (HIV-1) capsid inhibitor approved for the treatment of HIV-1 infection, in combination with other antiretroviral(s), in people who are heavily treatment-experienced with multi-drug resistant HIV-1. | |
| **Company & Product Logos:** *[Format: attach EPS file or high-res (300 dpi) jpeg file]* | 12 Gilead Sciences - Contract Pharma |  |
| **Drug Innovation Description:** *[Text, limited to 350 words. You can cut and paste from your submission. We will publish exactly what you have provided in this section.]* | HIV remains a global public health threat. To end the epidemic globally, new approaches are needed. Contemporary HIV treatments can suppress virus to undetectable levels, resulting in a full lifespan and eliminating risk of onward transmission; for individuals who do not have HIV, use of anti-HIV medicines as pre-exposure prophylaxis (PrEP) can virtually eliminate HIV acquisition risk. Yes, despite tremendous innovation in HIV treatment and prevention, more than 1.5 million new cases of HIV occur each year and a third of individuals living with the virus are not successfully treated.  Sunlenca (lenacapavir) represents a breakthrough in HIV innovation. It is a first of its kind capsid inhibitor, directly targeting the protein-protein interactions forming the structure protecting HIV’s genetic material. While most antivirals act on just one stage of viral replication, lenacapavir is designed to inhibit HIV at multiple stages of its lifecycle and has no known cross resistance to other existing drug classes. Lenacapavir’s unmatched picomolar potency and half-life (8-12 weeks) allow it to be given once every six months, as a subcutaneous injection.  Lenacapavir is approved for the treatment of multi-drug resistant HIV (MDR HIV) – i.e., for individuals who have exhausted most or all other HIV treatment options and have been unable to achieve viral suppression. This population – the most challenging to treat and most at risk for morbidity and mortality from HIV-associated immunosuppression – was chosen specifically for evaluation of lenacapavir’s potential to fulfill unmet clinical needs, given limited treatment options.  Building on lenacapavir’s unique mode of action, exceptional potency, long half-life, and its ability to be potetnailly dosed as an injectable agent or as a long-acting oral medication, lenacapavir is being further developed as a foundation for Gilead’s future therapies in HIV treatment and prevention. The goal is to offer multiple long-acting options that help address individual patient needs, optimize outcomes, and reduce the burden of care, including once weekly/monthly pills or injectable therapy quarterly or every six months. People with HIV, their communities, and healthcare professionals tell us that new strategies like lenacapavir are needed, because chronic daily pills taken for decades face tremendous challenges to adherence, including persistent HIV stigma. With this potential in mind, Gilead has ongoing multiple simultaneous investigational programs based on lenacapavir for long-acting HIV treatment and PrEP; these programs are, together, the most comprehensive HIV development program ever launched.  Sunlenca represents a step change in HIV innovation, helping people with limited treatment options today, and with significant potential to help a range of people affected by HIV in the future. Only with innovations like Sunlenca that meet the diverse needs of the people living with HIV, will we one day reach to end the epidemic for everyone, everywhere. | |
| **Product Name:** *[With correct representation of your trademark]* | Sunlenca® | |
| **For additional Product Information, including side effects, please refer to:** *[Provide Product or Company website links]* | [https://www.sunlenca.com](https://www.sunlenca.com ) | |
| **Compound Name:** | lenacapavir | |
| **Date of FDA Approval:** | December 22, 2022 | |