

For Immediate Release

Contacts:

Othman Mellouk, omellouk@itpcglobal.com + 212 (0) 6 66 45 28 11 (Morocco)

Christine Stegling, cstegling@itpcglobal.com + 44 7810 551313 (Botswana)

Karyn Kaplan, karyn.kaplan@treatmentactiongroup.org +1-646-316-8979 (U.S.A.)

Don't forget treatment on World Hepatitis Day

**The prohibitive price of hepatitis C virus medications will result in
needless deaths if we don't act now**

July 28, 2015—On World Hepatitis Day 2015, as the World Health Organization (WHO) emphasizes prevention, the International Treatment Preparedness Coalition (ITPC) and Treatment Action Group (TAG) urge pharmaceutical companies and the governments of middle-income countries (MICs) to act now to facilitate access to treatment for all people with hepatitis C virus (HCV), to avoid needless deaths from HCV complications and to prevent new infections.

Globally, more than 150 million people live with chronic HCV, the majority living in MICs, also home to 73% of the world's poorest people. Each year, HCV kills 700,000 people and 3-4 million are newly infected.

"Over the coming years, there is huge potential to transform the treatment of HCV infection, as new all-oral treatments, called direct-acting antivirals (DAAs), become available. DAAs have a shorter treatment period and more manageable side effects than the previous standard of care," explains Christine Stegling, Executive Director of ITPC. "HCV infection is curable in nearly all patients and eradication of the disease is feasible, but we must act now."

The combination of sofosbuvir (produced by Gilead Sciences/"Gilead") and daclatasvir (produced by Bristol-Myers Squibb/"BMS") is a robust combination that is well suited for use in resource-limited settings. This treatment combination can be used for all genotypes, in people with advanced liver disease, and is highly effective in HIV co-infected people on antiretroviral therapy.

"The problem is that the inflated price of such medicines, which is directly linked to intellectual property rights, is a major barrier to people getting the treatment they need," explains Karyn Kaplan, Director of International Hepatitis/HIV Policy & Advocacy at TAG.

Gilead issued a voluntary license (VL) that allows generic manufacturers to produce and sell their drugs in 91 low- and middle-income countries (LMICs), but this still excludes 49 million people in 50 MICs. Bristol-Myers Squibb announced a VL country list identical to Gilead's, except that it notably excludes Egypt, where more than 10 million people are in need of treatment. However, BMS has not publicly issued any voluntary licences yet.

"Competition from multiple generic manufacturers has already led to reductions in the price of sofosbuvir. This will enable low-cost access to quality-assured generic versions of the drug for many," explains Othman Mellouk, Intellectual Property Expert at ITPC. "But Gilead limits the number of countries able to procure such generics, and these versions have not yet been quality-assured by WHO."

Beyond patent and pricing barriers, there are regulatory and approval challenges to expanding DAA access. For example, having secured monopolies in several high-HCV burden MICs (such as China, Brazil and Ukraine) by excluding them from their VL, Gilead has also delayed or failed to register their drug in most countries. According to Gilead, sofosbuvir has only been granted marketing authorisation in seven MICs. Their sofosbuvir/ledipasvir combination, Harvoni, has been registered in just one country. BMS is even further behind. If an originator company fails to register their drug, it is difficult for generic manufacturers to get regulatory approval for their version of the product.

ITPC and TAG call on MIC governments to ensure access to affordable DAAs. We also urge Gilead and BMS to urgently reduce their prices, particularly in MICs, and expand the geographical scope of their licenses, to help stop HCV-related deaths -- and to prevent new infections.

ITPC calls on:

- Gilead to extend its “Global Access” program to all MICs where there is HCV, and to remove restrictive “anti-diversion” barriers that infringe on patient privacy
- Bristol-Myers Squibb to implement their global access program, and extend coverage to all countries with HCV epidemics
- Gilead and Bristol-Myers Squibb to speed up registration of sofosbuvir and daclatasvir, particularly in high-HCV burden MICs
- Generic producers to speed up process of pre-qualification and start production of daclatasvir
- WHO to actively support countries to use legal flexibilities to ensure affordable DAA access, and facilitate the expedited review of the safety and efficacy of generic DAAs
- Middle-income countries to remove intellectual property barriers to life-saving HCV medications, including by assessing the validity of DAA patent applications and utilizing legal flexibilities such as compulsory licenses, where needed; and to establish treatment plans and targets, and allocate resources for treatment.

###

About International Treatment Preparedness Coalition:

ITPC is a global coalition of HIV treatment activists formed in 2003 to respond to the needs of communities worldwide. Structured in eight regions, the global network is driven by individual activists, peer support groups, grassroots networks, community-based organizations, and non-governmental organizations. Each of the ITPC regional offices share our values and vision and come together to address issues around access to treatment issues in their countries, regions and at the global level. The Coalition includes organizations and networks run by key populations – lesbian, gay, bisexual, transgender and intersex people (LGBTI), sex workers and people who use drugs – as well as others marginalized within the current HIV response, such as women, girls and migrants. As a Coalition rooted in the Global South, ITPC established its global office in Botswana in early 2015. For more information please visit www.itpcglobal.org.

- ITPC China
- ITPC Central Africa
- ITPC East Africa
- ITPC Eastern Europe and Central Asia
- ITPC Latin America and Caribbean
- ITPC Middle East and North Africa
- ITPC South Asia
- ITPC West Africa

About Treatment Action Group and its Hepatitis/HIV Project:

Treatment Action Group (TAG) is an independent AIDS research and policy think tank fighting for better treatment, a vaccine, and a cure for AIDS. TAG works to ensure that all people with HIV receive lifesaving treatment, care, and information. We are science-based treatment activists working to expand and accelerate vital research and effective community engagement with research and policy institutions. TAG catalyzes open collective action by all affected communities, scientists, and policy makers to end AIDS.

TAG's Hepatitis/HIV Project draws from the core values and history of HIV activism. The Hepatitis/HIV Project is focused on optimizing quality of, and creating access to HCV information, prevention, care and treatment. We work with domestic and global allies, including people living with, or at risk for HIV and HCV and their communities, regulatory agencies, researchers, health care providers, policymakers, United Nations agencies and pharmaceutical companies. For more information please visit www.treatmentactiongroup.org and www.hepcoalition.org.