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Safety and clinical effects of IDX12899 in HIV-1 infection

Submission date	Recruitment status	[_] Prospectively registered
21/12/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/02/2008	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
18/09/2008	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

NV-05A-002

Study information

Scientific Title
A phase I/IIa, double-blind study to evaluate the safety and tolerability, antiretroviral activity, pharmacokinetics and pharmacodynamics of IDX12899 in antiretroviral treatment-naïve HIV-1-infected subjects

Study objectives
The safety profile and antiviral activity demonstrated in vitro by IDX12899 predicts acceptable safety and antiviral activity in HIV-1-infected patients.

As of 27/06/2008, the anticipated end date of this trial has been updated. The previous anticipated end date was 28/02/2008.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Independent Ethics Committee in Clinical Research c/o Dr Virgilio G. Foglia Registration OHRP No: IRB 00001678 - USA.
Tucumán 335 -7o piso "D" - (C1049AAG) Buenos Aires, Argentina) approval ref 653/65/2007.

Study design
Phase I/IIa, randomized, double-blind, placebo-controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Chronic HIV-1 infection

Interventions
From 27/06/2008: Sequential cohorts of 10 subjects will be randomised at an 8:2 ratio to receive IDX12899 (oral capsule) 800 mg, 400 mg, 200 mg and 100 mg or placebo once daily for 7 days.

Before 27/06/2008: Subjects will be randomised at an 8:2 ratio to receive IDX12899 (oral capsule) 800 mg once daily or placebo for 7 days.

Intervention Type
Drug

Phase
Phase I/II

Drug/device/biological/vaccine name(s)
IDX12899 (antiretroviral drug)

Primary outcome measure
1. Proportion of subjects experiencing adverse events and laboratory abnormalities, followed-up until Study day 14 (7 days after the last dose of study drug)
2. Decrease from baseline through Day 8 in plasma HIV-1 RNA

Secondary outcome measures
1. Change from baseline at Day 8 in Reverse Transcriptase (RT) sequences of HIV-1
2. Change from baseline at Day 8 in CD4+ and CD8+ T-lymphocyte cell count
3. Plasma concentrations and calculated PharmacoKinetic (PK)/PharmacoDynamic (PD) parameters. The last PK sample is collected on Day 8 (24 hours after the last dose of study drug)
4. Profiling of metabolites. The last PK sample is collected on Day 8 (24 hours after the last dose of study drug)

Overall study start date
03/01/2008

Completion date
30/09/2008

Eligibility

Key inclusion criteria
1. Male or Female, 21 to 65 years of age
2. Female of non-childbearing potential
3. Plasma HIV-1 RNA value >=5000 copies/mL
4. CD4+ count >=200 cells/mm3
5. Subject is antiretroviral treatment-naïve
6. Subject agrees to start a standard HAART regimen on Day 8 of the study or Kaletra® monotherapy for 28 days within 24 hours after the last dose of study medication
7. Subject has provided written informed consent to participate in the study

Participant type(s)
Patient

Age group
Adult

Sex

Both

Target number of participants
Target number of participants as of 27/06/2008: 40; Previous target number of participants: 10

Key exclusion criteria
1. Pregnant or breastfeeding
2. Male of reproductive potential and unwilling to use double barrier method of contraception during and for at least 30 days after the last dose of the study drug
3. Co-infection with acute hepatitis A (HAV), chronic hepatitis B (HBV) or active hepatitis C (HCV)
4. Alcohol or illicit drug abuse, or history of alcohol abuse or illicit drug abuse within the preceding one year
5. Potential allergy to the study medication or the follow-up HAART or Kaletra® therapy
6. Received an immunomodulating agent or immunotherapeutic vaccine within 30 days before Day -1
7. Receiving co-medication that is a known substrate, inhibitor and/or inducer of CYP3A4
8. Enrollment in another clinical study of an investigational agent
9. Subject who has received any investigational drug within 90 days prior to Day -1
10. History of AIDS-defining illness
11. History of or currently active disease that may put the subject at risk because of participation in this study
12. Subject with an intestinal malabsorption
13. Subject with a pre-existing Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI) drug resistance based on genotyping at Screening
14. Subject who has had a significant blood loss 30 days prior to Day -1
15. Subject has any of the following laboratory parameters at Screening: hemoglobin <8.5 g/dL, neutrophil count <1,000 cells/mm3, platelet count <100,000 cells/mm3, serum creatinine > the Upper Limit of Normal (ULN), ASpartate aminoTransferase (AST) or ALanine aminoTransferase (ALT) >=2.5 x ULN, Total bilirubin >ULN

Date of first enrolment
03/01/2008

Date of final enrolment
30/09/2008

Locations

Countries of recruitment
Argentina

Study participating centre
Hospital Privado Modelo
Buenos Aires
Argentina
-

Sponsor information

Organisation
Idenix Pharmaceuticals (USA)

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Sponsor type
Industry

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ROR
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Funder(s)

Funder type
Industry

Funder Name
Idenix Pharmaceuticals (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