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CR018721 - VX-950HPC3006: Open-Label, Phase 3b Study To Determine Efficacy and Safety of Telaprevir, Pegylated-Interferon-alfa-2a and Ribavirin in Hepatitis C Genotype 1 Infected, Stable Liver Transplant Subjects(18137)

Version: 35.19 Form is checked in. Status: **Draft**

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Protocol Registration Form

31 Notes, 1 Hints

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Title

Study ID:	CR018721
Brief Title:	An Efficacy and Safety Study of Telaprevir in Patients With Genotype 1 Hepatitis C Infection After Liver Transplantation
Acronym:	REPLACE
Official Title:	Open-Label, Phase 3b Study To Determine Efficacy and Safety of Telaprevir, Pegylated-Interferon-alfa-2a and Ribavirin in Hepatitis C Genotype 1 Infected, Stable Liver Transplant Subjects
Study Type:	Interventional
Is FDA Regulated Intervention:	No
Is IND/IDE Protocol:	NOTE: IND Protocol? has not been entered.

Secondary Ids

Secondary Id	Id Type	Id Domain
VX-950HPC3006	Other Identifier	Janssen-Cilag International NV, Belgium
2011-004724-35	EudraCT Number	

FDA

FDA Section not applicable.

> Study is not an FDA Regulated Intervention.

> Study is not an IND/IDE Protocol.

Oversight

Board Approval:	Submitted, approved 25/11/2011

Board Name:	Hospital Clinic I Provincial Comite Etico De Investigacion Clinica
Board Affiliation:	Hospital Clinic i Provincial
Board Contact:	+34 93 227 54 00 Dra. Neus Riba Garcia Hospital Clinic I Provincial Comite Etico De Investigacion Clinica C/ Villarroel, 170 Agencia De Ensayos Clínicos Barcelona 08036
Data Monitoring Committee:	Yes
Oversight Authorities:	Spain: Agencia Española de Medicamentos y Productos Sanitarios Germany: Ethics Commission Great Britain: Medicines and Healthcare Products Regulatory Agency Germany: Federal Institute for Drugs and Medical Devices Great Britain: Research Ethics Committee

Sponsor

Responsible Party:	Sponsor
Deprecated Responsible Party data:(These fields are no more on CTGov)	Compound Development Team Leader Janssen-Cilag International NV, Belgium 32 14 64 13 70
Sponsor:	Janssen-Cilag International NV
Collaborators:	

Summary

Brief Summary:	The purpose of this study is to evaluate the effectiveness of telaprevir in combination with Peg-IFN-alfa-2a and ribavirin in stable liver transplant patients with chronic hepatitis C virus (HCV) genotype 1.
Detailed Description:	This is an open-label (all people know the identity of the intervention), multicenter study in genotype 1 chronic HCV infected liver transplant patients who will be treated for 12 weeks with telaprevir 750 mg every 8 hours given in combination with Peg-IFN-alfa-2a and ribavirin followed by 36 weeks of treatment with Peg-IFN-alfa-2a and ribavirin alone. The total treatment duration will be 48 weeks. Safety will be evaluated throughout the study and will include evaluations of adverse events, clinical laboratory tests, electrocardiogram, vital signs, and physical examination.

Status

Record Verification Date:	Verification Date is entered/updated on the Create Submission screen.
Overall Recruitment Status:	Completed
Why Study Stopped:	
Study Start Date:	2012-02
Primary Completion Date:	2014-04 Actual
Study Completion Date:	2014-07 Actual

Design

Primary Purpose:	Treatment
Study Phase:	Phase 3
Intervention Model:	Single Group Assignment
Number of Arms:	1
Masking:	Open Label
Allocation:	N/A
Control:	
Study Endpoint Classification:	Safety/Efficacy Study
Enrollment:	74 Actual

Outcome Measures

Primary Outcome Measures

Outcome Measure	TimeFrame	Description	Safety Type
Number of patients achieving sustained virologic response (SVR) 12 planned	Week 60	SVR12 planned is defined as having plasma hepatitis C virus (HCV) ribonucleic acid (RNA) level less than 25 IU/mL 12 weeks after the last planned dose of study medication.	No

Secondary Outcome Measures

Outcome Measure	TimeFrame	Description	Safety Type
Number of patients achieving SVR12 planned(c)	Week 60	SVR12 planned(c) is defined as having undetectable plasma HCV RNA levels 12 weeks after the last planned dose of study drugs.	No
Number of patients achieving SVR24 planned	Week 72	SVR24 planned is defined as having plasma HCV RNA levels less than 25 IU/mL 24 weeks after the last planned dose of study medication.	No
Number of patients achieving SVR24 planned(c)	Week 72	SVR24 planned(c) is defined as having an undetectable plasma HCV RNA level 24 weeks after the last planned dose of study medication.	No
Number of patients having an undetectable HCV RNA level at Week 4 of treatment	Week 4		No
Number of patients having an undetectable HCV RNA level at Week 12 of treatment	Week 12		No
Number of patients having undetectable HCV RNA levels at Week 4 and Week 12 of treatment	Week 4 and Week 12		No
Number of patients having an undetectable HCV RNA level at the actual end of treatment	Week 48		No
Number of patients having an undetectable HCV RNA level at the planned end of treatment	Week 48		No

Number of patients having less than 25 IU/mL at the planned end of treatment	Week 48		No
Number of patients with on-treatment virologic failure	Week 48	Virologic failure is defined as patients who meet a virologic stopping rule and/or meet the definition of viral breakthrough.	No
Number of patients with relapse after undetectable HCV RNA at actual end of treatment	Week 48	Number of patients who relapse, defined as having confirmed detectable HCV RNA during the follow-up period after previous undetectable HCV RNA (less than 25 IU/mL, target not detected) at actual end of treatment.	No
Number of patients with relapse after undetectable HCV RNA at planned end of treatment	Week 48	Number of patients who relapse, defined as having confirmed detectable HCV RNA during the follow-up period after previous undetectable HCV RNA (less than 25 IU/mL, target not detected) at planned end of treatment.	No
Number of patients with relapse after previous HCV RNA less than 25 IU/mL at planned end of treatment	Week 48	Number of patients who relapse, defined as having confirmed detectable HCV RNA during the follow-up period after previous HCV RNA less than 25 IU/mL at planned end of treatment.	No
Number of patients with viral breakthrough	Week 48	Number of patients with viral breakthrough (defined as an increase more than 1 log in HCV RNA level from the lowest level reached, or a value of HCV RNA more than 100 IU/mL in patients whose HCV RNA has previously become less than 25 IU/mL during treatment).	No
Change from baseline in log HCV RNA values	Up to Week 52	Change from baseline in log HCV RNA values at each time point during treatment.	No
Number of patients who have changes in liver graft biopsy histology	Up to Week 72		No
Number of patients with adverse events	Up to Week 72		Yes

Other Pre-specified Outcome Measures

Outcome Measure	TimeFrame	Description	Safety Type

Interventions

Arms

Arm Number or Name	Type	Description
Telaprevir+Peg-IFN-alfa-2a+Ribavirin	Experimental	Patients will be treated for 12 weeks with telaprevir in combination with Pegylated interferon alfa-2a (Peg-IFN-alfa-2a) and ribavirin followed by 36 weeks of treatment with Peg-IFN-alfa-2a and ribavirin alone.

Interventions

Intervention Name	Type	Associated Arms	Description
Telaprevir	Drug	Telaprevir+Peg-IFN-alfa-2a+Ribavirin	Type=exact number, unit=mg, number=375, form=tablet, route=oral. Patients will receive 2 oral tablets (750 mg) every 8 hours for 12 weeks.

NOTE: Intervention Other Names have not been specified

Pegylated interferon	Drug	Telaprevir+Peg-IFN-alfa-	Type=exact number, unit=µg, number=180, form=injection, route=subcutaneous, 180 microgram (µg) per week, subcutaneous injection

alfa-2a		2a+Ribavirin	for 48 weeks.

NOTE: Intervention Other Names have not been specified

Ribavirin	Drug	Telaprevir+Peg-IFN-alfa-2a+Ribavirin	Type=exact number, unit=mg, number=200, form=tablet, route=oral. Starting from 600 mg (3 tablets) per day on Day 1. This dose will become higher or lower based on blood results and the investigators opinion (to a goal of 1000 to 1200 mg/day [5 to 6 tablets] based on subject weight), twice daily regimen, for 48 weeks.

NOTE: Intervention Other Names have not been specified

Conditions

Conditions or Focus of Study:	Chronic hepatitis C virus (HCV) infection
Keywords:	Chronic HCV infection Genotype 1 chronic HCV Liver transplantation Hepatitis C Hep C HCV Telaprevir Pegylated-Interferon-alfa-2a Ribavirin

Eligibility

Eligibility Criteria:	Inclusion Criteria: - First time liver transplant recipient whose primary pre-transplant diagnosis was chronic hepatitis C genotype 1 - More than 6 months to 10 years post-liver transplant - Patient did or did not receive treatment for HCV prior to liver transplantation - Patient must agree to have a liver graft biopsy during the screening period unless they had a biopsy within three months of the screening period (for patients between 6 months and one year post transplant) or within six months of the screening period (for patients who are more than one year post transplant) - A female patient of childbearing potential and a nonvasectomized male patient who has a female partner of childbearing potential must agree to the use of 2 effective methods of birth control from screening until 6 months (female patient) or 7 months (male patient) after the last dose of ribavirin Exclusion Criteria: - Patient is currently infected or co-infected with HCV of another genotype than genotype 1 - Patient received treatment for hepatitis C following liver transplantation - Patient has history of decompensated liver disease or shows evidence of significant liver disease in addition to hepatitis C - Patient with human immunodeficiency virus or hepatitis B virus co-infection - Patient with active malignant disease or history of malignant disease within the past 5 years (with the exception of treated basal cell carcinoma or hepatocellular carcinoma)
Gender:	Both
Age Limits:	18 Years 70 Years
Accepts Healthy Volunteers:	No

Locations

Contact

Central Contact:	For more information, please email JNJ.CT@sylogent.com
Central Contact Backup:	

Study Officials / Investigators

First	MI	Last	Degree	Role	Organizational Affiliation
Janssen-Cilag International NV, Belgium		Clinical Trial		Study Director	Janssen-Cilag International NV, Belgium

Locations

View Locations

Citations

Medline Identifier	Results Reference	Description

Links

URL	Description

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