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Project Name: GS-US-248-0132

Form: 12-Lead ECG [ECG12]

Generated On: Jul-31-2013 11:41:36

Was an ECG performed?

☐ Yes

☐ No

If No, please comment why ECG was not done:

Date of ECG:

Time of ECG:

HR Rate (bpm):

PR Interval (msec):

QRS Interval (msec):

QT Interval (msec):

QTcF Interval (msec) (Calculated)

Overall Assessment of ECG:

☐ Normal

☐ Abnormal

If Abnormal, please describe the abnormality:

Significance of Abnormality:

☐ Not Clinically Significant

☐ Clinically Significant

Project Name: GS-US-248-0132

Form: Adverse Event Summary [AES]

Generated On: Jul-31-2013 11:41:36

Did the subject experience any Adverse Events during the course of the study?

☐ Yes

☐ No

Project Name: GS-US-248-0132

Form: Adverse Event [AE]

Generated On: Jul-31-2013 11:41:36

Adverse Event:

(List diagnosis or each symptom separately)

AE serious:

(If the Adverse Event is Serious, please click the [?] help text to open the SAE Report Form in another window. Print and fill in all the information for the first three pages on the SAE form and fax to the appropriate CRO contact)

☐ Yes

☐ No

Start Date: (DD-MMM-YYYY)

End Date: (DD-MMM-YYYY)

Please check if Ongoing:

☐

Related to any of the Study Drugs:

☐ Yes

(All study drugs are to be considered in assessment of relationship to study drugs: GS-5885, GS-9451, Tego buvir/Placebo , RBV/Placebo)

☐ No

Related to Study Procedures:

☐ Yes

☐ No

Study Drug Action Taken - GS-5885:

☐ No change

☐ Interrupted

☐ Discontinued

☐ Dose Reduced

Study Drug Action Taken - GS-9451:

☐ No change

☐ Interrupted

☐ Discontinued

☐ Dose Reduced

Study Drug Action Taken - Tego buvir/Placebo:

☐ No change

☐ Interrupted

☐ Discontinued

☐ Dose Reduced

Project Name: GS-US-248-0132

Form: Adverse Event [AE]

Generated On: Jul-31-2013 11:41:36

Study Drug Action Taken - RBV/Placebo:

- ☐ No change
☐ Interrupted
☐ Discontinued
☐ Dose Reduced

Severity:

- ☐ Mild
☐ Moderate
☐ Severe
☐ Life-Threatening

Other Action Taken: (Check all that apply)
None:

☐

Medication Required:

☐

Other Treatment Required:

☐

Hospitalized/Prolonged Hospitalization:

☐

Hidden field for AE_AESER_ALERT

Note: To add additional adverse events, please complete an additional form, by clicking on 'Add a new log line'.

If Adverse Event is Serious, please refer to the regulatory binder for an SAE Report form. Complete an SAE Report and E-mail or fax the SAE Report within 24 hours of the Reporter's knowledge of the event. Contact information for faxing and e-mailing this form is found in the study protocol in section 8.5.1.

A Serious Adverse Event is any adverse experience that results in any of the following outcomes:

- (1) Death,**
- (2) Is life-threatening (at immediate risk of death at time of the event),**
- (3) Requires subject hospitalization or prolonged hospitalization,**
- (4) Persistent or significant disability/incapacity,**
- (5) Congenital abnormality/birth defect or**
- (6) Any other important Medical Event based on clinician's judgment or may require medical or surgical intervention to prevent one of the other serious criteria.**

Refer to protocol for protocol-specific SAE definitions.

Project Name: GS-US-248-0132
Form: Complete Physical Examination [PE]
Generated On: Jul-31-2013 11:41:36

Select a response for each body system. If a body system is not examined, select "Not Done."

Body System

- ☐ Head, Neck & Thyroid
- ☐ Eyes, Ears, Nose, Throat, Mouth & Tongue
- ☐ Chest (Excluding breasts)
- ☐ Respiratory
- ☐ Cardiovascular
- ☐ Lymph Nodes
- ☐ Abdomen
- ☐ Skin, Nails & Hair
- ☐ Musculoskeletal
- ☐ Neurological
- ☐ Retinal Exam Results
- ☐ Other

If Body System is Other, please specify:

Result:

- ☐ Abnormal
- ☐ Normal
- ☐ Not Done

If "Abnormal", please describe abnormal physical findings:

If additional Body Systems are needed then click on 'Add New Log Line' at the bottom of the form.

Project Name: GS-US-248-0132

Form: Concomitant Medication Summary [CMS]

Generated On: Jul-31-2013 11:41:36

Did the subject take any Medications from time of informed consent signing through study completion?

☐ Yes

☐ No

Project Name: GS-US-248-0132

Form: Concomitant Medication [CM]

Generated On: Jul-31-2013 11:41:36

Drug Name:

Indication: (Use Medical Terminology)

Route:

- ☐ Inhalation
- ☐ Intradermal
- ☐ Intralesional
- ☐ Intramuscular
- ☐ Intranasal
- ☐ Intravenous
- ☐ Intraocular
- ☐ Intraperitoneal
- ☐ Oral
- ☐ Rectal
- ☐ Subcutaneous
- ☐ Sublingual
- ☐ Topical
- ☐ Vaginal
- ☐ Other

If "Other", please specify:

Start Date: (DD-MMM-YYYY)

Stop Date: (DD-MMM-YYYY)

Please check if Ongoing:

☐

Note: To add additional concomitant medications, please complete an additional form, by clicking on 'Add a new log line'.

Project Name: GS-US-248-0132
Form: Death Report [DEATH]
Generated On: Jul-31-2013 11:41:36

In addition to this eCRF, please refer to the regulatory binder for an SAE Report form. Complete an SAE Report and E-mail or fax the SAE Report within 24 hours of the Reporter's knowledge of the event. Please also send a copy of the discharge/death summary and autopsy report, if available.

Contact information for faxing and e-mailing these forms is found in the study protocol in section 8.5.1 (Click the [?] help text to open the SAE Report Form in another window. Please fill in all appropriate information on the first three pages before faxing the forms to the appropriate CRO contact.)

Please update the Adverse Event eCRF, as needed.

Date of Death: (DD-MMM-YYYY)

Immediate Cause of Death:

Project Name: GS-US-248-0132

Form: Demographics [DM]

Generated On: Jul-31-2013 11:41:36

Date of Birth: (DD-MMM-YYYY)

Age:

Sex:

☐

Male

☐

Female

Ethnicity:

☐

Hispanic or Latino

☐

Not Hispanic or Latino

☐

Not Permitted

Race:

☐

American Indian or Alaska Native

☐

Asian

☐

Black or African Heritage

☐

Native Hawaiian or Pacific Islander

☐

White

☐

Not Permitted

☐

Other

If "Other", please specify:

Year of Birth (yyyy)

Project Name: GS-US-248-0132

Form: Dose Administration (Day 1) [PKEX]

Generated On: Jul-31-2013 11:41:36

Name of Actual Treatment:

- ☐ GS-5885
- ☐ GS-9451
- ☐ Tegobuvir/Placebo
- ☐ RBV/Placebo

Date of First Dose: (DD-MMM-YYYY)

Time of First Dose: (00:00-23:59)

Dose:

Dose Units:

- ☐ mg
- ☐ ug
- ☐ tablets
- ☐ capsules

Dose Taken With Food

- ☐ Yes
- ☐ No

Project Name: GS-US-248-0132

Form: Dose Administration (Serial PK) [PKEX2]

Generated On: Jul-31-2013 11:41:36

Dose Timepoint:

- ☐ Pre-PK Day Dose
- ☐ PK Day AM Dose
- ☐ PK Day PM Dose
- ☐ Post-PK Day AM Dose

Name of Actual Treatment:

- ☐ GS-5885
- ☐ GS-9451
- ☐ Tego buvir/Placebo
- ☐ RBV/Placebo

Date of Dose: (DD-MMM-YYYY)

Time of Dose: (00:00-23:59)

Dose:

Dose Units:

- ☐ mg
- ☐ ug
- ☐ tablets
- ☐ capsules

Dose Taken With Food:

- ☐ Yes
- ☐ No

Project Name: GS-US-248-0132

Form: Dose Administration (Single PK) [PKEX1]

Generated On: Jul-31-2013 11:41:36

Check 'Not Applicable' box if Subject is participating in Serial PK Substudy at this visit:

☐

Name of Actual Treatment:

☐

GS-5885

☐

GS-9451

☐

Tegobuvir/Placebo

☐

RBV/Placebo

Date of Dose prior to Sample Draw: (DD-MMM-YYYY)

Time of Dose prior to Sample Draw: (00:00-23:59)

Dose:

Dose Units:

☐

mg

☐

ug

☐

tablets

☐

capsules

Dose Taken With Food

☐

Yes

☐

No

Project Name: GS-US-248-0132

Form: Dose Administration (Viral Dynamic Substudy) [PKEX3]

Generated On: Jul-31-2013 11:41:36

Name of Actual Treatment:

- ☐ GS-5885
- ☐ GS-9451
- ☐ Tegobuvir/Placebo
- ☐ RBV/Placebo

Date of Dose prior to Sample Draw: (DD-MMM-YYYY)

Time of Dose prior to Sample Draw: (00:00-23:59)

Dose:

Dose Units:

- ☐ mg
- ☐ ug
- ☐ tablets
- ☐ capsules

Dose Taken With Food:

- ☐ Yes
- ☐ No

Project Name: GS-US-248-0132

Form: General Comments [CO]

Generated On: Jul-31-2013 11:41:36

Visit:

- ☐ Screening
 - ☐ Initial Treatment Visits
 - ☐ Baseline/Day 1
 - ☐ Week 1
 - ☐ Week 2
 - ☐ Week 4
 - ☐ Week 6
 - ☐ Week 8
 - ☐ Week 10
 - ☐ Week 12
 - ☐ Week 16
 - ☐ Week 20
 - ☐ Week 24
 - ☐ Early Termination (Initial Treatment)
 - ☐ Study Drug Completion (Initial Treatment)
 - ☐ PK and/or Viral Dynamic Substudies
 - ☐ Day 1
 - ☐ Day 2
 - ☐ Day 3
 - ☐ Day 4
 - ☐ Day 5
 - ☐ Day 10
 - ☐ PK Week 2
 - ☐ Post-Treatment Follow-Up Visits
 - ☐ Post-Treatment Follow-Up Week 4
 - ☐ Post-Treatment Follow-Up Week 8
 - ☐ Post-Treatment Follow-Up Week 12
 - ☐ Post-Treatment Follow-Up Week 16
 - ☐ Post-Treatment Follow-Up Week 20
-

Project Name: GS-US-248-0132

Form: General Comments [CO]

Generated On: Jul-31-2013 11:41:36

- ☐ Post-Treatment Follow-Up Week 24
 - ☐ Post-Treatment Follow-Up Month 6
 - ☐ Adverse Events
 - ☐ Concomitant Medication
 - ☐ Study Drug Administration
 - ☐ Study Drug Accountability
 - ☐ Pregnancy Report
 - ☐ Death
 - ☐ General Comments
 - ☐ Unscheduled
 - ☐ Study Completion
 - ☐ Missed Dose Overdose Log
-

Project Name: GS-US-248-0132

Form: General Comments [CO]

Generated On: Jul-31-2013 11:41:36

Form:

- ☐ Adverse Event
- ☐ Adverse Event Summary
- ☐ Complete Physical Examination
- ☐ Concomitant Medication
- ☐ Concomitant Medication Summary
- ☐ Death Report
- ☐ Demographics
- ☐ Dose Administration (Day 1)
- ☐ Dose Administration (Single PK)
- ☐ Dose Administration (Serial PK)
- ☐ Dose Administration (Viral Dynamic Substudy)
- ☐ General Comments
- ☐ Inclusion/Exclusion Criteria
- ☐ Investigator's Signature
- ☐ Liver Fibrosis Assessment
- ☐ Medical History
- ☐ Pregnancy Report
- ☐ Randomization
- ☐ Single PK Plasma
- ☐ Serial PK Plasma
- ☐ PK Plasma (Viral Dynamic Substudy Day 1)
- ☐ Stop Treatment
- ☐ Study Completion
- ☐ Study Drug Accountability - GS-5885
- ☐ Study Drug Accountability - GS-9451
- ☐ Study Drug Accountability - Tego buvir/Placebo
- ☐ Study Drug Accountability - RBV
- ☐ Study Drug Administration - Initial Treatment
- ☐ Study Drug Completion (Initial Treatment)

Project Name: GS-US-248-0132
Form: General Comments [CO]
Generated On: Jul-31-2013 11:41:36

- ☐ Subject Follow-Up Status
- ☐ Urine Pregnancy Test
- ☐ Urine Pregnancy Test (Baseline)
- ☐ Visit Date
- ☐ 12-Lead ECG
- ☐ Missed Dose and Overdose Log
– Initial Treatment
- ☐ Prior HCV Treatment History
- ☐ Interferon Classification
- ☐ Interferon Ineligibility Reasons
- ☐ Interferon Intolerant Reasons
- ☐ Vital Signs
- ☐ Vital Signs (Screening)
- ☐ Vital Signs with Weight

General Comments:

General Comments (Continued)

Note: To add additional comments, please complete an additional form, by clicking on 'Add a new log line'.

Project Name: GS-US-248-0132

Form: Inclusion/Exclusion Criteria [IE]

Generated On: Jul-31-2013 11:41:36

Date informed Consent Signed: (DD-MMM-YYYY)

Under which protocol version was the subject enrolled?

☐

Original

☐

Amendment 1

Was subject a Screen Failure?

☐

Yes

☐

No

Did the subject meet all eligibility criteria?

☐

Yes

☐

No

If “No”, Please complete the following (Please tick all Inclusion criteria not met or Exclusion criteria met):

Inclusion/Exclusion criteria:

- ☐ Inclusion 1
 - ☐ Inclusion 2
 - ☐ Inclusion 3
 - ☐ Inclusion 4
 - ☐ Inclusion 5
 - ☐ Inclusion 6
 - ☐ Inclusion 7
 - ☐ Inclusion 8
 - ☐ Inclusion 9
 - ☐ Inclusion 10
 - ☐ Inclusion 11
 - ☐ Inclusion 12
 - ☐ Inclusion 13
 - ☐ Inclusion 14
 - ☐ Inclusion 15
 - ☐ Inclusion 16
 - ☐ Inclusion 17
 - ☐ Exclusion 1
 - ☐ Exclusion 2
 - ☐ Exclusion 3
 - ☐ Exclusion 4
 - ☐ Exclusion 5
 - ☐ Exclusion 6
 - ☐ Exclusion 7
 - ☐ Exclusion 8
 - ☐ Exclusion 9
 - ☐ Exclusion 10
 - ☐ Exclusion 11
 - ☐ Exclusion 12
-

Project Name: GS-US-248-0132
Form: Inclusion/Exclusion Criteria [IE]
Generated On: Jul-31-2013 11:41:36

- ☐ Exclusion 13
- ☐ Exclusion 14
- ☐ Exclusion 15
- ☐ Exclusion 16
- ☐ Exclusion 17
- ☐ Exclusion 18
- ☐ Exclusion 19
- ☐ Exclusion 20
- ☐ Exclusion 21
- ☐ Exclusion 22
- ☐ Exclusion 23
- ☐ Exclusion 24
- ☐ Exclusion 25
- ☐ Exclusion 26
- ☐ Exclusion 27
- ☐ Exclusion 28
- ☐ Exclusion 29

Inclusion criteria not met/Exclusion criteria met?

☐

If subject that did not meet inclusion/exclusion criteria was enrolled, please provide an explanation.

For subjects who are screen failures but meet eligibility criteria - ONLY:
Provide the most significant reason why the subject was not randomized in the IWRS.

- ☐ Adverse Event
 - ☐ Investigator Decision
 - ☐ Subject Withdrew Consent
 - ☐ Lost to Follow-Up
 - ☐ Outside of Visit Window
 - ☐ Study Enrollment Closed
 - ☐ Other
-

Project Name: GS-US-248-0132

Form: Inclusion/Exclusion Criteria [IE]

Generated On: Jul-31-2013 11:41:36

If "Other", specify:

Project Name: GS-US-248-0132

Form: Interferon Classification [INTC]

Generated On: Jul-31-2013 11:41:37

Please indicate if subject is interferon ineligible or interferon intolerant

☐

Interferon ineligible

☐

Interferon intolerant

Project Name: GS-US-248-0132
Form: Interferon Ineligibility Reasons [INTIR]
Generated On: Jul-31-2013 11:41:37

Please choose the primary Interferon Ineligibility Reason as per Inclusion Criteria #6.

If additional secondary reasons are present, please click on the 'Add a new log line' link at the bottom of the table below.

Primary/Secondary Reasons	<input type="checkbox"/> Primary Reason
	<input type="checkbox"/> Secondary Reason(s)

Interferon Ineligibility Reasons as per Inclusion Criteria #6	<input type="checkbox"/> Autoimmune Disorder
	<input type="checkbox"/> Significant Psychiatric Disease
	<input type="checkbox"/> Seizure Disorder
	<input type="checkbox"/> Thyroid Dysfunction
	<input type="checkbox"/> Retinal Disease
	<input type="checkbox"/> Poorly Controlled Diabetes
	<input type="checkbox"/> Other (as approved by the Medical Monitor)

Interferon Ineligibility Reasons Specify	<input type="text"/>
--	----------------------

Date of Diagnosis:(DD-MMM-YYYY)	<input type="text" value="/ /"/>
---------------------------------	----------------------------------

Project Name: GS-US-248-0132
Form: Interferon Intolerant Reasons [INTIAE]
Generated On: Jul-31-2013 11:41:37

Please choose the primary Interferon Intolerant Reason as per Inclusion Criteria #6.

If additional secondary reasons are present, please click on the 'Add a new log line' link at the bottom of the table below.

Primary/Secondary Reasons

- ☐ Primary Reason
☐ Secondary Reason(s)
-

Interferon Intolerant Reasons as per Inclusion Criteria #6

- ☐ Significant Local or Systemic Adverse Reaction
☐ Psychiatric Disease
☐ Significant Cognitive Impairment
☐ Neuropathy
☐ Disabling Flu-Like Symptoms
☐ Gastrointestinal Toxicity
☐ Thrombocytopenia
☐ Neutropenia
☐ Retinal Disease
☐ Autoimmune Disorder
☐ Other (as approved by the Medical Monitor)
-

Interferon Intolerant Reason Specify

Date of Onset

Project Name: GS-US-248-0132

Form: Investigator's Signature *[INVSIG]*

Generated On: Jul-31-2013 11:41:37

By entering my Medidata password, I affirm that I have reviewed and evaluated the case report forms and verify that they accurately reflect the information in the source documents for this subject. I understand source documentation can include (but is not limited to) medical records, laboratory results, x-rays, electronic communications, etc.

Project Name: GS-US-248-0132
Form: Liver Fibrosis Assessment [BIOPSY]
Generated On: Jul-31-2013 11:41:37

LIVER BIOPSY

Check if Biopsy not done:

☐

Date of Liver Biopsy: (DD-MMM-YYYY)

Fibrosis Staging Method:

☐

Metavir

☐

Ishak

☐

Knodell

☐

Batts-Ludwig

☐

Scheuer

Fibrosis Staging Result:

☐

F0

☐

F0-F1

☐

F1

☐

F1-F2

☐

F2

☐

F2-F3

☐

F3

☐

F3-F4

☐

F4

☐

F5

☐

F6

Cirrhosis:

☐

Yes

☐

No

NON-INVASIVE ALTERNATIVE TO LIVER BIOPSY

Check if not done:

☐

Date of Procedure: (DD-MMM-YYYY)

Project Name: GS-US-248-0132
Form: Liver Fibrosis Assessment *[BIOPSY]*
Generated On: Jul-31-2013 11:41:37

Method:

- ☐ FibroTest
- ☐ FibroScan
- ☐ Acoustic Radiation Force
Impulse Imaging
- ☐ Other

If Method is Other, please specify:

Result:

Cirrhosis

- ☐ Yes
- ☐ No

Project Name: GS-US-248-0132
Form: Medical History [MH]
Generated On: Jul-31-2013 11:41:37

Please record date of diagnosis for Hepatitis C on row 1 and indicate if ongoing by checking the ‘Ongoing’ box.

In addition, click on the 'Add a new Log line' link below and add any relevant medical history.

Condition:	<input type="text"/>
------------	----------------------

Start Date: (DD-MMM-YYYY)	<input type="text" value="/ /"/>
---------------------------	----------------------------------

Stop Date: (DD-MMM-YYYY)	<input type="text" value="/ /"/>
--------------------------	----------------------------------

Check if Condition is Ongoing:	<input type="checkbox"/>
--------------------------------	--------------------------

Note: To add additional Medical History entries, please complete an additional form, by clicking on 'Add a new log line'.

Project Name: GS-US-248-0132

Form: Missed Dose and Overdose Log [EXMSOV]

Generated On: Jul-31-2013 11:41:37

Only enter a record for days on which the dairy indicates a missed dose or overdose of a study drug. Enter all dosing information for that day.

If a subject mistook an evening dose for the QD drugs GS-9451 or GS-5885 and this was indicated in the dairy, please enter them in the last two columns. If an evening dose of GS-9451 or GS-5885 were not taken, please leave the column blank.

Date (dd-mmm-yyyy)	<input type="text" value="/ /"/>
--------------------	----------------------------------

Morning Dosing:	<input type="text"/>
------------------------	----------------------

Please record number of tablets taken: **Ribavirin**

Morning Dosing:	<input type="text"/>
------------------------	----------------------

Please record number of capsules taken: **Tegobuvir**

Morning Dosing:	<input type="text"/>
------------------------	----------------------

Please record number of tablets taken: **GS-9451**

Morning Dosing:	<input type="text"/>
------------------------	----------------------

Please record number of tablets taken: **GS-5885**

Evening Dosing:	<input type="text"/>
------------------------	----------------------

Please record number of tablets taken: **Ribavirin**

Evening Dosing:	<input type="text"/>
------------------------	----------------------

Please record number of capsules taken: **Tegobuvir**

Evening Dosing:	<input type="text"/>
------------------------	----------------------

Please record number of tablets taken: **GS-9451**

Evening Dosing:	<input type="text"/>
------------------------	----------------------

Please record number of tablets taken: **GS-5885**

If and overdose of study drug has been reported, please click on the [?] help text to open the Oversdose Form in another window. Fax or email the completed form to the appropriate CRO contact.

Project Name: GS-US-248-0132

Form: PK Plasma (Viral Dynamic Substudy Day 1) [PKS1]

Generated On: Jul-31-2013 11:41:37

Will a serial PK profile be collected for this subject?

☐ Yes

☐ No

IF YES, COMPLETE THE REMAINDER OF THIS FORM

Date of PK Collection: (DD-MMM-YYYY)

Dose Time Point:

☐ Collection Time 4.0 Hours Post-dose

☐ Collection Time 6.0 Hours Post-dose

☐ Collection Time 8.0 Hours Post-dose

Time of PK Collection: (00:00-23:59)

Not Collected

☐

Please specify why this timepoint was not collected:

Project Name: GS-US-248-0132
Form: Pregnancy Report [PREGREP]
Generated On: Jul-31-2013 11:41:37

If a pregnancy occurs, please complete as much information as possible on this form.

In addition to this eCRF, refer to the regulatory binder and complete the ‘Pregnancy Report’ and email or fax the report within 24 hours of the Reporter’s knowledge of the event. When the outcome of the pregnancy is known, complete the ‘Pregnancy Outcome Report’.(Click the [?] help text to open the Pregnancy Report Form in another window. Please fill in all information before faxing the forms to the appropriate CRO contact.)

Contact information for faxing and e-mailing these forms to the CRO during the conduct of the study is found in the study protocol in section 8.5.1. Additional reporting details may be found in protocol section 8.7.

Please also report the pregnancy to the Ribavirin Pregnancy Registry at ribavirinpregnancyregistry.com

Last Menstrual Period: (DD-MMM-YYYY)

Pregnancy Confirmed: (DD-MMM-YYYY)

Estimated Date of Delivery: (DD-MMM-YYYY)

(Click the [?] help text to open the Pregnancy Outcome Report Form in another window. Please fill in all information on the first 3 pages before faxing the forms to the appropriate CRO contact.)

Project Name: GS-US-248-0132

Form: Prior HCV Treatment History [PRHCV2]

Generated On: Jul-31-2013 11:41:37

HCV Treatment:

- ☐ Interferon-alfa
- ☐ Pegylated Interferon-alfa
- ☐ Other Interferon (specify)
- ☐ Ribavirin
- ☐ Other HCV treatment (specify)

HCV treatment Specify

Starting Dose:

Dose Unit:

- ☐ IU
- ☐ Ug
- ☐ ug/kg
- ☐ Mg
- ☐ Other

Dose Unit Specify

Frequency

- ☐ Once a Week
- ☐ Three Times a Day
- ☐ Once a Day
- ☐ Twice a Week
- ☐ Other

Frequency Specify

Start Date: (DD-MMM-YYYY)

Stop Date: (DD-MMM-YYYY)

Start Year (yyyy)

Project Name: GS-US-248-0132
Form: Prior HCV Treatment History [PRHCV2]
Generated On: Jul-31-2013 11:41:37

Stop Year (yyyy)

Project Name: GS-US-248-0132

Form: Randomization [RAND]

Generated On: Jul-31-2013 11:41:37

Note: All baseline tests and procedures, including ECGs, must be completed prior to randomization and dosing/dispensing of GS-5885, GS-9451, Tegobuvir/Placebo or RBV/Placebo.

Was the Subject Randomized?

☐ Yes
☐ No

4-Digit Subject Number as assigned by IWR system

Will the subject participate in the PK Substudy?

☐ Yes
☐ No

Date of PK Substudy Consent (DD-MMM-YYYY)

Will the subject participate in the Viral Dynamic Substudy?

☐ Yes
☐ No

Date of Viral Dynamic Substudy Consent: (DD-MMM-YYYY)

Will the subject participate in Pharmacogenomic Testing?

☐ Yes
☐ No

Date of Pharmacogenomic Testing Consent: (DD-MMM-YYYY)

RANDNUM+Z_SUBID

Project Name: GS-US-248-0132

Form: Registry Substudy [REGISTRY]

Generated On: Jul-31-2013 11:41:37

Which Registry study is the subject eligible to enroll in?

☐

None

☐

SVR Registry (248-0122)

☐

Sequence Registry (248-0123)

☐

NA, Site Not Participating

Will the subject enroll in the registry study?

☐

Yes

☐

No

If No, state the primary reason why the subject will not enroll?

☐

Subject is not interested in participating

☐

Subject will receive other HCV treatment

☐

Lost to follow-up

☐

Other

Other, specify

Project Name: GS-US-248-0132

Form: Serial PK Plasma [PKS]

Generated On: Jul-31-2013 11:41:37

Will a serial PK profile be collected for this subject?

☐ Yes

☐ No

IF YES, COMPLETE THE REMAINDER OF THIS FORM

Date of PK Collection: (DD-MMM-YYYY)

PK Time Point:

- ☐ Collection Time Pre-dose
- ☐ Collection Time 1.0 Hour Post-dose
- ☐ Collection Time 2.0 Hours Post-dose
- ☐ Collection Time 3.0 Hours Post-dose
- ☐ Collection Time 4.0 Hours Post-dose
- ☐ Collection Time 6.0 Hours Post-dose
- ☐ Collection Time 8.0 Hours Post-dose
- ☐ Collection Time 10.0 Hours Post-dose
- ☐ Collection Time 12.0 Hours Post-dose
- ☐ Collection Time 24.0 Post-dose

Time of PK Collection: (00:00-23:59)

Not Collected

☐

Please specify why this timepoint was not collected:

Collection Time 24.0 Hours Post-Dose: Not Collected

☐

Collection Time 24.0 Hours Post-Dose: Date of PK Collection: (DD-MMM-YYYY)

Collection Time 24.0 Hours Post-Dose: Time of PK Collection: (00:00-23:59)

Collection Time 24.0 Hours Post-Dose: Please specify why this timepoint was not collected:

Project Name: GS-US-248-0132

Form: Single PK Plasma [PK]

Generated On: Jul-31-2013 11:41:37

Was Single PK Plasma Sample collected?

☐ Yes

☐ No

Date of PK Collection: (DD-MMM-YYYY)

/ /

Time of PK Collection: (00:00-23:59)

:

Project Name: GS-US-248-0132

Form: Study Completion [STUDCOMP]

Generated On: Jul-31-2013 11:41:37

Did the subject complete the protocol-planned duration of the study?

☐ Yes

☐ No

If "No", please specify reason for study discontinuation.

☐ Adverse Event

☐ Death

☐ Pregnancy

☐ Efficacy Failure

☐ Protocol Violation

☐ Subject Withdrew Consent

☐ Lost to Follow-Up

☐ Investigator Decision

☐ Study Discontinued by Sponsor

Project Name: GS-US-248-0132

Form: Study Drug Accountability - GS-5885 [DA1]

Generated On: Jul-31-2013 11:41:37

Visit Dispensed:

- ☐ Baseline
- ☐ Week 4
- ☐ Week 8
- ☐ Week 12
- ☐ Week 16
- ☐ Week 20
- ☐ Unscheduled

Drug Name:

- ☒ GS-5885
- ☐ GS-9451
- ☐ RBV/Placebo
- ☐ Tego buvir/Placebo
- ☐ GS-5885 Rescue Therapy
- ☐ GS-9451 Rescue Therapy
- ☐ RBV Rescue Therapy
- ☐ Tego buvir/Placebo Rescue Therapy
- ☐ PEG Rescue Therapy

Date Dispensed:

5-Digit Bottle Number:

Number of Tablets Dispensed:

Date Returned:

Number of Tablets Returned:

Study Drug Not Returned:

☐

Project Name: GS-US-248-0132

Form: Study Drug Accountability - GS-9451 [DA2]

Generated On: Jul-31-2013 11:41:37

Visit Dispensed:

- ☐ Baseline
- ☐ Week 4
- ☐ Week 8
- ☐ Week 12
- ☐ Week 16
- ☐ Week 20
- ☐ Unscheduled

Drug Name:

- ☐ GS-5885
- ☒ GS-9451
- ☐ RBV/Placebo
- ☐ Tenofovir/Placebo
- ☐ GS-5885 Rescue Therapy
- ☐ GS-9451 Rescue Therapy
- ☐ RBV Rescue Therapy
- ☐ Tenofovir/Placebo Rescue Therapy
- ☐ PEG Rescue Therapy

Date Dispensed:

5-Digit Bottle Number:

Number of Tablets Dispensed:

Date Returned:

Number of Tablets Returned:

Study Drug Not Returned:

☐

Project Name: GS-US-248-0132

Form: Study Drug Accountability - RBV/Placebo [DA4]

Generated On: Jul-31-2013 11:41:37

Visit Dispensed:

- ☐ Baseline
- ☐ Week 4
- ☐ Week 8
- ☐ Week 12
- ☐ Week 16
- ☐ Week 20
- ☐ Unscheduled

Drug Name:

- ☐ GS-5885
- ☐ GS-9451
- ☒ RBV/Placebo
- ☐ Tego buvir/Placebo
- ☐ GS-5885 Rescue Therapy
- ☐ GS-9451 Rescue Therapy
- ☐ RBV Rescue Therapy
- ☐ Tego buvir/Placebo Rescue Therapy
- ☐ PEG Rescue Therapy

Date Dispensed:

5-Digit Bottle Number:

Number of Tablets Dispensed:

Date Returned:

Number of Tablets Returned:

Study Drug Not Returned:

☐

Project Name: GS-US-248-0132

Form: Study Drug Accountability - Tegobuvir/Placebo [DA3]

Generated On: Jul-31-2013 11:41:37

Visit Dispensed:

- ☐ Baseline
- ☐ Week 4
- ☐ Week 8
- ☐ Week 12
- ☐ Week 16
- ☐ Week 20
- ☐ Unscheduled

Drug Name:

- ☐ GS-5885
- ☐ GS-9451
- ☐ RBV/Placebo
- ☒ Tegobuvir/Placebo
- ☐ GS-5885 Rescue Therapy
- ☐ GS-9451 Rescue Therapy
- ☐ RBV Rescue Therapy
- ☐ Tegobuvir/Placebo Rescue Therapy
- ☐ PEG Rescue Therapy

Date Dispensed:

5-Digit Bottle Number:

Number of Capsules Dispensed:

Date Returned:

Number of Capsules Returned:

Study Drug Not Returned:

☐

Project Name: GS-US-248-0132

Form: Study Drug Administration [EX]

Generated On: Jul-31-2013 11:41:37

Drug Name:

☐

GS-5885

☐

GS-9451

☐

Tegobuvir/Placebo

☐

RBV/Placebo

Dose:

Dose Units / Frequency:

☐

capsules/day

☐

tablets/day

☐

Other

If "Other", please specify:

Start Date: (DD-MMM-YYYY)

Stop Date: (DD-MMM-YYYY)

Ongoing:

☐

Check box if study drug was permanently discontinued:

☐

Project Name: GS-US-248-0132

Form: Study Drug Completion [SDRGCOMP]

Generated On: Jul-31-2013 11:41:37

Did subject complete study drug treatment through Week 24?

☐ Yes

☐ No

If "No", please specify reason for study drug discontinuation:

☐ Adverse Event

☐ Death

☐ Pregnancy

☐ Efficacy Failure

☐ Protocol Violation

☐ Subject Withdrew Consent

☐ Lost to Follow-Up

☐ Investigator Decision

☐ Randomized but Subject Never
Dosed with Study Drug

☐ Study Discontinued by Sponsor

Project Name: GS-US-248-0132

Form: Subject Follow-Up Status *[DS]*

Generated On: Jul-31-2013 11:41:37

Provide the subject status:

If subject has discontinued, please complete the Study Completion form. For female subjects of childbearing potential, please also continue to complete the follow-up Urine Pregnancy Tests until Month 6

Project Name: GS-US-248-0132

Form: Subject Number [SUBID]

Generated On: Jul-31-2013 11:41:37

Screening Number (XXX):

Subject Initials (XXX):

SCRNID + SUBJINIT

Project Name: GS-US-248-0132

Form: Urine Pregnancy Test (Baseline) [PREGTEST1]

Generated On: Jul-31-2013 11:41:37

Is female subject of childbearing potential?

☐ Yes

☐ No

Date Test Performed: (DD-MMM-YYYY)

Test Result:

☐ Negative

☐ Positive

☐ Not Done

Note: A positive urine pregnancy test must be immediately confirmed with a serum pregnancy test, and the subject must not be enrolled.

Project Name: GS-US-248-0132

Form: Urine Pregnancy Test [PREGTEST]

Generated On: Jul-31-2013 11:41:37

Is female subject of childbearing potential?

☐ Yes

☐ No

Date Test Performed: (DD-MMM-YYYY)

Test Result:

☐ Negative

☐ Positive

☐ Not Done

Note: A positive urine pregnancy test must be immediately confirmed with a serum pregnancy test.

Project Name: GS-US-248-0132

Form: Visit Date [VISDT]

Generated On: Jul-31-2013 11:41:37

Was Post-Treatment Follow-Up Week 4 visit performed?

☐ Yes

☐ No

Visit Date: (DD-MMM-YYYY)

Was visit performed on the same day as Week 1

☐ Yes

☐ No

Reason for Unscheduled Visit: (Check all that apply)

Evaluation of AE and/or Concomitant Medications:

☐

Vital Signs:

☐

Physical Exam:

☐

ECG:

☐

PK:

☐

Lab Evaluations:

☐

Study Drug Adjustment or Dispensation:

☐

Other:

☐

Other, Specify:

Project Name: GS-US-248-0132

Form: Vital Signs (Screening) [VS1]

Generated On: Jul-31-2013 11:41:38

Weight:

kg/ lb

Height:

cm/ in

Blood Pressure Systolic: (mmHg)

Blood Pressure Diastolic: (mmHg)

Pulse (beats/minute):

Respiration: (breaths/minute)

Temperature:

Celsius/
Fahrenheit

Project Name: GS-US-248-0132
Form: Vital Signs with Weight [VS2]
Generated On: Jul-31-2013 11:41:38

Weight:	<input type="text"/>	kg/ lb
Blood Pressure Systolic: (mmHg)	<input type="text"/>	
Blood Pressure Diastolic: (mmHg)	<input type="text"/>	
Pulse (beats/minute):	<input type="text"/>	
Respiration: (breaths/minute)	<input type="text"/>	
Temperature:	<input type="text"/>	Celsius/ Fahrenheit

Project Name: GS-US-248-0132
Form: Vital Signs [VS]
Generated On: Jul-31-2013 11:41:38

Blood Pressure Systolic: (mmHg)

Blood Pressure Diastolic: (mmHg)

Pulse (beats/minute):

Respiration: (breaths/minute)

Temperature:

 Celsius/
Fahrenheit