

Evaluation of IDX375 in healthy and hepatitis C-infected subjects

Submission date 02/07/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 26/08/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 26/08/2010	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
IDX-09B-001

Study information

Scientific Title
A phase I/IIa study assessing single and multiple doses of hepatitis C virus (HCV) non-nucleoside polymerase inhibitor IDX375 in healthy and genotype 1 HCV-infected subjects

Study objectives

Evaluation of the safety, tolerability and antiviral activity of IDX375.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Belgium: Secretariaat Commissie Medische Ethiek approved on the 10th March 2010
2. Moldova: National Ethic Committee approved on the 29th April 2010

Study design

Two part randomised double-blind placebo controlled dose escalation and proof-of-concept trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Genotype 1 chronic hepatitis C virus

Interventions

1. Dose escalation in healthy subjects - 8 subjects per dosing cohort, randomised 6:2 (active: placebo):
 - 1.1. 200 mg IDX375 (or placebo) x 1 day
 - 1.2. 400 mg IDX375 (or placebo) on days 1 and 8
 - 1.3. 300 mg IDX375 (or placebo) x 1 day
 - 1.4. 1200 mg IDX375 (or placebo) x 1 day
 - 1.5. 800 mg IDX375 twice daily (BID) or (placebo BID) x 1 day
 - 1.6. 800 mg IDX375 BID or (placebo BID) x 3 days
2. Proof-of-concept in HCV-infected subjects - 10 subjects per dosing cohort, randomised 8:2 (active:placebo):
 - 2.1. 400 mg IDX375 BID or (placebo BID) x 3 days
 - 2.2. 800 mg IDX375 BID or (placebo BID) x 3 days
 - 2.3. 1200 mg IDX375 four times a day (QD) or (placebo QD) x 3 days

Total duration of treatment: maximum 3 days dosing

Total duration of follow-up: maximum 25 days follow-up

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

IDX375

Primary outcome(s)

1. Adverse events, physical examination, vital signs, electrocardiograms (ECGs), standard safety laboratory tests
2. Change in plasma HCV RNA, emergence of resistance mutations

Measured daily during research unit confinement up to 14 days maximum, with weekly visits for follow-up.

Key secondary outcome(s)

Plasma concentrations of IDX375. Measured daily during research unit confinement up to 14 days maximum, with weekly visits for follow-up.

Completion date

02/11/2010

Eligibility

Key inclusion criteria

All participants:

1. Aged 18 - 65 years
2. Body mass index (BMI) 18 - 35 kg/m²
3. Must agree to use an acceptable double-barrier method of birth control
4. Male subject must agree not to donate sperm for 90 days after the last dose of study drug
5. Subject has provided written informed consent to participate in the study

Specific to healthy subjects:

6. Subject must be male
7. Subject must be a non-smoker

Specific to HCV-infected subjects:

8. Female subjects must be of non-childbearing potential
9. Documented clinical history compatible with chronic hepatitis C
10. Plasma HCV ribonucleic acid (RNA) greater than or equal to 5 log₁₀ IU/mL at screening
11. HCV genotype 1
12. HCV treatment-naive

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

Key exclusion criteria

All participants:

1. Co-infected with hepatitis B virus and/or human immunodeficiency virus (HIV)
2. Donated blood or had significant blood loss 60 days prior to dosing
3. Use of alcohol and/or drugs that could interfere with adherence to study requirements as judged by the Investigator
4. Use of other investigational drugs within 60 days of dosing, or plans to enrol in another clinical trial of an investigational agent while participating in the present study
5. Subject with known allergy to the study medication or any of its components
6. Clinically significant laboratory or electrocardiogram (ECG) abnormalities
7. Any clinically significant medical condition that, in the opinion of the Investigator, would jeopardise the safety of the subject or impact the validity of the study results

Specific to healthy subjects:

8. Concomitant use of prescription medications or systemic over-the-counter (OTC) medications. A washout period of at least 5 half-lives must be observed prior to study drug dosing, if the Investigator feels that the medication can be safely discontinued for the duration of the study.
9. Positive screen for anti-HCV antibody

Specific to HCV-infected subjects:

10. Subject is pregnant or breastfeeding
11. History or signs of decompensated liver disease: Child-Pugh class B or C, ascites, variceal bleeding, hepatic encephalopathy, spontaneous bacterial peritonitis, or other clinical signs of portal hypertension or hepatic insufficiency
12. History of hepatocellular carcinoma (HCC) or findings suggestive of possible HCC

Date of first enrolment

09/06/2010

Date of final enrolment

02/11/2010

Locations

Countries of recruitment

Belgium

Moldova

United States of America

Study participating centre

Idenix Pharmaceuticals, Inc.

Cambridge

United States of America

02139

Sponsor information

Organisation

Idenix Pharmaceuticals, Inc. (USA)

ROR

<https://ror.org/02891sr49>

Funder(s)

Funder type

Industry

Funder Name

Idenix Pharmaceuticals, Inc. (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration