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Singapore: US-based AbbVie has announced that the company has submitted a New Drug Application (NDA) to the Japanese Ministry of Health, Labour and Welfare (MHLW) seeking approval for its investigational, once-daily dosed, all-oral, ribavirin (RBV)-free and interferon (IFN)-free, 12-week, two direct-acting antiviral treatment consisting of ombitasvir/paritaprevir/ritonavir (OBV/PTV/r). The submission is for the treatment of patients with genotype 1 (GT1) chronic hepatitis C virus (HCV) infection.

Paritaprevir is Enanta's lead protease inhibitor identified within the ongoing Enanta-AbbVie collaboration and is one of the two direct-acting antivirals in the treatment regimen. AbbVie is responsible for all development and commercialization activities for regimens that contain paritaprevir.

AbbVie studied a two direct-acting antiviral regimen without RBV in Japan due to patient and viral characteristics specific to the Japanese population, including high prevalence of GT1b. In Japan, approximately 1.5 to 2 million people are living with HCV. Genotype 1 is the most common HCV genotype in Japan with 60 to 70 percent of patients infected and, of those, about 95 percent are infected with the GT1b sub-type. AbbVie had previously announced that they expect regulatory approval in Japan in the second half of 2015. Upon commercialization regulatory approval in Japan, Enanta will be entitled to a $30 million milestone payment from AbbVie.