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Gilead Sciences, Inc.
Medical Affairs
Call for Proposals for HBV TREAT Program
(**HBV –** Linkage to **TREAT**ment for Patients Already in Care)

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. Therapy for HBV has greatly improved, with effective and safe oral antivirals with high barriers to resistance.[1-4] Additionally, treatment has been shown to decrease the occurrence of complications such as liver decompensation and hepatocellular carcinoma.[5,6]

As many as 257 million people are infected with CHB globally, of which 22 million patients are diagnosed and 8% receive treatment. In the United States, up to 2 million patients have CHB. Approximately 25% of these patients are eligible to receive treatment, 15% are receiving care, and only 6% are on treatment.[7-8] In China, out of the 86 million patients with CHB, 12% are in care, and 4% are on treatment.[9] In South Korea, 1.5 million are infected, 28% are in care, and 17% are on treatment. In Japan, 1.2 million are infected, 27% are in care, and 9% are on treatment.[10] Clinical practice guidelines for HBV such as AASLD, EASL, and APASL largely limit treatment to a subset of the infected population, based upon disease activity, risk of disease progression, and likelihood of intervention effectiveness.[2-4] Collectively, these data suggest that among individuals already in treater care, only a small proportion actually receive treatment. There is a significant need to 1) identify the reasons why these patients are not being treated 2) develop effective strategies to facilitate treatment of eligible patients.

To further understand this patient population, Gilead Medical Affairs is launching the **HBV – Linkage to TREATment for Patients Already in Care (HBV TREAT)** program. The **HBV TREAT** program will support individual programs of no more than $150,000 USD or equivalent sum; projects that are more than $150,000 will require approval by Gilead prior to submission.

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 any proposals that request HBV study drug. Proposals should be agnostic as to choice of treatment and should not require the use of a specific HBV drug.

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

- Identification of individuals with CHB under treater care who meet treatment criteria but are not treated
- Characterization of why these individuals are not treated, with elaboration on treatment barriers
- Development and/or implementation of methods to improve linkage to treatment

Examples include, but not limited to: EMR best practice alerts, database searches, provider alerts, multidisciplinary care models, patient and provider education etc.

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

- ☐ Proposed budget is ≤$150,000 USD or equivalent sum; Gilead approval will be required prior to submission for proposals with a budget of >$150,000
  - Including overhead costs and applicable taxes
  - Proposed overhead costs should not exceed 30% of the total budget
- ☐ The proposed study design will not take longer than 24 months to complete
- ☐ Funding request for the sole purpose of screening costs is not acceptable for **HBV TREAT**
- ☐ Funding for or contribution of study drug is not acceptable for **HBV TREAT**
- ☐ No more than one sponsor for contract negotiations and/or Institutional Review Board (IRB) / Ethics Committee (EC) review
- ☐ Entered on the provided LOI form
- ☐ Research plan should not exceed the 1,000-word limit

*The letters of Intent are not binding documents on either party. The purpose of the LOI is a brief summary of the proposed study to enable Gilead to determine on a preliminary basis whether the proposed study and related budget are aligned with the criteria, timeline and scope of this RFP.

Key Dates & Program Specifics:

- Gilead will evaluate LOI based on the following timelines:
- Submission window:
  - **Sep 21, 2020**: submission window opens
  - **Oct 2, 2020**: submission window closes
- Applicants should download and complete the **LOI** and **ISR Overhead Policy** forms available at: https://www.gilead.com/science-and-medicine/research/investigator-sponsored-research/hbv-treat-rfp
- **LOI, curriculum vitae, and overhead policy forms should be submitted to GOptics: ****Link to be provided on website soon****
- After Oct 2, 2020, 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 will depend on availability of funds and receipt of meritorious and complete proposals. No individual study may exceed $150,000 USD unless approved by Gilead prior to submission. Awards shall be granted solely on the merit of the research and alignment with the criteria of this RFP.

Note: Gilead approval of awards does not take into account the past, present, or future volume or value of any business or referrals between the parties, and are not being given, directly or indirectly, as an inducement or reward with respect to the formulary placement of any Gilead product. Further, the awardee is not required to purchase, order, recommend or prescribe to any patients any products manufactured or available through Gilead.

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

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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 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.

References

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