MAVYRET: FOR CHRONIC HCV

TREAT ALL GENOTYPES IN AS FEW AS 8 WEEKS

THE ONLY 8-WEEK PANGENOTYPIC REGIMEN FOR TREATMENT-NAÏVE, NON-CIRRHOTIC PATIENTS

OVERALL

98%

CURE* RATE (SVR12)

per the USPI, in GT 1–6 patients who took the recommended regimen for 8, 12, or 16 weeks (n=1034/1060)[1]

SVR12 varied by GT and prior treatment experience. Range: 92-100% (ITT); 94-100% (mITT)[1]

- **NO** ribavirin[1]
- **NO** baseline viral load restrictions[1]
- **NO** baseline resistance testing required[1]
- **NO** dose adjustment for renal impairment[1]

*Cure = sustained virologic response (SVR12); HCV RNA < LLOQ 12 weeks after the end of treatment.

GT = genotype, LLOQ = lower limit of quantification, mITT = ITT population modified to exclude subjects who did not achieve SVR12 for reasons other than virologic failure.

0.1%

OVERALL DISCONTINUATION RATE OF MAVYRET

due to adverse reactions (n=3/2265), including a placebo-controlled trial[1,2]

- The most common adverse reactions (>10% prevalence) were headache (13%) and fatigue (11%) in patients treated with MAVYRET[1]
- Most adverse reactions were mild in severity[1]
- 1 subject experienced a serious adverse reaction[1]

SIMPLE, ONCE-DAILY DOSING[1]

- 3 tablets in a single-dose pack, taken once daily with food

8 WEEK TREATMENT	GT 1–6	TREATMENT-NAÏVE	NON-CIRRHOTIC
12 WEEK TREATMENT	GT 1–6	TREATMENT-NAÏVE	COMPENSATED CIRRHOTIC
16 WEEK TREATMENT	GT 1	NS5A-EXPERIENCED (NS3/4A PI-NAÏVE)†	COMPENSATED CIRRHOTIC/ NON-CIRRHOTIC

Refer to the full Prescribing Information for further dosing information.

†In clinical trials, subjects were treated with prior regimens containing ledipasvir (LDV) and sofosbuvir (SOF) or daclatasvir (DCV) with pegylated interferon (pegIFN) and ribavirin (RBV).

INDICATION[1]

MAVYRET™ (glecaprevir and pibrentasvir) tablets are indicated for the treatment of adult patients with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A). MAVYRET is also indicated for the treatment of adult patients with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor (PI), but not both.

SAFETY CONSIDERATIONS[1]

Test all patients for evidence of current or prior hepatitis B virus (HBV) infection before initiating treatment with MAVYRET. HBV reactivation has been reported in HCV/HBV coinfected patients who were undergoing or had completed treatment with HCV direct-acting antivirals and were not receiving HBV antiviral therapy. Some cases have resulted in fulminant hepatitis, hepatic failure, and death. Monitor HCV/HBV coinfected patients for hepatitis flare or HBV reactivation during HCV treatment and post-treatment follow-up. Initiate appropriate patient management for HBV infection as clinically indicated. MAVYRET is contraindicated in patients with severe hepatic impairment (Child-Pugh C) and with coadministration of atazanavir or rifampin. Carbamazepine, efavirenz, and St. John's Wort may significantly decrease plasma concentrations of glecaprevir and pibrentasvir, leading to reduced therapeutic effect of MAVYRET. The use of these agents with MAVYRET is not recommended.

Please see Important Safety Information, including BOXED WARNING on Hepatitis B Virus reactivation, on the following page.

Please see full Prescribing Information.

MAVYRET™
glecaprevir/pibrentasvir
100 mg/40 mg tablets

IMPORTANT SAFETY INFORMATION[1]

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF HEPATITIS B VIRUS REACTIVATION IN PATIENTS COINFECTED WITH HCV AND HBV: Test all patients for evidence of current or prior hepatitis B virus (HBV) infection before initiating treatment with MAVYRET. HBV reactivation has been reported in HCV/HBV coinfected patients who were undergoing or had completed treatment with HCV direct-acting antivirals and were not receiving HBV antiviral therapy. Some cases have resulted in fulminant hepatitis, hepatic failure, and death. Monitor HCV/HBV coinfected patients for hepatitis flare or HBV reactivation during HCV treatment and post-treatment follow-up. Initiate appropriate patient management for HBV infection as clinically indicated.

CONTRAINDICATIONS

MAVYRET is contraindicated:

- In patients with severe hepatic impairment (Child-Pugh C)
- With the following drugs: atazanavir or rifampin

WARNINGS AND PRECAUTIONS

Risk of Reduced Therapeutic Effect Due to Concomitant Use of MAVYRET with Carbamazepine, Efavirenz-containing Regimens, or St. John's Wort

- Carbamazepine, efavirenz, and St. John's Wort may significantly decrease plasma concentrations of glecaprevir and pibrentasvir, leading to reduced therapeutic effect of MAVYRET. The use of these agents with MAVYRET is not recommended.

ADVERSE REACTIONS

Most common adverse reactions observed with MAVYRET:

- >10% of subjects: headache and fatigue
- ≥5% of subjects: headache, fatigue, and nausea

Please see full Prescribing Information.

STUDY DESIGNS

EXPEDITION 1[1]
A single-arm, open-label, phase 3 study to evaluate the efficacy and safety of MAVYRET for 12 weeks in 146 treatment-naïve or prior treatment-experienced [ie, interferon (IFN) or pegIFN ± RBV, or SOF + RBV ± pegIFN] GT 1, 2, 4–6-infected adults with compensated cirrhosis. Primary endpoint: SVR12.

MAGELLAN 1[1]
A randomized, open-label, 2-part, phase 2 study to evaluate the efficacy, safety, and pharmacokinetics of MAVYRET with or without RBV for 12 or 16 weeks in 141 direct-acting antiviral-experienced GT 1, 4-infected adults without cirrhosis or with compensated cirrhosis. Part 1: GT 1 non-cirrhotic patients were administered MAVYRET with or without RBV for 12 weeks. Part 2: GT 1, 4 patients without cirrhosis or with compensated cirrhosis were administered MAVYRET for 12 or 16 weeks. Primary endpoint: SVR12.

ENDURANCE 1[3]
A randomized, open-label, multicenter, phase 3 study to evaluate the efficacy and safety of MAVYRET for 8 or 12 weeks in 703 treatment-naïve or prior treatment-experienced (ie, IFN or pegIFN ± RBV, or SOF + RBV ± pegIFN) GT 1-infected adults without cirrhosis and with or without HIV-1 coinfection. Primary endpoints: SVR12 in the 12-week ITT-PS population (ITT population excluding patients with HIV coinfection and patients with SOF experience); SVR12 in the 8-week arm compared with the 12-week arm in the ITT-PS and per-protocol ITT-PS populations ("per-protocol" excludes patients with premature discontinuation or virologic failure prior to week 8 and missing data in the SVR12 window).

ENDURANCE 3[4]
A partially randomized, open-label, active-controlled, multicenter, phase 3 study to evaluate the efficacy and safety of MAVYRET for 8 or 12 weeks vs SOF + DCV for 12 weeks in 505 treatment-naïve GT 3-infected adults without cirrhosis. Primary endpoints: demonstrate noninferiority in the percentage of subjects achieving SVR12 with 12 weeks of MAVYRET treatment to 12 weeks of treatment with SOF + DCV, and demonstrate noninferiority of 8 weeks of MAVYRET treatment to 12 weeks of MAVYRET treatment.

SURVEYOR 2[5-8]
A randomized, open-label, multicenter, 4-part, phase 2 study to evaluate the efficacy, safety, and pharmacokinetics of MAVYRET with or without RBV in 691 treatment-naïve or treatment-experienced (ie, IFN or pegIFN ± RBV, or SOF + RBV ± pegIFN) GT 2–6-infected adults, without cirrhosis or with compensated cirrhosis. Part 2: GT 2, 3 non-cirrhotic patients were administered MAVYRET for 8 weeks and GT 3 patients without cirrhosis or with compensated cirrhosis were administered MAVYRET with or without RBV for 12 weeks. Part 3: GT 3 patients without cirrhosis or with compensated cirrhosis were administered MAVYRET for 12 or 16 weeks. Part 4: GT 2, 4–6 non-cirrhotic patients were administered MAVYRET for 8 weeks. Primary endpoints: SVR12 in each treatment arm and noninferiority of SVR12 for GT 2 (Part 4) to historical control with 12 weeks of SOF + RBV.

References: 1. MAVYRET [package insert]. North Chicago, IL: AbbVie Inc.; 2017. **2.** Data on file. ABVRRTI64685. AbbVie Inc.; 2017. **3.** Zeuzem S, Feld J, Wang S, et al. ENDURANCE-1: A phase 3 evaluation of the efficacy and safety of 8- versus 12-week treatment with glecaprevir/pibrentasvir (formerly ABT-493/ABT-530) in HCV genotype 1 infected patients with or without HIV-1 co-infection and without cirrhosis. Poster presented at: The Liver Meeting® 2016. American Association for the Study of Liver Disease; November 11-15, 2016; Boston, MA. **4.** Foster GR, Gane E, Asatryan A, et al. ENDURANCE-3: safety and efficacy of glecaprevir/pibrentasvir compared to sofosbuvir plus daclatasvir in treatment-naïve HCV genotype 3-infected patients without cirrhosis. Abstract presented at: 52nd Annual Meeting of the European Association for the Study of the Liver; April 19-23, 2017; Amsterdam, the Netherlands. **5.** Data on file. ABVRRTI64729. AbbVie Inc.; 2017. **6.** Kwo PY, Wyles DL, Wang S, et al. 100% SVR12 with ABT-493 + ABT-530 with or without ribavirin in treatment-naïve HCV genotype 3-infected patients with cirrhosis. Poster presented at: 51st Annual Meeting of the European Association for the Study of the Liver; April 16, 2016; Barcelona, Spain. **7.** Wyles D, Poordad F, Wang S, et al. SURVEYOR-II, Part 3: efficacy and safety of glecaprevir/pibrentasvir (ABT-493/ABT-530) in patients with hepatitis C virus genotype 3 infection with prior treatment experience and/or cirrhosis. Poster presented at: The Liver Meeting® 2016. American Association for the Study of Liver Disease; November 11-15, 2016; Boston, MA. **8.** Hassanein T, Wyles D, Wang S, et al. SURVEYOR-II, Part 4: glecaprevir/pibrentasvir demonstrates high SVR rates in patients with HCV genotype 2, 4, 5, or 6 infection without cirrhosis following an 8-week treatment duration. Poster presented at: 52nd Annual Meeting of the European Association for the Study of the Liver; April 19-23, 2017; Amsterdam, the Netherlands.

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