Long-term Follow-up of Patients Treated With Sofosbuvir in the Phase 3 Studies FISSION, POSITRON, FUSION, and NEUTRINO

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Introduction

- High sustained virologic response rates 24 weeks after treatment end (SVR24) were achieved with sofosbuvir (SOF)-based regimens in Phase 3 studies.1–3
- No resistance to SOF has been detected in patients with hepatitis C virus (HCV) who did not achieve SVR24 in the Phase 3 studies.

Study Objectives

- To assess progression of liver disease and hepatocellular carcinoma in patients who completed treatment in the SOF Phase 3 studies.
- To assess persistence of resistance-associated variants in the viral population of patients who did not achieve SVR24 in the SOF Phase 3 studies.
- To evaluate the duration of SVR24 in patients from the SOF Phase 3 studies.

Study Methods

- Patients without an SVR24 had a higher incidence of liver-related events compared to patients with an SVR24.
- Of 480 patients with an SVR24 from the Phase 3 trials, 435 (91%) and 90 (19%) had available Week 24 and Week 48 data, respectively.

Patient Disposition

- The demographic characteristics of the patients enrolled in the SVR and Sequence Registries were similar.
- The Sequence Registry had a greater proportion of patients with cirrhosis and with genotype 3 HCV infection compared to the SVR Registry.

Duration of Time in Registry

- Of 480 patients with an SVR24 from the Phase 3 trials, 435 (91%) and 90 (19%) had available Week 24 and 48 data, respectively.
- SVR24 was durable in 100% of these patients.

Liver-Related Events

- No hepatocellular carcinoma or deaths were reported.
- Two patients had hepatocellular carcinoma at study entry; 1 death reported.

Laboratory Evaluations

- ALT, alanine aminotransferase; AST, aspartate aminotransferase; INR, international normalized ratio; ULN, upper limit of normal.

Conclusions

- All patients who achieved an SVR24 with SOF-based regimens in the Phase 3 studies and entered the SVR Registry have maintained virologic response.
- Median time of follow-up: 170 days (~24 weeks) after SVR24.
- No sequencing was performed in patients who did not achieve an SVR24, as no resistance-associated variants were detected at relapse during the Phase 3 studies.
- Patients without an SVR24 had a higher incidence of grades 3–4 laboratory abnormalities.

References