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**PRESS RELEASE: FIRST PUBLIC MEETING OF CROSS-SECTOR HIV CURE PROJECT
CONVENES JUNE 17TH IN WASHINGTON, DC**

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WASHINGTON, DC (June 17, 2014) – At a time when dozens of research trials are challenging the long-held assumption that HIV is incurable, the Forum for Collaborative HIV Research is convening the first public meeting of the *Forum HIV Cure Project: Focus on Regulatory Issues*, a multi-stakeholder project that involves expert working groups and engagement with the broader HIV community to address emerging scientific and regulatory hurdles in HIV cure research.

The all-day meeting, held June 17th at the Kaiser Family Foundation Barbara Jordan Conference Center, will showcase the work of the 100+ experts from academia, federal and regulatory agencies, government research agencies, pharmaceutical and biotech industry, and patient advocacy community who have worked together over the past several months to prepare draft consensus recommendations on how to address the regulatory hurdles in HIV cure research.

Unlike early-stage HIV drug trials in the 1980s and 1990s, which offered the possibility of new or improved treatments, many cure research trials provide little personal benefit, include potentially risky interventions, and may require participants to temporarily stop antiretroviral therapy – a safe and highly effective treatment that would otherwise afford them a near normal life span. By bringing together a diverse group of experts from the HIV community with representatives from the Food and Drug Administration's (FDA) Centers for Drug and Biologics Evaluation Research (CDER and CBER), this meeting provides a much-needed platform to discuss the novel regulatory, ethical, and scientific challenges inherent in conducting early cure research.



“Bringing all the key players – industry, academics, regulators, and the HIV community – into one room is essential for the advancement of cure research,” said Veronica Miller, Ph.D., Director of the Forum for Collaborative HIV Research (the Forum) and co-chair of the project’s steering committee. “A dedicated space for ongoing dialogue in a neutral and independent setting provides the necessary framework for consensus on issues such as definitions, management of benefit-risk, and ensuring fair and ethical patient recruitment processes, to evolve in real-time. It allows the science and regulatory guidance to evolve hand-in-hand.”

The meeting will serve as a venue for engaging the broader HIV community and seeking public input on these topics. With registration open to the public and simultaneous webcast to facilitate participation, the meeting – and the Forum’s HIV Cure Project as a whole – is committed to fostering inclusive, community-oriented discussion around HIV cure research.

“Through discussions of clinical trial designs and new scientific discoveries, as well as frank assessments of future needs within the development pipeline, the *Forum HIV Cure Project* addresses key issues of importance to multiple stakeholders including the FDA,” said Dr. Margaret Hamburg, Commissioner of the Food and Drug Administration (FDA). “Most importantly, it is an effective mechanism for extending and continuing our discussions with the patient community, which is a high priority and a commitment within the PDUFA V framework.”

“This is a unique opportunity to work collaboratively on strategies that could change the very nature of a disease whose name has too often been synonymous with stigma, grief, marginalization and discrimination,” said Mark Harrington, Executive Director of Treatment Action Group and a member of the *Forum HIV Cure Project*’s steering committee. “A framework for sorting out the regulatory issues is a prerequisite for public and private commitment to this area of research.”

Cure Project Steered by HIV Experts

Convened by the Forum and funded by the National Institutes of Health (NIH), with special support from the Bill & Melinda Gates Foundation, amFAR, and ViiV Healthcare, and the Kaiser Family Foundation the *Forum HIV Cure Project: Focus on Regulatory Issues* enlists a diverse cadre of experts. The project is steered by a committee of experts that includes representatives from the FDA’s CDER and CBER, NIAID’s Division of AIDS (DAIDS), the NIH’s Office of AIDS Research (OAR), the U.S. Military HIV Research Program (MHRP), Treatment Action Group (TAG), Project Inform, amFAR, the Gates Foundation, University of North Carolina, Chapel Hill, University of Pittsburgh, Brigham and Women’s Hospital, Harvard University, and various pharmaceutical and biotech companies.

The meeting will feature a series of presentations, case studies, and panel discussions, focusing on the three key issue areas tackled by the expert working groups:



- Preclinical testing, definition of cure, and biomarkers predictive of cure
- Management of risk-benefit in cure trials
- Ethics and fairness in patient recruitment and informed consent

Other topics for discussion will include updates on the research implications of the “Mississippi baby” and a discussion of the scientific, ethical, and regulatory issues surrounding the development of a pediatric cure for HIV. Dr. Karen Midthun, Director of the FDA’s Center for Biologics Evaluation and Research will open the conference.

“When you can bring all these parties together on a level playing field like this group does, it really helps overcome the siloes that often hamper cross-sector communication and creates a venue for the kind of cross-pollination that can be a game-changer for drug discovery and development,” said Dr. Dan Kuritzkes, Professor of Medicine, Harvard Medical School and Brigham and Women’s Hospital, and co-chair of the project’s steering committee.

The webcast is free and open to the public; registration to watch the webcast is available at www.hivforum.org/hivcure. Registration for this meeting is complimentary for members of the media. Please contact Courtney Hutchison at CHutchison@hivforum.org with any questions.

About the Forum for Collaborative HIV Research

Part of the University of California, Berkeley School of Public Health and based in Washington, DC, the Forum was founded in 1997 as the outgrowth of a White House initiative. Representing government, industry, patient advocates, healthcare providers, foundations and academia, the Forum is a public/private partnership that organizes roundtables and issues reports on a range of HIV/AIDS and Hepatitis C issues. Forum recommendations have changed the ways clinical trials are conducted, helped to spur national momentum toward universal testing for HIV, and accelerated the delivery of new drugs for HIV and Hepatitis C.

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