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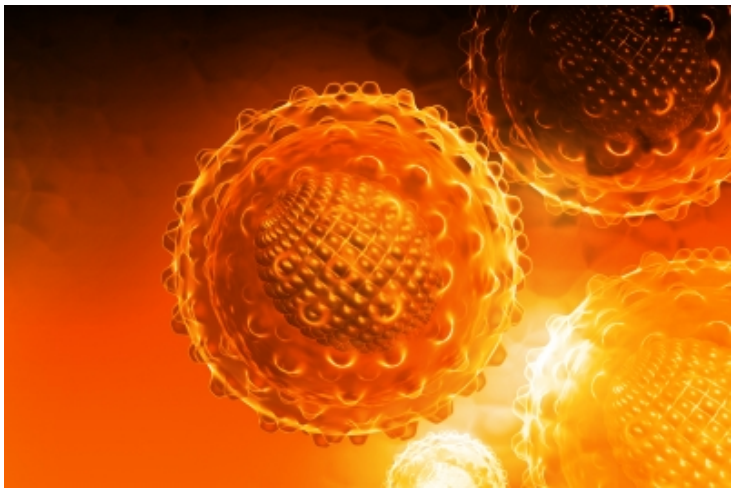
Bristol seeks Japanese nod of all-oral hepatitis C treatment

04 November 2013 | Regulatory | By BioSpectrum Bureau



Singapore: US drugmaker, Bristol-Myers Squibb co has said that it is seeking Japanese health regulators approval of its experimental all-oral combination of hepatitis C treatments.

This is the first time that any drugmaker has filed for approval with Japan's Pharmaceutical and Medical Devices Agency for a hepatitis C treatment regimen that does not include either of the standard older treatments - the injected, difficult-to-tolerate interferon, or ribavirin, a pill.

The Bristol-Myers filing was based on data from a Phase III study of Japanese patients who either could not tolerate interferon, which causes miserable flu-like symptoms, or those who had previously failed to be helped by treatment with the older drugs - a particularly tough-to-treat patient population.

Patients in the trial were given a combination of daclatasvir, from a promising new class of drugs called NS5A inhibitors, and the protease inhibitor asunaprevir for 24 weeks. Those who had no detectable levels of the virus in their blood 24 weeks after completing the therapy were deemed to be cured, a measure known as SVR24, for sustained virologic response.

The overall cure rate in the 222 patient study was 84.7 percent, according to the data to be presented next week at the American Association for the Study of Liver Diseases (AASLD) meeting in Washington.

Of those who were either ineligible for or intolerant of treatment with interferon, the cure rate was 87.4 percent, while 80.5 percent of past nonresponders to the older drugs were deemed cured.

"The Phase III study results of daclatasvir plus asunaprevir are exciting to see, especially in this difficult-to-treat patient population," Kazuaki Chayama, the study's lead investigator from Hiroshima University said in a statement.

It further said that twenty-eight patients dropped out of the study - a 12.6 percent discontinuation rate and about 6 percent, or 13 patients, reported serious side effects, primarily elevated liver enzymes, an indication of inflammation.

About 1.2 million people in Japan suffer from hepatitis C. The patients tend to be older than those in other developed

countries and about 70 percent have Genotype 1b, a form of the virus with very low response rates to the older treatments.

A Reuters report said that several other companies are also developing all-oral hepatitis C treatments, including AbbVie Inc, Merck & Co and Johnson & Johnson, and expect to be able to shorten treatment duration to 12 weeks from the current 24 or 48 week regimens.