Gilead Sciences, Inc. Medical Affairs HIV/HCV NoCo program: Toward Elimination of HCV in HIV-Infected Populations

Through Medical Affairs, Gilead supports the research efforts of academic institutions, clinical investigators, community organizations and research networks to help inform the scientific community about the impact of hepatitis C on HIV-infected patients and the health care system. Specifically, Gilead intends to support investigators focused on addressing the challenges associated with HCV elimination for individuals co-infected with HIV and hepatitis C. Targeting elimination of HCV in HIV-infected individuals is a positive step toward more global HCV elimination and may be a more proximate short term goal.

The advantages of targeting HIV/HCV include: i) liver disease is the most common cause of death in HIV/HCV co-infected patients, ii) viral hepatitis progresses faster and causes more liver-related health problems among people with HIV than among those who do not have HIV, iii) most HIV-infected people have at least one HCV screening test done; iv) most HIV-infected individuals are receiving medical care; v) many have health care access and availability to HCV medications; vi) treatment recommendations for patients with HIV/HCV co-infection with DAAs are the same as for patients with HCV mono-infection; vii) management of drug interactions with HCV medications and ARV is feasible; viii) the HIV/HCV population is better identified than the HCV mono-infection; ix) non-specialist treatment models exist; x) high rates of re-infection allow demonstration of incidence reduction if coupled with surveillance and molecular epidemiology; and xi) HCV elimination strategies in HIV infected people have already started in some cities (i.e. Amsterdam)!

Through the Medical Affairs Investigator Sponsored Research process, Gilead will evaluate support of programs which address the following objectives:

- To develop and perform implementation science projects, including data collection or modeling, of elimination of HCV in HIV-infected populations that may include, but are not limited to, the following elements:

    - Contain a defined population. A population may be defined by a clinic, a health system, a geographic location (city) or other clearly defined group that can be followed for HCV elimination outcomes.
    - Evaluate the percent of patients within the defined study population who have achieved HCV elimination within the study time frame
    - Define specific data collection methods
    - Can be completed within 3 years
    - Collect appropriate metrics
    - Define the prevalence of HCV and successfully treated HCV in an HIV population
    - Evaluate the incidence of new HCV infection in an HIV population including re-infection rates and change in incidence over time
    - Evaluate the proportion treated over time and define sub-populations that are problematic for HCV treatment
    - Define HCV treatment outcomes
    - Evaluate HIV treatment outcomes, including maintenance of HIV suppression and whether there was any need for HIV regimen changes
    - Study molecular epidemiology of transmission

Proposals must contain the following:

- Clear scientific objectives based on a scientific hypothesis
- Potential scalability and sustainability of program to other practice settings

- Plan to publish and present results in scientific forums and to other organizations

Key Dates & Program Specifics:

Letter of Intent (LOI: 2-page concise overview of proposed project and draft budget)

01 February 2017: LOI submission window opens
13 March 2017: LOI submission window closes

The LOI should use the format attached to this document and should be submitted to: NoCo@Gilead.com

Full Application Submission

A review of the LOIs will result in invitations for selected LOI applicants to submit a full application. The timelines below will be followed for those full submissions.

3 April 2017: Notice of LOI outcome, either approved for full application submission or declined
15 May 2017: Deadline for receipt of full application
12 June 2017: Notice of full application outcome, either approved provisionally or declined

Investigators who meet criteria for a standard Gilead ISR are encouraged to apply (http://www.gilead.com/research/investigator-sponsored). There are no geographic limitations to applications.

The program provides awards for proposals completed in up to 3 years. Awards shall be for research purposes only; ***requests that include routine medical care, HCV screening costs or HCV study drug will not be considered*.** Proposals should not require treatment with any particular HCV or HIV medication or drug regimen.

Budget Considerations

Gilead plans to award a total of approximately $3,000,000 in funds for these research proposals, dependent upon availability of funds and receipt of meritorious applications. Gilead anticipates that 3-6 awards will be granted.

Full Application

Once notice of approval to submit a full application has been received, a full application should be submitted to http://www.gilead.com/research/investigator-sponsored. Questions about the announcement or application process should be submitted to your local medical scientist.

Gilead reserves the right to approve or decline any application. Applications are reviewed by an internal review committee. Award of a grant in any one cycle does not imply that a subsequent grant will be awarded without further application and approval.

About Gilead Sciences Gilead Sciences, Inc. is a biopharmaceutical company that discovers, develops and commercializes innovative therapeutics in areas of unmet medical need. The company's mission is to advance the care of patients suffering from life-threatening diseases worldwide. Gilead has operations in more than 30 countries worldwide, with headquarters in Foster City, California.