HIV, Hep C Drug Development Pipeline is 'Robust,' Says Report

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The HIV drug development pipeline is robust, with 12 novel agents and fixed-dose combinations (FDCs) in Phase II or III studies—and several promising compounds in Phase I clinical trials—according to an optimistic report produced by U.K.–based i-Base in collaboration with U.S.–based Treatment Action Group (TAG).

Released ahead of the 6th IAS Conference on HIV Pathogenesis, Treatment and Prevention in Rome, the 2011 Pipeline Report "makes clear, medically, [that] the prospect for people with HIV, hepatitis C virus (HCV) and tuberculosis (TB) to live long and healthy lives—and in the cases of HCV and TB, to be cured rapidly with safe, effective, oral combination therapy—[has] never been better," write Polly Clayden of i-Base and Mark Harrington of TAG write.

Globally, Clayden and Harrington point out in the report's introduction and executive summary, 34 million people are living with HIV, an estimated 2 billion with latent *Mycobacterium tuberculosis* (TB), and up to 130 million with chronic HCV. At least 1.8 million people died of AIDS in 2009, one quarter of them from TB, which on its own killed 1.7 million people. There is neither global nor national surveillance for HCV-related illness and death, they add, but more than 300,000 people die from HCV complications each year, and HCV mortality will continue to increase in the coming decade.

The prospects for dramatic—indeed in some cases revolutionary—changes in prevention and treatment for HIV, TB and HCV in the next decade are amazingly good, the authors suggest. "Decades of high-quality research, increased investment, and growing and targeted community-based activism have set the scene for the possibility—for the first time since HIV/AIDS emerged in 1981—to make dramatic reductions in new HIV infections worldwide, while saving the lives of as many of the 34 million currently infected who can access therapy. Treatment is continually improving, with modern combinations dramatically less toxic, more tolerable and easier to take than the first-generation [antiretroviral, or ARV] combinations of the 1990s."

With respect to ARVs in development for the treatment of HIV, Collins's encouraging review of experimental agents challenges "predictions of obstinate pessimists who constantly bemoan the imminent emptying of the ARV pipeline." In addition to the promising compounds in clinical trials, including the integrase inhibitors elvitegravir and dolutegravir, the report highlights two new agents approved in the last year: the non-nucleoside reverse transcriptase inhibitor Edurant

(rilpivirine) and Boehringer Ingelheim's extended-release formulation of nevirapine, Viramune XR.

"This year's pipeline is at least as full as that of any year documented by TAG in our annual ARV pipelines since 2003," the authors state.

HIV cure-related research is also summarized in the report, as are ARV-related prevention strategies.

The future looks particularly bright for HCV treatment options. According to the report, several generations of new direct-acting antivirals (DAAs) are in the pipeline, holding out the promise that it may be possible to cure people with oral drugs in the future. Currently, 14 HCV protease inhibitors—not including the just-approved Victrelis (boceprevir) and Incivek (telaprevir)—6 NS5a inhibitors, 10 non-nucleoside polymerase inhibitors, 8 nucleoside or nucleotide polymerase inhibitors, 3 host-targeting agents, 4 novel interferons, 3 immunomodulators, a microRNA inhibitor and an extract of milk thistle are in development.

"If the promise of all-oral DAA cures is realized," Clayden and Harrington write, "the potential to roll out HCV treatment globally would then become dramatically easier, and hundreds of millions of lives could be saved. But most people with hepatitis C will not be cured—or even treated. The drugs are simply too expensive. New HCV treatments must be accessible to those who need them."

The 2011 Pipeline Report can now be accessed on the i-Base or TAG websites.
