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Evaluation of IDX375 in healthy and hepatitis C-infected subjects

Submission date	Recruitment status	[_] Prospectively registered
02/07/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/08/2010	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
26/08/2010	Infections and Infestations	[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the sponsor contact details below to request a patient information sheet

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 measure
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.

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

Overall study start date
09/06/2010

Completion date
02/11/2010

Eligibility

Key inclusion criteria
All participants:
1. Aged 18 - 65 years
2. Body mass index (BMI) 18 - 35 kg/m^2
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

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
78

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.
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Sponsor information

Organisation
Idenix Pharmaceuticals, Inc. (USA)

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
Idenix Pharmaceuticals, Inc. (USA)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration