

NASH(Nonalcoholic Steatohepatitis) Patients

Treatment Drug:

Selonsertib

INCLUSION Criteria : (Patient should meet the Inclusion criteria mentioned below to be eligible to participate)

1. Age 18-70
2. Liver biopsy consistent with NASH (defined as the presence of at least grade 1 steatosis, hepatocellular ballooning and lobular inflammation according to the NAFLD Activity score [NAS] and cirrhosis (F4Cirrhosis) according to the NASH CRN classification, in the opinion of the central reader.
 - a) A historical liver biopsy within 12 months of the screening visit may be accepted as the Screening biopsy if the sample is deemed acceptable for interpretation by the central reader.
 - b) If the subject is deemed ineligible for this study, the liver biopsy, if performed according to protocol specifications and is within 6 months of the Screening visit, may be used to determine eligible for study GS-US-384-1944.
3. Subject has the following laboratory parameters at the Screening visit, as determined by the central laboratory:
 - a)ALT<8Xuln
 - b) CLcr>30 ml/min.
 - c)HbA1c<9.5%
4. Body Mass Index(BMI) > 18kg/m at the Screening

ALL THE BELOW MENTIONED TESTS WILL BE FREE OF COST.

(If the patient meets the inclusion criteria)

STEP-1	Liver biopsy, Ultrasound Elastography	Patient has cirrhosis/Fibrosis
STEP-2	ECG	ECG Should be Normal
STEP-3	HEMATOLOGY/BIOCHEMISTRY	CBP, HB, Serum electrolytes, Glucose, Albumin – Normal Values

Duration of the study: Five Years

No of Visits to the Hospital: Once in a month (02 Screening visits+01 year-12 visits for Medication 02 year-04 visits +03year- 04visits +04 year-04 visits+05 year-04 visits) **Total-30 visits.**

Travelling amount per visit: Rs 1200.