A Multi-Center, Continuation Trial of Belimumab (HGS1006, LymphoStat-B), a Fully Human Monoclonal Anti-BLyS Antibody, in Subjects with Systemic Lupus Erythematosus (SLE) who Completed the Phase 3 Protocol HGS1006-C1056 or HGS1006-C1057

Published: 30-12-2008
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Objectives: • To provide continuing treatment to subjects with SLE who complete HGS1006-C1056 or HGS1006-C1057.• To evaluate the long-term safety and tolerability of belimumab in subjects with SLE.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON39387

Source
ToetsingOnline

Brief title
HGS1006-C1074

Condition

- Autoimmune disorders

Synonym
SLE, Systemische Lupus Erythematosus

Research involving
Human

Sponsors and support

Primary sponsor: Human Genome Sciences, Inc.
Source(s) of monetary or material Support: HGS Inc.

Intervention

Keyword: Belimumab, Continuation, LymphoStat-B, SLE

Outcome measures

Primary outcome

As this is a follow-up study studying the long-term safety aspects of the use

of the study medication, the only study variable is the number of adverse

events.

Secondary outcome

As this is a follow-up study studying the long-term safety aspects of the use

of the study medication, there are no other study variables than the number of

adverse events.

Study description

Background summary

This trial provides subjects who complete either the HGS1006-C1056 or HGS1006-C1057 trial the option of continuing treatment with belimumab, as an add-on to their standard of care SLE therapy. Subjects in HGS1006-C1056 or HGS1006-1057 who have tolerated study drug, and wish to continue to receive belimumab may do so, under the conditions of this protocol. Those subjects randomized to placebo plus SOC in HGS1006-C1056 or HGS1006-1057 will receive belimumab (10mg.kg) plus SOC in the continuation trial. This is an optional trial in which eligible subjects will be enrolled at the discretion of the investigator and consent of the subject. The trial will also provide data on

long-term safety of belimumab.

Study objective

Objectives:
• To provide continuing treatment to subjects with SLE who complete HGS1006-C1056 or HGS1006-C1057.

• To evaluate the long-term safety and tolerability of belimumab in subjects with SLE.

Study design

This is a multi-center, continuation trial of belimumab plus standard of care (SOC) in SLE subjects who completed the Phase 3 HGS1006-C1056 or HGS1006-C1057 protocol. Subjects participating in this protocol will continue to be monitored for safety. The frequency of safety laboratory evaluations has been reduced in this protocol compared with HGS1006-C1056 or HGS1006-C1057 based on the safety profile of belimumab studies to date and is not anticipated to compromise the well being and safety of subjects. In the Phase 2 and the Phase 2 continuation trials, the incidence rates of adverse events (AEs) in general and by SOC (including infections), serious AEs, and malignancies were comparable to placebo per 100 subject years of exposure. The overall incidence rate of adverse events remained stable or decreased over 2.5 years of exposure to belimumab. HGS will remain blinded to subjects* treatment until all data from the Phase 3 study in which they participated, HGS1006-C1056 or HGS1006-C1057, are locked and unblinded. Clinical sites will remain blinded until after the results of HGS1006-C1056 and HGS1006-C1057 are publicly disclosed.

Intervention

Subjects on active drug will continue to receive belimumab at their present dose every 28 days intravenously (IV) over 1 hour. Subjects on placebo will receive belimumab at a dose of 10mg/kg every 28 days IV over 1 hour. The 1st dose on the continuation trial must be given 4 weeks (minimum of 2 weeks, maximum of 8 weeks) after the last dose in HGS1006-C1056 or HGS1006-C1057.

Study burden and risks

Subjects who complete the study will have a total of 6 blood and urine samples in the first year and 2 samples every next year. At the exit-visit and follow-up post last infusion visit there will also be taken blood and urine samples (females will have a urine pregnancy test at every visit). Subjects will be asked for adverse events at every visit. Study agent is administered at every visit except at the Exit visit, unscheduled visits and at the 8-week follow-up visit.

The main side effects from the study drug that have been reported in clinical trials were arthralgia, headache, skin rash, diarrhea, nausea, tiredness, infections in the upper respiratory tract, arthritis, back pain, urinary tract infections, peripheral edema, sinusitis and myalgia.

A possible safety risk of belimumab is weakening of the immune system, with the possible consequence of reduction of the amount of antibodies, which will cause an increased recovery time for infections. Increase of infections and more severe infections is also a possibility.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Have completed the HGS1006-C1056 or HGS1006-C1057 Protocol through the week 72 or

week 48 visits, respectively.
2. Be able to receive the 1st dose of belimumab for HGS1006-C1074 four weeks (minimum of 2 weeks, maximum of 8 weeks) after the last dose in HGS1006-C1056 or HGS1006 C1057.

Exclusion criteria

1. Have developed clinical evidence of significant, unstable or uncontrolled, acute or chronic diseases not due to SLE (ie, cardiovascular, pulmonary, hematologic, gastrointestinal, hepatic, renal, neurological, malignancy or infectious diseases), or experienced an adverse event (AE) in the Phase 3 study that could, in the opinion of the principal investigator, put the subject at undue risk.;2. Have developed any other medical diseases (eg, cardiopulmonary), laboratory abnormalities, or conditions (eg, poor venous access) that, in the opinion of the principal investigator, makes the subject unsuitable for the study.

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-04-2009
Enrollment:	5
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	LymphoStat-B
Generic name:	LymphoStat-B

Ethics review

Approved WMO Date:	30-12-2008
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO Date:	07-04-2009
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO Date:	28-10-2010
Application type:	Amendment
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO Date:	02-12-2010
Application type:	Amendment
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO Date:	12-09-2011
Application type:	Amendment
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO Date:	07-10-2011
Application type:	Amendment
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO Date:	21-11-2011
Application type:	Amendment
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO	

Date:	15-12-2011
Application type:	Amendment
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO Date:	16-05-2012
Application type:	Amendment
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO Date:	24-05-2012
Application type:	Amendment
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO Date:	03-05-2013
Application type:	Amendment
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO Date:	16-05-2013
Application type:	Amendment
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO Date:	10-04-2014
Application type:	Amendment
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO Date:	06-05-2014
Application type:	Amendment
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2007-007648-85-NL
ClinicalTrials.gov	NCT00712933
CCMO	NL26234.101.08