

Bristol-Myers pulls U.S. marketing application for hepatitis C treatment

Oct 7 (Reuters) - Bristol-Myers Squibb said it withdrew its U.S. marketing application for a drug combination to treat hepatitis C.

The drugmaker will continue to pursue marketing approval of daclatasvir, one part of the combination, the company said in a statement.

Bristol-Myers said the combination treatment of daclatasvir and asunaprevir was approved in July for use in Japan.

Bristol-Myers Squibb Statement about Asunaprevir in the U.S.

PRINCETON, N.J.--(BUSINESS WIRE)--

Given the rapidly evolving hepatitis C (HCV) treatment landscape in the U.S., Bristol-Myers Squibb (BMY) has decided that it will not pursue U.S. Food and Drug Administration (FDA) approval of the dual regimen of daclatasvir and asunaprevir for the treatment of HCV genotype 1b patients in the United States and has therefore withdrawn its new drug application (NDA) for asunaprevir, an NS3/4A protease inhibitor. The company will continue to pursue FDA approval of daclatasvir, a potent, pan-genotypic NS5A complex inhibitor (in vitro), which is currently being investigated globally in multiple treatment regimens for HCV patients with high unmet need.

Bristol-Myers Squibb's HCV strategy has always been to focus on the unique unmet medical need of each local market. For example, in Japan we were pleased to receive regulatory approval for the dual regimen of daclatasvir and asunaprevir in July, bringing Japanese patients with HCV the first all-oral, interferon- and ribavirin-free treatment regimen.

The dual regimen was developed to meet the distinct need of the Japanese patient population, and we believe this treatment has the potential to play a major role in curing HCV patients in Japan, as well as in other markets where the HCV patient population is similar to Japan. In the EU, daclatasvir was recently approved for use in combination with other medicinal products across genotypes 1, 2, 3 and 4 for the treatment of HCV infection in adults. Similarly, we believe that daclatasvir-based regimens have the potential to fill continued unmet medical need in the U.S. and elsewhere in the world.

We plan to submit additional data for daclatasvir to the FDA from our ongoing clinical trial program focused on difficult-to-treat patients, including patients with HCV genotype 3, patients who are pre- and post-liver transplant, and patients co-infected with HIV. Next month at the annual meeting of The American Association for the Study of Liver Diseases (AASLD), we will present new data from several daclatasvir-based regimens. We look forward to bringing daclatasvir to patients in the U.S. and will continue to work closely with the FDA to advance our regulatory application, with the aim of bringing the investigational product to market as quickly as possible.