A Long Term Follow-up Registry of Subjects Treated in A Gilead-Sponsored Trial in Subjects with Chronic Hepatitis B Infection

Published: 25-05-2016
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The primary objective of this Registry is:*To evaluate the long term effects of Hepatitis B Virus (HBV) treatment of the parental study on the HBV serologic changes through Week 144 The secondary objective of this Registry is :*To evaluate the long...

Ethical review	Approved WMO
Status	Pending
Health condition type	Viral infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON43924

Source
ToetsingOnline

Brief title
GS-US-330-1508

Condition

- Viral infectious disorders

Synonym
Chronic Hepatitis B, inflammation of liver

Research involving
Human

Sponsors and support

Primary sponsor: Gilead Sciences, Inc

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

Intervention

Keyword: Chronic Hepatitis B, Long Term Follow-up Registry

Outcome measures

Primary outcome

The primary endpoints of this Registry are:

*For subjects who are HBsAg positive at Baseline:

The proportion of subjects with serum HBsAg decline * 0.5 log10 IU/ml from

Baseline at Week 48

*For subjects who are HBsAg negative at Baseline:

The proportion of subjects who remain HBsAg negative at Week 48

Secondary outcome

The secondary endpoints of this Registry are:

*For subjects who are HBsAg positive at Baseline:

The proportion of subjects with serum HBsAg decline * 0.5 log10 IU/ml from

Baseline at Week 144

The proportion of subjects who achieve HBsAg loss at Weeks 48 and 144

*For subjects who are HBsAg negative at Baseline:

The proportion of subjects who remain HBsAg negative at Week 144

*For subjects HBeAg positive at Baseline:

proportions of subjects with HBeAg loss and seroconversion at Week 48

proportions of subjects with HBeAg loss and seroconversion at Week 144

*For HBeAg positive subjects who achieved HBeAg seroconversion during the

parental study:

proportions of subjects who remain HBeAg negative and HBeAb positive at

Week 48-proportions of subjects who remain HBeAg negative and HBeAb positive at

Week 144

*For subjects on treatment with OAV anti-HBV, the proportion of subjects with

HBV-DNA < LLOQ at Weeks 48, 96 and 144

The change from Baseline in HBV DNA at Weeks 48, 96, and 144

The exploratory endpoints of this Registry are:

*For subjects on treatment with OAVs anti-HBV, the proportion of subjects with

HBV DNA < LLOQ target detected and proportion of subjects with HBV DNA < LLOQ

target not detected, at Weeks 48, 96 and 144

*Quality of Life measures in subjects who achieve HBsAg loss and in subjects

who do not achieve HBsAg loss

Study description

Background summary

See protocol page 10, 1.1 Background

Study objective

The primary objective of this Registry is:
*To evaluate the long term effects of Hepatitis B Virus (HBV) treatment of the parental study on the HBV serologic changes through Week 144
The secondary objective of this Registry is :
*To evaluate the long term effects of HBV treatment of the parental study on changes in HBV DNA levels through Week 144
The exploratory objective of this Registry is:
*To assess quality of life following treatment in a Gilead sponsored chronic hepatitis B study.

Study design

This Registry will enroll subjects who were treated in a Gilead sponsored chronic hepatitis B (CHB) study. Subjects who were treated in selected Gilead-sponsored studies for CHB are eligible to participate in this Registry. In order to manage the total study enrollment, Gilead Sciences, Inc. will determine which treatment protocols and sites to include in this Registry study. At its sole discretion, Gilead may at any time discontinue enrollment, suspend screening, and/or early withdraw individual subjects from individual treatment protocols prior to study completion (upon written notice to the site) regardless of the progress or outcome of the protocol assessments performed. Once enrolled, subjects will be followed for up to 144 weeks (three years). A Baseline visit will be scheduled within 120 days from the final visit of the parental protocol, except for subjects from previous Gilead-sponsored study number GS-US-174-0149, who will have up to one year from their last visit in that protocol. Clinic visits will occur at Baseline (Day 1) and at Weeks 12, 24, 48, 72, 96, 120 and 144. For subjects from previous Gilead-sponsored study number GS US 174 0149, a Screening visit is also required to determine eligibility for study participation.
During the Registry, subjects* CHB treatment will be managed per standard of care. Subjects who begin an investigational agent(s) for HBV infection during the course of the Registry will discontinue participation in the Registry.

Intervention

not applicable

Study burden and risks

not applicable

Contacts

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US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Subjects must meet all of the following inclusion criteria to be eligible to participate in the study.
1. Must have participated in a Gilead-sponsored CHB study no more than 120 days prior to Baseline (Day 1), except for subjects from previous Gilead-sponsored study number GS-US-174-0149, who will have up to one year from their last visit in that protocol
2. Must have the ability to understand and sign a written informed consent form, which must be obtained prior to initiation of study procedures
3. Must be willing and able to comply with the visit schedule and study requirements
For subjects from previous Gilead-sponsored study number GS-US-174-0149, subjects must meet either one of the following inclusion criteria to be eligible to participate in the study:
4. Must have documented HBV DNA < 2,000 IU/mL at time of Screening visit, which shall occur no later than 1 year post last study visit in GS-US-174-0149
5. Must have documented HBsAg negative status anytime during participation in GS-US-174-0149 regardless of ongoing HBV treatment

Exclusion criteria

Subjects who meet any of the following exclusion criteria are not eligible to participate in the study.

1. Participating or plans to participate in another clinical study with an investigational agent
2. History or current presence of clinically-significant illness or any other major medical disorder that may interfere with subject follow-up, assessments or compliance with the protocol.
3. Believed by the Study Investigator to be inappropriate for study participation for any reason not otherwise listed
For subjects from previous Gilead-sponsored study number GS-US-174-0149 meeting Inclusion Criteria #4, subjects who meet the following exclusion criteria are not eligible to participate in the study:
4. Received TDF monotherapy either as part of GS-US-174-0149 Arm C (TDF monotherapy arm) or for TDF retreatment, and have taken any HBV antiviral therapy since completion of GS-US-174-0149

Study design

Design

Study phase:	2
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	30-06-2016
Enrollment:	7
Type:	Anticipated

Ethics review

Approved WMO

Date:	25-05-2016

Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-03-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
ClinicalTrials.gov	NCT0225858
CCMO	NL55437.078.16