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Why highly effective drugs are not enough: an affordable solution to eradicating HCV

Global eradication of HCV is possible because it is the only chronic virus infection that can be cured with a drug. The last decade has been a period of incredible advancements where the "Holy Grail" of an all-oral, highly tolerable therapy with a >95% SVR12 (sustained viral response or cure) rate for chronic HCV infections was achieved. However, high prices in many middle- and high-income countries have resulted in severely restricted access, straining private and public healthcare resources (even in high-income countries such as those in Western Europe, and the US). This situation has presented a significant impediment to the development of i) "test-and-treat" programs with inexpensive, decentralized, and rapid HCV RNA diagnostic assays; ii) affordable and accessible HCV drugs for all patients; and iii) a medical infrastructure that is able to treat all patients effectively and efficiently. Current HCV treatment is focused on treating a pool of rapidly diminishing, already-diagnosed patients. 3.4 million people in the EU have chronic HCV infections; this includes injection drug users, prisoners, and migrants. Depending on the country, ~50-90% of patients have not been diagnosed, and <10% of HCV patients are treated each year (Romania and Poland treat ≤ 2% of up to 1 million HCV patients). Lack of timely diagnosis and cure increases the risk of liver cirrhosis, liver failure, liver cancer, and premature death. Within high-income countries, pockets of high unmet medical need also exist. Germany treated 20,100 patients in 2015 at a cost of €1.3 billion, yet they have 129,000 immigrants alone with HCV. In the United States, 1 in 3 HCV-infected people pass through the US Corrections Systems each year and the vast majority remains untreated. Trek Therapeutics, PBC (Trek) is an infectious disease pharmaceutical public benefit corporation (PBC) based in Cambridge, MA, USA whose mission is to make affordable and accessible drugs to treat infectious diseases AND be profitable. Trek has an integrated management team with deep experience in discovery, clinical & CMC development, pricing and medical affairs, and has helped launch 8 antiviral drugs, including 5 HCV drugs. Trek is developing drugs to address the remaining barrier to hepatitis C virus (HCV) care by providing ACCESS to curative treatment. The goal is to develop an HCV regimen at a $10,000 price point that is as good or better than the standard of care (~$40,000 to $95,000/treatment). Trek will drive revenue with a volume-based, value-driven, "test-and-treat" strategy. Trek has in-licensed a pipeline of four HCV drugs, most of which are second- and third-generation drugs with Phase 2 and 3 clinical data. They include TD-6450 (third-generation NS5A inhibitor from Theravance), MIV-802 (second-generation nucleoside inhibitor from Medivir), faldaprevir (FDV, second-generation NS3 protease inhibitor from Boehringer Ingelheim), and VX-222 (first-generation non-nucleoside inhibitor from Vertex). Trek's clinical program is risk-reduced with favorable Ph2a clinical data: Patients receiving FDV + TD-6450 + ribavirin for 12 weeks had no SAEs or discontinuations, and achieved SVR12 (viral cure) in 16/16 patients with HCV genotype (GT) 4, and in 14/15 patients with HCV GT1b. Trek is developing 3 HCV regimens: TRK-1 to treat HCV GT1&4 and launch in 2021 in the EU; TRK-1SD (short duration) will also target GT1&4 in the US, EU, and Mexico and launch in 2022; TRK-2/3 will target GT2&3 in high prevalence countries, and launch in 2023.

Conclusion: It is not enough to have highly effective and safe HCV treatment regimens. Industry, academia, patients and their families, non-government organizations (NGOs), ministries of health, regulators, and the investment community need to collaborate to apply the same ingenuity, energy, and funding used to develop highly effective HCV drugs, to eradicate HCV. Trek will partner with providers, insurers, patients, and government health authorities to promote testing and other care necessary to identify and cure patients, and to help the World Health Organization (WHO) reach their goal of eliminating HCV by 2030.

Biography

Ann D Kwong is an internationally recognized industry leader in antiviral drug discovery and development and a co-founder of HCV DRAG (HCV Drug Development Advisory Group), a consortium of industry, clinical trial, community, and regulatory leaders working to optimize HCV drug development. Ann is the co-founder, President and CEO of Trek Therapeutics which is committed to developing affordable and accessible drugs to treat infectious diseases. Trek is conducting Ph2 clinical trials to develop a potentially best-in-class and affordable regimen to cure HCV. Prior to Trek, Ann founded the infectious disease group at Vertex Pharmaceuticals and played a leading role in the discovery, development, and commercialization of VX-787, a PB2 flu inhibitor currently in Ph2, and telaprevir (INCIVEK), a HCV inhibitor with >$2B in sales (Kwong, et al. (2011). Discovery and development of telaprevir: an NS3-4A protease inhibitor for treating genotype 1 chronic hepatitis C virus. Nat Biotech 29:1-11.

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