

# A Phase IIa, Open-Labelled Study of Visilizumab in Patients with Moderate to Severe Inflammatory, Non-Stricturing, Non-Penetrating Forms of Crohn's Disease

<b>Submission date</b> 08/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/02/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/02/2019	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

NCT00267722

**Secondary identifying numbers**

291-412

## **Study information**

**Scientific Title**

A Phase IIa, Open-Labelled Study of Visilizumab in Patients with Moderate to Severe Inflammatory, Non-Stricturing, Non-Penetrating Forms of Crohn's Disease

**Study objectives**

To evaluate the clinical activity of two consecutive daily doses of 10 mcg/kg of visilizumab administered intravenously to patients with moderate to severe inflammatory, non-stricturing, non-penetrating forms of Crohn's disease

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved by the Medical Ethics Committee on 03/02/2005, (ref: 04/325)

**Study design**

Treatment, non-randomized, open label, uncontrolled, single group assignment, efficacy study

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Not specified

**Study type(s)**

Treatment

**Participant information sheet****Health condition(s) or problem(s) studied**

Crohn's disease

**Interventions**

Two consecutive daily doses of 10 mcg/kg of visilizumab administered intravenously. Taking of blood samples, endoscopy and biopsies.

**Intervention Type**

Drug

**Phase**

Phase II

**Drug/device/biological/vaccine name(s)**

Visilizumab

**Primary outcome measure**

To evaluate the clinical activity of two consecutive daily doses of 10 mcg/kg of visilizumab administered intravenously to patients with moderate to severe inflammatory, non-stricturing, non-penetrating forms of Crohn's disease

**Secondary outcome measures**

1. To evaluate the pharmacokinetics of two consecutive daily doses of visilizumab administered intravenously in this patient population
2. To determine the risk-benefit relationship of visilizumab in this patient population
3. To assess immunogenicity of visilizumab in this patient population
4. To evaluate the safety, tolerability, clinical activity, pharmacokinetics and immunogenicity of retreatment (if warranted) of two consecutive daily doses of 10 mcg/kg visilizumab in patients with moderate-to-severe inflammatory, non-stricturing, non-penetrating forms of Crohn's disease

**Overall study start date**

01/10/2004

**Completion date**

31/08/2007

**Eligibility****Key inclusion criteria**

1. Male or female, 18 to 70 years of age
2. A diagnosis of moderate-to-severe inflammatory, non-stricturing, non-penetrating Crohn's disease, defined as Crohn's Disease Activity Index (CDAI)  $\geq 250$ , C-Reactive Protein (CRP)  $\geq$  Upper Limit of Normal (ULN) and endoscopic evidence of moderate-to-severe active inflammatory disease
3. Patients with reproductive potential who agree to use double-barrier methods of contraception during the study and for three months after receiving the study drug
4. Women of childbearing potential who have negative serum pregnancy test
5. Patients who have been tested negative for Clostridium difficile within three weeks prior to treatment with the study drug
6. Patients who are capable of understanding the purpose and risks of the study and who provide signed and dated informed consent and an authorization to use protected health information (US sites only)
7. Patients who have Epstein-Barr virus (EBV) Deoxyribonucleic Acid (DNA) titers up to 30,000 copies/ml

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

20

**Key exclusion criteria**

1. History of lymphoproliferative disorder or a prior malignancy within five years or current malignancies (excluding non-melanoma skin cancers or in situ carcinoma of the cervix that has been adequately treated)
2. Pregnant women or nursing mothers
3. Any of the following hematologic abnormalities: White Blood Cell (WBC)  $<2500 /\text{mm}^3$ , platelets  $<150,000 /\text{mm}^3$ , hemoglobin  $<10 \text{ g/dl}$
4. Serologic evidence of infection with Human Immunodeficiency Virus (HIV) or Hepatitis B or C virus (HBV, HCV)
5. Presence of obstructive symptoms, confirmed by endoscopy showing an impassable stricture or Computed Tomography (CT) or barium studies showing stricture with prestenotic bowel dilation, within six months prior to receiving the study drug
6. Serious infections, particularly those of viral etiology e.g. known active cytomegalovirus (CMV) colitis, and patients who have had a history of opportunistic infections within the past year
7. Active infections that require antibiotic therapy (not to include use of antibiotics to control Crohns disease)
8. Started, or have a dose change of, sulfasalazine, 5-aminosalicylic acid (5-ASA), or antibiotics, probiotics, or topical therapies for Crohns disease within two weeks prior to receiving the study drug
9. Serious infections that required intravenous (IV) antibiotic therapy or hospitalization within eight weeks prior to receiving the study drug
10. Had an increased dose in corticosteroid medication two weeks prior to receiving the study drug, is receiving IV steroids, or, is receiving a daily dose of  $>40 \text{ mg}$  prednisone,  $>9 \text{ mg}$  budesonide, or equivalent
11. Received a live vaccine within six weeks prior to receiving the study drug (patients may not receive a live vaccine during treatment or for 12 weeks after treatment with the study drug)
12. Received any monoclonal antibodies (including infliximab) or investigational agents or biologics within three months prior to receiving the study drug
13. Received cyclosporine or tacrolimus (FK506) within four weeks of receiving the study drug
14. Had a dose change of, or discontinued from, 6-mercaptopurine, azathioprine, or methotrexate within four weeks prior to receiving the study drug
15. Significant organ dysfunction, including cardiac, renal, liver, Central Nervous System (CNS), pulmonary, vascular, non-Crohn's disease-related gastrointestinal, endocrine, or metabolic (e.g. creatinine  $>1.6 \text{ mg/dl}$ , alanineamino transferase [ALT] or aminotransferase [AST]  $>$  twice the Upper Limit of Normal [ULN], alkaline phosphatase  $>1.5 \times \text{ULN}$ , history of myocardial infarction, congestive heart failure, or arrhythmias within six months prior to receiving the study drug)
16. Likely to require surgery in the next six months, such as those with clinically apparent abscesses or severely symptomatic stenoses
17. History of lymphoproliferative disorder
18. History of tuberculosis (TB) or other mycobacterial infection, or chest X-ray positive for

previous TB infection

19. History of thrombophlebitis or pulmonary embolus

20. Histories of immune deficiency or autoimmune disorders other than Crohns disease (not including joint, skin, hepatic, and ocular inflammatory conditions that may be more typically associated with Crohns disease)

21. History of seizure with subtherapeutic blood levels of anticonvulsive medication (documented) within one week before study enrolment

**Date of first enrolment**

01/10/2004

**Date of final enrolment**

31/08/2007

## **Locations**

**Countries of recruitment**

Germany

Netherlands

United States of America

**Study participating centre**

**Academic Medical Center**

Amsterdam

Netherlands

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## **Sponsor information**

**Organisation**

PDL BioPharma Inc. (USA)

**Sponsor details**

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United States of America

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**Sponsor type**

Industry

**ROR**

## Funder(s)

### Funder type

Industry

### Funder Name

Protein Design Labs Inc

## 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

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	cytokine release syndrome results	01/04/2009	08/02/2019	Yes	No