

1-PAGE SUMMARY: GLECAPREVIR/PIBRENTASVIR (G/P) COMBO FOR HCV

Areas of unmet medical need which are covered well by AbbVie's glecaprevir/pibrentasvir (G/P) combo:

- **GT3-infection with compensated cirrhosis** (no ascites, no varices, no hepatic encephalopathy; Child-Pugh scores 5-6). Higher chance of SVR than with existing drugs, and no need for ribavirin. Treatment-naïve: **98% - 100% cure rate**. Treatment-experienced: **96% cure rate**.
- Genotypes 2, 3, 5, and 6 patients with **chronic kidney disease (CKD 4 & 5)**, even severe **renal impairment: 98% - 100% cure rate**.
- **Failed treatment** with one of the newer hepatitis C drugs (DAAs): **89% cure rate**.

Use in **other populations** very similar to existing DAA drugs:

- Genotypes 1, 2, 4, 5, and 6 patients with **compensated cirrhosis (Child-Pugh scores 5-6): 99% cure rate**.
- Presence of **HIV co-infection did not affect cure rate**, and in most cases treatment for HIV did not have to be interrupted.

Treatment Details:

- Once per day, oral treatment (3 tablets), ribavirin-free.
- 8 weeks of treatment for those without cirrhosis, 12 weeks for those with cirrhosis
- Covers all genotypes
- Glecaprevir is an NS3/4A protease inhibitor; pibrentasvir is an NS5A inhibitor.

Adverse events (side-effects) occurring in more than 10% of patients, in order of frequency:

- Fatigue
- Headache
- Nausea
- Pruritis
- 40% - 76% of patients (depending on the study) reported some adverse event (related to the G/P or to some other cause)
- 2% - 8% of patients (depending on the study) reported a serious adverse event, and one died. It was determined that all serious events and the death were **unrelated to the G/P combo** study drug.
- Two patients discontinued treatment due to an adverse event.