

Unique Protocol ID:	<b>HGS1006-C1056</b>
Secondary IDs:	BLISS-76
ClinicalTrials.gov ID:	NCT00410384
Brief Title:	A Study of Belimumab in Subjects With Systemic Lupus Erythematosus (SLE)
Official Title:	A Phase 3, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, 76-Week Study to Evaluate the Efficacy and Safety of Belimumab (HGS1006, LymphoStat-B™), a Fully Human Monoclonal Anti-BLyS Antibody, in Subjects With Systemic Lupus Erythematosus (SLE)
Study Type:	Interventional
Sponsor:	Human Genome Sciences
Collaborators:	GlaxoSmithKline
Responsible Party:	Name/Official Title: William Freimuth, MD, PhD/Vice President of Clinical Research, Immunology, Rheumatology and Infectious Diseases Organization: Human Genome Sciences, Inc. Phone: 240-314-1200 Ext: Email: william_freimuth@hgsi.com
Oversight Authorities:	United States: Food and Drug Administration Canada: Health Canada Mexico: Ministry of Health Germany: Paul-Ehrlich-Institut Belgium: Ministry of Social Affairs, Public Health and the Environment Netherlands: Independent Ethics Committee Czech Republic: State Institute for Drug Control Slovakia: State Institute for Drug Control United Kingdom: Department of Health France: Ministry of Health Spain: Ministry of Health Poland: Ministry of Health Italy: Ministry of Health Austria: Agency for Health and Food Safety <b>Israel: Ministry of Health</b> Sweden: Medical Products Agency
Detailed Description:	The purpose of this SLE trial study is to evaluate the efficacy, safety, tolerability, and impact on quality of life of two different doses of belimumab administered in addition to standard therapy in subjects with active Systemic Lupus Erythematosus (SLE) disease.
Overall Status:	Recruiting
Study Start Date:	December 2006
Study Completion Date:	June 2009 [Anticipated]

Study Design:	Primary Purpose: Treatment Study Phase: Phase 3 Intervention Model: Parallel Assignment Number of Arms: 3 Masking: Double Blind (Subject, Investigator) Allocation: Randomized Control: Placebo Control Endpoint Classification: Safety/Efficacy Study Enrollment: 810 [Anticipated]
Arms:	1: Active Comparator 1mg/kg 2: Active Comparator 10mg/kg 3: Placebo Comparator Placebo
Eligibility Criteria:	Key Exclusion Criteria: <ul style="list-style-type: none"> <li>• Pregnant or nursing</li> <li>• Have received treatment with any B cell targeted therapy.</li> <li>• Have received treatment with a biological investigational agent in the past year.</li> <li>• Have received IV cyclophosphamide within 180 days of Day 0.</li> <li>• Have severe lupus kidney disease.</li> <li>• Have active central nervous system (CNS) lupus.</li> <li>• Have required management of acute or chronic infections within the past 60 days.</li> <li>• Have current drug or alcohol abuse or dependence.</li> <li>• Have a historically positive test or test positive at screening for HIV, hepatitis B, or hepatitis C.</li> </ul>
Gender and minimum age:	Both genders are included, minimum 18 years old
<b>Locations:</b>	<b>Facility:</b> Soroka Medical Center Beer-Sheva, Israel Tel. 08-6403123 <b>Facility:</b> Rabin Medical Center Petach Tikva, Israel Tel. 03-9377077 <b>Facility:</b> Kaplan Medical Center Rehovot, Israel, Tel. 08-9441403 <b>Facility:</b> Sourasky Medical Center Tel-Aviv, Israel, Tel. 03-6974835 <b>Facility:</b> Carmel Medical Center Haifa, Israel, Tel. 04-8568222 <b>Facility:</b> Rambam Medical Center Haifa, Israel, Tel. 04-8542889 <b>Facility:</b> Bnai-Zion Medical Center Haifa, Israel, Tel. 04-8359685 <b>Facility:</b> Sheba Medical Center Ramat Gan, Israel, Tel. 052-2741335