AbbVie Files NDA For All-Oral Hep C Regimen

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AbbVie announced it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for its investigational all-oral, interferon-free regimen for the treatment of adult patients with chronic genotype 1 (GT1) hepatitis C virus (HCV) infection.

Scott Brun, VP of Pharmaceutical Development at AbbVie, said, “This NDA submission is a significant advancement for AbbVie's HCV development program. Based on the robust data that have been generated in our international Phase 3 HCV program, we believe our all-oral, interferon-free regimen holds the potential to be a promising new therapy for patients living with this chronic infection.”

The application was based on data from what is currently the largest all-oral, interferon-free clinical program in GT1 patients. The program consisted of six Phase III studies that included over 2,300 patients in more than 25 countries.

The investigational regime comprises a fixed-dose combination of ABT-450/ritonavir (150/100mg) co-formulated with ombitasvir (ABT-267) 25 mg, dosed once daily, and dasabuvir (ABT-333) 250 mg with or without RBV (weight-based), dosed twice daily. The company said the combination of three different mechanisms of action disrupts the virus’ replication process. The combo regimen aims to optimize sustained virologic response rates across different patient groups.

Hepatitis C virus (HCV) is liver disease caused by the blood borne virus. The severity of the disease can range from a mild illness lasting a few weeks to a serious, lifelong disease. An estimated 130 to 150 million people have chronic hepatitis C infection around the world. Approximately 3.2 million people in the U.S. alone are living with HCV. Infection is most prevalent among those born between 1945 and 1965.

The FDA designated AbbVie’s investigational direct-acting antiviral (DAA) regimen with and without ribavirin for HCV genotype 1 as a Breakthrough Therapy. The company said it plans to file regulatory approval applications of its regimen in the E.U. early next month.