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Gilead Sciences, Inc.

Medical Affairs

Call for Proposals for HBV CARE Program (HBV - Linkage to CARe & Epidemiology in Special Populations)

Chronic hepatitis B (CHB) can be a life-threatening liver infection caused by the hepatitis B virus (HBV). CHB continues to be a major public health issue despite the availability of an effective vaccine and potent antiviral treatments. As many as 257 million people are infected with HBV globally, of which only 22 million were diagnosed and only 8% of these patients receiving treatment. In the United States, up to 2 million patients have CHB, of which up to 1.4 million are undiagnosed (Cohen 2011). Of the approximate 500,000 patients eligible to receive treatment in the US, only 15% are receiving care, and 2.5% are receiving antiviral therapy (Cohen 2011). These statistics showed the diagnosis and linkage to care for CHB patients remained suboptimal, which makes achieving the WHO 2030 goal of viral hepatitis elimination illusive. In order to improve the diagnosis and linkage to care for CHB patients, more up-to-date epidemiology data in populations with high burden of HBV such as immigrants from countries with high HBV prevalence, people who inject drugs (PWID) and men who have sex with men (MSM) are needed.

Gilead is committed to support the efforts of governments and partner with professional organizations, patient advocacy groups, payers and healthcare professionals who have declared their intention and commitment to work toward the WHO goal of eliminating viral hepatitis around the world by 2030. Some of the defining features of the WHO goal for HBV are:

- 90% of infants have HBV birth dose vaccination
- 90% are aware of their HBV infection
- 80% of eligible people are treated

In an effort to further understand HBV epidemiology in underserved groups and improve screening and linkage to care efforts, the Gilead Medical Affairs team is launching the HBV Linkage to CARe & Epidemiology in Special Populations (**HBV CARE**) program. The **HBV CARE** program will support individual projects of no more than \$150,000 USD or equivalent sum. It is Gilead's intent to support up to 6 well-defined projects.

Successful projects should demonstrate clear objectives, defined timelines, a comprehensive operational plan, and propose data that has relevance to the medical community and policy makers.

Gilead will not consider proposals that solely request HBV screening costs (including test kits) or proposals that request HBV study drug. Proposals should be agnostic to a specific HBV drug.

Gilead will consider support for research proposals that do the following:

- ☐ Focus on a defined population such as, but not limited to:
 - HBV epidemiology in a specific demographic (i.e. African immigrants, MSM, PWID)
 - Defined geographical area such as neighborhood, city, state, or region



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- ☐ Focus on a data gap for the defined population. Examples include:
 - ☐ Surveillance data pertaining to the cascade of care in geographies or populations which currently have inadequate data or strategic information systems for monitoring HBV infection
 - ☐ Understanding or intervening on a 'leakage in the cascade of care'
- ☐ Consider presenting data to policy makers

Letter of intent (LOI) should adhere to the following:

- ☐ Proposed budget is \leq \$150,000 USD or equivalent sum
 - ☐ Including overhead costs and applicable taxes
 - ☐ Proposed overhead costs are \leq 30% of the total budget
- ☐ The proposed study design will not take longer than 24 months to complete
- ☐ Funding request for sole purpose of screening costs is not acceptable for **HBV CARE program**
- ☐ Funding for or contribution of HBV study drug is not acceptable for **HBV CARE program**
- ☐ Agnostic to a specific HBV drug
- ☐ No more than one subsite that will require contract negotiations and/or Institutional Review Board (IRB) or Ethics Committee (EC) review, or other barriers that will lead to delays in study start-up
- ☐ Entered into the provided LOI template
- ☐ Proposals should not exceed 1,000 word limit

Key Dates & Program Specifics:

- Gilead will evaluate and award submissions following submission deadline.
- LOI –
 - **August 1, 2019:** LOI submission window opens
 - **September 15, 2019:** LOI submission window closes

LOI applicants should use the downloadable **LOI Form** available at

www.gilead.com/science-and-medicine/research/investigator-sponsored-research/hbv-care-rfp

LOI forms and Overhead Policy forms should be submitted to: HBV-CARE@gilead.com

- After submission window closes, Gilead will evaluate and rank all LOIs. Top ranked LOIs will be invited to submit a full application and additional instructions will be provided to the submitter.

Gilead approval of awards for research proposals depend on availability of funds and receipt of meritorious applications. Gilead anticipates that approximately 6 awards will be granted. No individual study may exceed \$150,000 USD or equivalent sums. Awards shall be for research purposes only.

Questions about the **HBV CARE** Program announcement or application process should be submitted to your local Gilead Medical Scientist or HBV-CARE@gilead.com. Gilead reserves the right to approve or decline any application. Applications are reviewed by an internal review committee

About Gilead Sciences

Gilead Sciences, Inc. is a research-based biopharmaceutical company that discovers, develops and commercializes innovative therapeutics in areas of unmet medical need. The company strives to



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transform and simplify care for people with life-threatening illnesses around the world. Gilead has operations in more than 35 countries worldwide, with headquarters in Foster City, California.

1. Cohen et al, J Viral Hepat. 2011 18(6), 377-383
2. Lazarus et al, J Hepatology 2017 vol. 67, 665-666
3. WHO. Global Hepatitis Report 2017 Available at: <http://www.who.int/hepatitis/publications/global-hepatitis-report2017/en/> (accessed April 2018)