Title:
Antiviral treatment with Sofosbuvir plus ribavirin in “waitlisted” patients with HCV-related end stage liver disease (ESLD) without HCC

Promoter:
Pierluigi Toniutto, on behalf of the Italian Association for the Study of the Liver (AISF)

Financial support:
Gilead Sciences

Participants:
All AISF hepatologists involved in the management of liver transplanted patients after local ethic committee approval
Rationale
HCV infection is the major indication for liver transplantation worldwide, and its recurrence is virtually universal. Once reinfection is established, progression to cirrhosis can occur in about 25-30% of the recipients within 5 years. Interferon-based antiviral treatments strongly limit number of potentially treatable ESLD patients. The pre-transplant IFN-free treatment aiming to achieve HCV-RNA negativity at transplant could be the preferred strategy.

Objectives
To determine if the administration of a combination of Sofosbuvir plus ribavirin up to the transplant procedure (maximum for 48 weeks) in waitlisted patients with liver cirrhosis can prevent post-transplant HCV re-infection as determined by a sustained post-transplant virological response (HCV RNA <LLoQ) at 24 weeks post-transplant

Secondary Objectives:
MELD score improvement during treatment - removal from waitlist
HCV-RNA kinetics in advanced liver disease
**Eligibility:**
- Males or females, age > 18 years old;
- All ESLD patients with HCV active mono-infection included in a waiting list for first OLT (MELD score between 15 and 24 or accepted MELD exceptions)
- All HCV genotypes

**Exclusion:**
- Patients with known HCC
- < 6 months from previous PI treatment
- Combined liver-kidney transplant
- CrCl < 30ml/min

**Projected Duration of Treatment** up to 48 weeks

**Study Duration** Up to 72 weeks (up to 48 w treatment + 24 w follow-up)

**Start of protocol:** after Gilead International Scientific board approval