Hep C News: Gilead's Hepatitis C Treatment - One Pill For All Genotypes in the Works

February 3, 2015 By Connie M. Welch

Gilead Sciences announced Jan. 26, 2015, that they have expanded their generic licensing agreements to include the investigational NS5A inhibitor GS-5816, which is under evaluation in Phase 3 clinical trial studies as part of a single tablet regimen which combines the compound and Sovaldi (sofosbuvir) for the treatment of all six genotypes of hepatitis C. There are six known genotypes (virus strains) with multiple subtypes of the hepatitis c virus, all throughout the regions of the world.

Expanded agreements will allow Gilead's India-based partners to manufacture GS-5816 with Sovaldi (sofosbuvir) into a single tablet, once approved for distribution in 91 developing countries, which accounts for 54 percent of the total worldwide individuals infected with the hepatitis C virus (HCV).

Once approved by regulatory authorities, the combination of sofosbuvir/GS-5816 regimen would become the first pan-genotypic, all-oral single tablet regimen for HCV. One pill to treat all six genotypes is a major breakthrough for hepatitis C.

The pan-genotypic drug option is particularly important to developing countries, where genotype testing is often unreliable or not readily available.

Gregg H. Alton, Executive Vice-President of Corporate and Medical Affairs for Gilead Sciences states, "Today's announcement marks an important milestone in Gilead's effort to makes effective hepatitis C treatment accessible to as many patients, in as many places, as quickly as possible. Developing countries are home to a diverse mix of hepatitis C genotypes, and the development of a medicine that has the potential to cure any patient, regardless of genotype, could help accelerate access to treatment."

Abhijit Chowdhury, Head of Hepatology, Institute of Post Graduate Medical Education and Research, Kolkata, stated, "Pan-genotypic hepatitis C treatments have the potential to radically change the treatment landscape in developing countries, removing the need for patients to undergo burdensome laboratory tests. Even if testing facilities are available, their cost is a barrier to treatment access, so a regimen that can be used for any genotype is going to be a real attribute in tacking this disease on a global level."

Sovaldi (sofosbuvir) recently received regulatory approval in India in January 2015 and regulatory submissions have been completed in additional countries, including Pakistan, Thailand, Brazil, Uganda, South Africa and Nigeria.

Phase 3 studies evaluating the combination of GS-5816 and sofosbuvir are currently underway, with data anticipated in the second half of 2015.

Gilead states this regarding their approach to treatment access in developing countries, “Gilead makes it a priority to increase access to its medications for people who can benefit from them, regardless of where they live or their economic means. In developing countries, Gilead’s treatment access strategies include tiered pricing, voluntary-generic licensing (often in advance of U.S./EU regulatory approval), negotiation with national governments, regional business partnerships, product registration, medical education and partnerships with non-profit organizations. This approach has been successfully applied to Gilead’s humanitarian program in HIV over the past 10 years, where seven million patients are now receiving Gilead-based HIV medicines in developing countries.”

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