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Mylan expands hep C licensing agreement with Gilead

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The expansion agreement will include the non-exclusive rights to manufacture and distribute the investigational NS5A inhibitor GS-5816 and single tablet regimen of sofosbuvir (Sovaldi)/GS-5816, once approved, in 91 developing countries.

The single tablet regimen is being evaluated in Phase 3 clinical studies for the treatment of all six genotypes of hepatitis C.

If approved by regulatory authorities, the sofosbuvir/GS-5816 regimen would become the first all-oral single tablet regimen for all hepatitis C genotypes.

A pan-genotypic therapeutic option is particularly important for developing countries, where genotype testing is often unreliable or not readily available.

Mylan's president Mr Rajiv Malik said, "We are proud to partner with Gilead, once again, in our joint effort to quickly expand access to high quality, affordable medications to the more than 100 million people living with hepatitis C in developing countries. The potential to offer the sofosbuvir/GS-5816 regimen is particularly exciting, as it is an innovative compound that is being studied to treat all hepatitis C genotypes - a medical advancement that could significantly increase access to treatment."

This agreement is in addition to the licensing and technology transfer agreement that Mylan entered into with Gilead in September 2014, which grants Mylan the non-exclusive rights to manufacture and distribute sofosbuvir and ledipasvir/sofosbuvir in 91 developing countries.

Mylan also partners with Gilead on expanding access to high quality, affordable antiretrovirals for the treatment of HIV/AIDS in India and other developing countries.