An Open-Label Study of GS-7977+ Ribavirin with or without Peginterferon Alfa-2a in Subjects with Chronic HCV Infection who Participated in Prior Gilead HCV Studies

Published: 18-09-2012
Last updated: 26-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatic and hepatobiliary disorders
Study type	Interventional

Summary

ID

NL-OMON39611

Source
ToetsingOnline

Brief title
Open label GS-7977

Condition

- Hepatic and hepatobiliary disorders
- Viral infectious disorders

Synonym
liver disease, liver inflammation

Research involving
Human

Sponsors and support

Primary sponsor: Gilead Sciences
Source(s) of monetary or material Support: Gilead Sciences Inc.

Intervention

Keyword: chronic hepatitis C, GS-7977 (study product), ribavarin

Outcome measures

Primary outcome

The primary efficacy endpoint is SVR12 (HCV RNA
discontinuation of therapy) in the Full Analysis Set (FAS) population.

The primary safety endpoint is any AE leading to permanent discontinuation of

study drug(s).

Secondary outcome

Secondary efficacy endpoints include the proportion of subjects with: HCV RNA <

LLOQ at 4 and 24 weeks after discontinuation of therapy (SVR4 and SVR24); on

treatment virologic failure; and relapse.

Study description

Background summary

See protocol page 14, section 1.1

Study objective

The primary objectives of this study are:
* To determine the efficacy of GS-7977 + RBV with or without Peginterferon alfa-2a (PEG) as measured by the proportion of subjects with sustained viral response at 12 weeks after discontinuation of therapy (SVR12).
* To evaluate the safety and tolerability of GS-7977 + RBV with or without PEG as assessed by review of the accumulated safety data.

The secondary objectives of this study are:
* To determine the proportion of subjects who attain SVR at 4 and 24 weeks after discontinuation of therapy (SVR4 and SVR24)
* To evaluate the kinetics of plasma HCV RNA during and after treatment discontinuation
* To evaluate the emergence of viral resistance to GS 7977 during and after treatment discontinuation

The exploratory objectives of this study are:
* To assess the effect of treatment on quality of life
* To assess the association between insulin resistance and HCV infection

Study design

Open-labeled, multicenter study in subjects with chronic HCV infection and who participated in a prior Gilead HCV study.

Approximately 600 subjects will be enrolled into one of the following treatment arms:

* Arm 1 (genotype 2 HCV-infected subjects): GS-7977 400 mg QD + RBV (1000 or 1200 mg/day) for 12 weeks
* Arm 2 (genotype 2 and 3 HCV-infected subjects): GS-7977 400 mg QD + RBV (1000 or 1200 mg/day) for 24 weeks
* Arm 3 (all genotypes of HCV-infected subjects): GS-7977 400 mg QD + RBV (1000 or 1200 mg/day) + PEG (180 *g/week) for 12 weeks
HCV RNA results will be unblinded to the Investigator and Sponsor.

Subjects will be offered treatment based on prior treatment history, genotype, interferon tolerance and other individual factors including investigator judgment.

HCV RNA results will be unblinded to the Investigator and Sponsor.

Sequence Registry Study:
Subjects who do not achieve SVR will be eligible for enrollment in the Sequence Registry Study. The purpose of the Sequence Registry Study will be to monitor the persistence of resistant mutations for up to 3 years. The Sequence Registry Study is described in a separate protocol (GS US 248 0123).

SVR Registry Study:
All subjects who achieve SVR will be eligible for enrollment in the SVR Registry Study. The purpose of the SVR Registry Study will be to evaluate durability of SVR for up to 3 years post-treatment. The SVR Registry Study is described in a separate protocol (GS US-248-0122).

Intervention

* Arm 1 (genotype 2 HCV-infected subjects): GS-7977 400 mg QD + RBV (1000 or 1200 mg/day) for 12 weeks
* Arm 2 (genotype 2 and 3 HCV-infected subjects): GS-7977 400 mg QD + RBV (1000 or 1200 mg/day) for 24 weeks
* Arm 3 (all genotypes of HCV-infected subjects): GS-7977 400 mg QD + RBV (1000 or 1200 mg/day) + PEG (180 *g/week) for 12 weeks

Study burden and risks

For a complete overview of risks and discomforts related, please consult Appendix 2.

Contacts

Public
Gilead Sciences

Lakeside Drive 333
Foster City CA 94404
US
Scientific
Gilead Sciences

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Foster City CA 94404
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Subjects must meet the following eligibility criteria:
* Chronic HCV
* Subject must have participated in a prior Gilead HCV studie
* Eligibility for this study will be defined in the prior (parent) study with respect to prior treatment assignment, treatment outcome and completion of scheduled assessments. At a minimum, a subject must have completed all screening assessments and met all eligibility criteria in the parent study.
* If eligibility is not defined in the parent study, eligibility can be determined by the Medical Monitor on a case-by-case basis. The Medical Monitor will take into consideration the prior treatment assignment, treatment outcome and completion of scheduled assessments in the parent study.
* Agree to use two forms of contraception for the duration of the study and for 6 months after the last dose of study medication. Females of childbearing potential must have a negative pregnancy test at Screening and Baseline/Day 1

Exclusion criteria

Subjects will be ineligible if they meet any of the following criteria:
* Pregnant or nursing female or male with pregnant female partner
* Current or prior history of clinical hepatic decompensation (e.g., ascites, encephalopathy or variceal hemorrhage).
* Infection with hepatitis B virus (HBV) or human immunodeficiency virus (HIV)
* Chronic use of systemically administered immunosuppressive agents (e.g., prednisone equivalent > 10 mg/day)
* Active substance abuse which, in the opinion of the investigator, would make the candidate inappropriate for participation in this study.
* Use of any prohibited concomitant medications within 28 days of the Baseline/Day 1 visit

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-08-2013
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Copegus
Generic name:	ribavirin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	GS-7977
Generic name:	sofosbuvir or SOF
Product type:	Medicine
Brand name:	Pegasys
Generic name:	Peginterferon alfa-2a
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	18-09-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-12-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-04-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	10-06-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-07-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-10-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-11-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-05-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-06-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2012-000571-16-NL
ClinicalTrials.gov	NCT01625338
CCMO	NL41479.018.12