

PRESS RELEASE

AbbVie's Investigational, Pan-Genotypic Regimen of ABT-493 and ABT-530 Shows High SVR Rates in Genotype 1 Hepatitis C Patients Who Failed Previous Therapy with Direct-Acting Antivirals

- *95 percent of patients achieved SVR₁₂ with 12 weeks of ABT-493 and ABT-530 with and without RBV in GT1 chronic HCV infected patients without cirrhosis who failed previous therapy with DAAs in a modified intent-to-treat analysis*
- *91 percent achieved SVR₁₂ with RBV in the primary intent-to-treat analysis; 86 percent achieved SVR₁₂ without RBV*

BARCELONA, April 15, 2016 – AbbVie (NYSE: ABBV), a global biopharmaceutical company, today announced that 91 percent (n=20/22) of genotype 1 (GT1) chronic hepatitis C virus (HCV) infected patients who failed previous therapy with direct-acting antivirals (DAAs) achieved SVR₁₂ with 12 weeks of ABT-493 and ABT-530 with ribavirin (RBV) in the primary intent-to-treat analysis. Additionally, 86 percent (n=19/22) of GT1 patients who received ABT-493 and ABT-530 without RBV, achieved SVR₁₂.¹ SVR₁₂ was achieved in 95 percent of patients with and without RBV (n=20/21, n=19/20; respectively) in a modified intent-to-treat analysis, excluding patients who did not achieve SVR for reasons other than virologic failure.

The results were evaluated in the ongoing MAGELLAN-1 study of AbbVie's once-daily, investigational, pan-genotypic regimen of co-formulated ABT-493 (300mg) and ABT-530 (120mg) for the retreatment of non-cirrhotic patients with GT1 chronic HCV who have failed previous therapy with DAAs. These data were presented at The International Liver Congress™ (ILC) 2016 in Barcelona, Spain.

“Retreatment options for those patients who have previously failed therapy are limited, and present a particular challenge for treating physicians,” said Fred Poordad, M.D., vice president of academic and clinical affairs at The Texas Liver Institute in San Antonio. “The high SVR rates seen in the ongoing MAGELLAN-1 study are significant as they show promise in addressing this particular clinical challenge.”

No patients discontinued treatment due to adverse events, and two patients experienced virologic failure, one from each arm.¹ The most common adverse events (≥10 percent of patients overall; n=44) were headache (30 percent), fatigue (27 percent) and nausea (20 percent).¹

“While high virologic cure rates have been demonstrated in clinical studies with current DAA regimens, we recognise that not all patients achieve a cure,” said Rob Scott, M.D., vice president, development and chief medical officer, AbbVie. “Through our ongoing clinical development programme, we are striving to give HCV patients a potential option for retreatment.”

About MAGELLAN-1¹

MAGELLAN-1 is an ongoing Phase 2, randomised, open-label multicentre study to evaluate the efficacy, safety and pharmacokinetics of ABT-493 and ABT-530, with and without RBV, in adults with GT1 and genotypes 4-6 chronic HCV infection who failed a prior DAA-containing therapy.

In Part 1 of the study, 50 GT1 patients without cirrhosis who previously failed therapy containing a protease inhibitor and/or NS5A inhibitor, with or without a NS5B polymerase inhibitor, were randomised to receive once-daily ABT-493 and ABT-530 at doses of 200/80mg (Arm A), 300/120mg with 800mg RBV (Arm B), or 300/120mg without RBV (Arm C), for 12 weeks. The primary efficacy endpoint was SVR₁₂. Patients who failed previous treatment for reasons other than breakthrough or relapse were excluded. Deep sequencing (Illumina MiSeq) revealed pre-existing resistance-associated variants (RAVs) in 41 patients (82 percent), 15 in NS3, 10 in NS5A, and 16 with RAVs in both targets. Data presented at ILC 2016 were based on an analysis of the intent-to-treat population.

Data from the first six patients enrolled in Arm A (once-daily ABT-493 and ABT-530 at doses of 200/80mg) showed 100 percent achieved SVR₁₂. Additional patients were enrolled and received study drug at the higher doses of the combination, which will be used in Phase 3 clinical trials, 300/120mg ABT-493/ABT-530 with and without 800mg RBV. There were no grade 3 or 4 laboratory abnormalities.

Part 2 of the study is underway to examine once-daily ABT-493 (300mg) and ABT-530 (120mg) without RBV in a larger group of DAA treatment-experienced patients, including those with compensated cirrhosis and in genotypes 4-6.

About AbbVie's HCV Clinical Development Programme

AbbVie's HCV clinical development programme is intended to advance scientific knowledge and the clinical care of people with chronic HCV infection by investigating pan-genotypic (genotypes 1-6), all-oral, ribavirin-free, once-daily treatment for 12 weeks. An eight-week treatment duration with ABT-493 and ABT-530 will be investigated across all genotypes in our comprehensive Phase 2/Phase 3 clinical trial program, which focuses on areas of ongoing need in HCV.

AbbVie's investigational regimen includes 300mg ABT-493, an NS3/4A protease inhibitor, and 120mg ABT-530, an NS5A inhibitor.

ABT-493 was discovered during the ongoing collaboration between AbbVie and Enanta Pharmaceuticals (NASDAQ: ENTA) for HCV protease inhibitors and regimens that include protease inhibitors.

About AbbVie

AbbVie is a global, research-based biopharmaceutical company formed in 2013 following separation from Abbott Laboratories. The company's mission is to use its expertise, dedicated people and unique approach to innovation to develop and market advanced therapies that address some of the world's most complex and serious diseases. Together with its wholly-owned subsidiary, Pharmacyclics, AbbVie employs more than 28,000 people worldwide and markets medicines in more than 170 countries. For



further information on the company and its people, portfolio and commitments, please visit www.abbvie.co.uk.

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¹ Poordad, F et al. High Efficacy of ABT-493 and ABT-530 in HCV Genotype 1 Infected Patients Who Have Failed Direct-Acting Antiviral-Containing Regimens: The MAGELLAN-I Study. Oral presentation #GS11; presented at The International Liver Congress™ (ILC), the Annual Meeting of the European Association for the Study of the Liver (EASL) in Barcelona, Spain, April 13-17, 2016.