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## Low Dose Interferon Alpha Treatment for Oral Ulcers of Behcet's Disease

**This study is currently recruiting participants.**

Verified by Nobel Pharmaceuticals, June 2007

<b>Sponsors and Collaborators:</b>	<b>Nobel Pharmaceuticals</b> Amarillo Biosciences, Inc.
<b>Information provided by:</b>	Nobel Pharmaceuticals
<b>ClinicalTrials.gov Identifier:</b>	NCT00483184

### ► Purpose

The purpose of this study is to determine the safety and efficacy of natural human interferon alpha (IFN alpha) on size, number, incidence and pain of oral ulcers associated with Behçet's Disease (BD).

<a href="#">Condition</a>	<a href="#">Intervention</a>	<a href="#">Phase</a>
Behcet Syndrome Behcet Disease Mucocutaneous Ulceration	Drug: Veldona, very low dose oral natural human interferon alpha	<b>Phase II</b>

[Genetics Home Reference](#) related topics: [Skin Conditions](#)

[MedlinePlus](#) related topics: [Behcet's Syndrome](#) [Skin Conditions](#)

[ChemIDplus](#) related topics: [Interferon alfa-2a](#) [Interferon alfa-2b](#) [Interferons](#)

[U.S. FDA Resources](#)

Study Type: Interventional

Study Design: Treatment, Randomized, Double-Blind, Placebo Control, Parallel Assignment, Safety/Efficacy Study

Official Title: Phase II Study, Evaluation of Low Dose Natural Human Interferon Alpha Administered by the Oral Mucosal Route in the Treatment of Behçet's Disease

#### Further study details as provided by Nobel Pharmaceuticals:

Primary Outcome Measures:

- Assessment of changes in total oral ulcer area from baseline. [ Time Frame: 12 weeks ]

Secondary Outcome Measures:

- Time to initial response, Oral ulcer sustained response, Oral ulcer recurrence, Time to recurrence, Pain associated with oral lesions, General well-being, Safety [ Time Frame: 12 weeks ]

Estimated Enrollment: 90  
Study Start Date: April 2006  
Estimated Study Completion Date: December 2007

#### Detailed Description:

Behçet's disease is a severe chronic relapsing inflammatory disorder marked by oral and genital ulcers, uveitis and skin lesions, as well as varying multisystem involvement including the joints, blood vessels, central nervous system, and gastrointestinal tract. Oral ulcers are the initial symptom for most of Behçet's cases and are the single manifestation of the disease required for an official diagnosis, along with two other hallmark symptoms.

Ninety (90) patients will be enrolled in a randomized, parallel, double-blind, placebo-controlled study to evaluate the effectiveness of low dose natural human IFN  $\alpha$  administered by the oral mucosal route in reducing the number, size, incidence and pain of oral ulcers in patients with Behçet's disease.

The clinical trial will consist of 3 groups of patients randomized in a 1:1:1 ratio to twice daily receive 2 lozenges containing 500 IU IFN  $\alpha$  (2,000 IU daily, n=30), one active (500 IU) and one placebo lozenge (1,000 IU daily, n=30) or 2 placebo lozenges (n=30). Subjects will be monitored weekly over an initial 4 weeks of treatment and then bi-weekly over an additional 8 weeks of treatment. Medication will be self-administered as 2 lozenges taken twice daily (morning and

evening). Oral lesions will be counted and measured at each study visit, and patients will answer a series of questionnaires. Results will be subjected to statistical analysis at the completion of the study, with change in total ulcer burden of a patient, a measurement of the total oral mucosal surface area involved with ulcerous lesions at each visit, serving as the primary endpoint. The total ulcer burden from each treated visit will be compared to the baseline total ulcer burden and the amount of change determined. Patients with a 75% decrease in total ulcer burden will be considered responders.

## ► Eligibility

Ages Eligible for Study: 18 Years to 75 Years

Genders Eligible for Study: Both

### Criteria

#### Inclusion Criteria:

- Is a male or a non-pregnant, non-lactating female.
- Has a history and clinical presentation consistent with a diagnosis of Behçet's Disease and meets International Study Group criteria (Appendix B).
- Has a history of oral ulcers for at least 12 months.
- Has a history of monthly episodes of multiple oral ulcers.
- Has the presence of at least 2 oral ulcers at study entry, both of which are accessible to measurement, with a total diameter of at least 4 mm.
- Has signed an IRB approved subject consent form.
- Has completed all screening procedures satisfactorily, is deemed to be an acceptable subject and is otherwise eligible for entry into the study.
- Is willing and able to comply with the protocol.

#### Exclusion Criteria:

- Has a severe, acute, or chronic systemic disease other than Behçet's Disease such as congestive heart failure, hepatic failure, renal failure, Systemic Lupus Erythematosus (SLE), Stevens-Johnson syndrome, ulcerative colitis, cancer, leukemia, diabetes, AIDS or ARC, or any other condition for which they are immunocompromised.
- Is under active treatment for dental conditions, such that multiple dental office visits would be required during the study period, or presents with oral conditions which are not thought to be related to Behçet's Disease and, in the judgment of a qualified dentist, will require treatment during the study period.
- Is suffering from any medical condition other than Behçet's Disease known to cause oral ulcerations, such as erosive lichen planus, benign mucous membrane pemphigoid, SLE, Crohn's disease, Reiter's syndrome, or AIDS.
- Has an eating disorder and/or psychiatric illness requiring treatment.

- Has hypersensitivity to interferon-alpha.
- Is a pregnant or lactating female, or is of childbearing potential and is not using a medically acceptable contraceptive method throughout the study.
- Has had previous exposure to any parenteral interferon therapy.
- Has had exposure to IFN $\alpha$  lozenges within 30 days of screening.
- Has had exposure to thalidomide within 30 days of screening.
- Has had exposure to methotrexate within 30 days of screening.
- Has had exposure to any immune-suppressive medication within 30 days of screening.
- Has a history of, or is currently exhibiting, any disease or condition which, in the opinion of the Principal Investigator, would place the subject at increased risk during study therapy.
- Has any abnormality in a hematological or biochemical variable which, in the opinion of the Principal Investigator, would place the subject at increased risk during study therapy.

## ► Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00483184

### Contacts

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### Locations

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**Recruiting**

### Sponsors and Collaborators

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Principal Investigator: Cengiz Korkmaz, MD Osmangazi University Medical School

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### ▶ More Information

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Health Authority: Turkey: Ministry of Health; United States: Food and Drug Administration

Study placed in the following topic categories:

Interferon-alpha

Mouth Diseases

Uveitis, Anterior

Vascular Diseases

Behcet Syndrome

Uveitis

Panuveitis  
Interferon Type I, Recombinant  
Oral Ulcer  
Vasculitis  
Skin Diseases  
Ulcer  
Interferons

Connective Tissue Diseases  
Reaferon  
Interferon Alfa-2a  
Interferon Alfa-2b  
Behcet syndrome  
Ethanol

Additional relevant MeSH terms:

Skin and Connective Tissue Diseases  
Anti-Infective Agents  
Uveal Diseases  
Skin Diseases, Vascular  
Immunologic Factors  
Antineoplastic Agents  
Growth Substances  
Eye Diseases  
Physiological Effects of Drugs  
Adjuvants, Immunologic

Angiogenesis Inhibitors  
Antiviral Agents  
Pharmacologic Actions  
Therapeutic Uses  
Biological Response Modifiers  
Cardiovascular Diseases  
Growth Inhibitors  
Angiogenesis Modulating Agents  
Stomatognathic Diseases  
Central Nervous System Agents

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