Z9001

A phase III randomized double-blind study of adjuvant STI571 (Gleevec™) versus placebo in patients following the resection of Primary GastroIntestinal Stromal Tumor (GIST)

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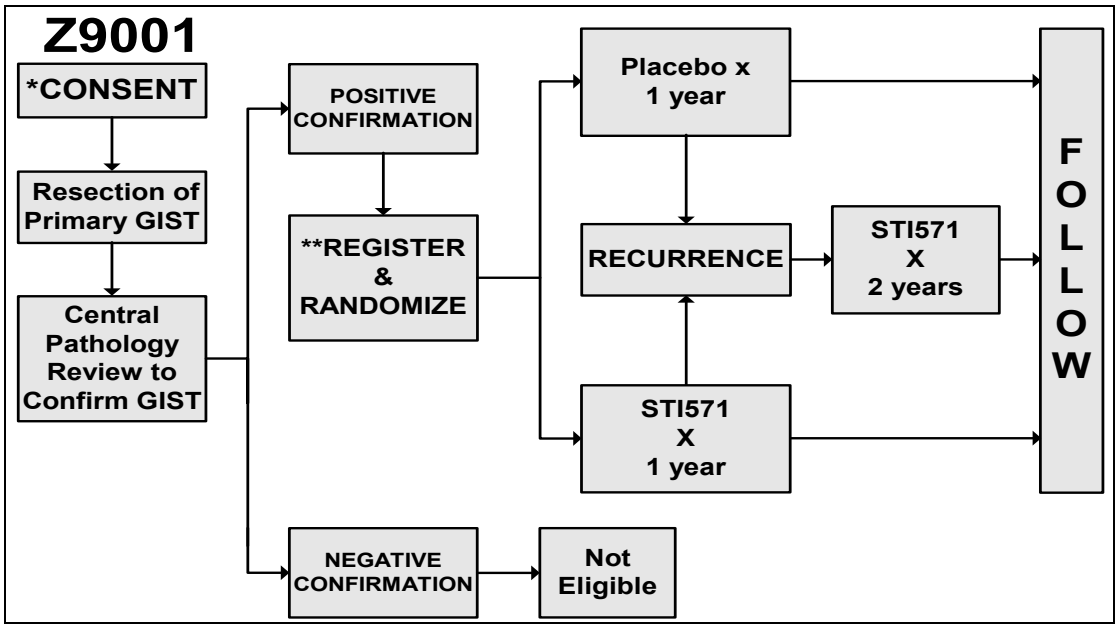

Objectives

Primary Objective: To ascertain whether patients with resected primary GIST who are randomized to the STI571 Arm have longer survival as compared to the patients randomized to the Placebo Arm.

Secondary Objectives: To determine whether patients with resected primary GIST who are randomized to the STI571 Arm have longer recurrence-free survival as compared to the patients randomized to the Placebo Arm.

To obtain from patients with GIST: tumor tissue (before therapy with STI571 and if the patient develops recurrence), blood specimens (before therapy with STI571), and serum specimens (before therapy with STI571, after completing therapy with STI571, and if the patient develops recurrence) for scientific correlative analyses.

To assess the safety/efficacy of oral STI571 therapy in the adjuvant setting.

Accrual goal

Accrual goal is to enroll 380 eligible patients.

Summary Statement

The first registration was on July 31, 2002, with 44 patients having been registered through April 30, 2003 from 21 Physician Groups. Because Z9001 is a double-blinded study, the actual treatment a patient is receiving is not reported when displaying data such as patient demographics and adverse events.

Patient Data Eligibility Review is ongoing for this study.

There was one Grade 4 Adverse Event (Neutropenia) which was possibly attributible to study intervention.

Registrations by Physician Group to Study Z9001

(Data as of 30APR03)

Physician Group	# Patients
CTSU / Rockville, MD	10
Reintgen / Lakeland, FL	4
Patel / Houston, TX	4
Bold / Sacramento, CA	3
Fong / New York, NY	3
Finlayson / Denver, CO	2
Niederhuber / Madison, WI	2
Swanson / Boston, MA	2
VanderMeer / Sayre, PA	2
Jacobs / Columbia, MO	1
Barth / Lebanon, NH	1
Winchester / Evanston, IL	1
Walker / Milwaukee, WI	1
Eberlein / St. Louis, MO	1
Levine / Winston-Salem, NC	1
Chao / Louisville, KY	1
Didolkar / Baltimore, MD	1
Gwin / Chattanooga, TN	1
Khan / Marshfield, WI	1
Sheppard / Portland, OR	1
Carloss / Paducah, KY	1
Total (21 Physician Groups)	**44**

Z9001 Patient Demographics

(Data as of 30APR03)

n=44

	Arm A n=21		Arm B n=23	
Age				
Median	56		49	
Minimum	40		35	
Maximum	77		79	
Sex				
Males	10	47.6%	10	43.5%
Females	11	52.4%	13	56.5%
Ethnicity				
Hispanic	1	4.8%	0	0%
Non-Hispanic	18	85.7%	14	60.9%
Race				
White	18	85.7%	19	82.6%
Black	3	14.3%	3	13%
Pacific Islander	0	0%	0	0%
Asian	0	0%	1	4.3%
Amer. Ind/Alaska Nat.	0	0%	0	0%
Other	0	0%	0	0%

Note: Summaries are based on available patient data

Z9001 Adverse Events

(Data as of 30APR03)

n=35

	Arm A n=17					**Arm B n=18**				
	Grade					**Grade**				
	1	**2**	**3**	**4**	**5**	**1**	**2**	**3**	**4**	**5**
Anorexia	1	0	0	0	0	0	0	0	0	0
Arthralgia	1	0	0	0	0	0	0	0	0	0
Constipation	1	0	0	0	0	0	0	0	0	0
Constitutional Symptoms-Other	0	0	0	0	0	0	1	0	0	0
Dehydration	0	0	0	0	0	1	0	0	0	0
Dermatitis exfoliative NOS	0	1	0	0	0	4	0	0	0	0
Diarrhoea NOS	2	0	0	0	0	5	0	0	0	0
Dizziness (exc vertigo)	1	1	0	0	0	0	0	0	0	0
Dry skin	0	0	0	0	0	0	0	1	0	0
Dyspepsia	2	0	0	0	0	1	0	0	0	0
Fatigue	1	0	0	0	0	5	3	0	0	0
Flatulence	3	0	0	0	0	1	0	0	0	0
Haemoglobin decreased	0	0	0	0	0	2	0	0	0	0
Headache NOS	3	1	0	0	0	1	0	0	0	0
Hypercalcaemia	1	0	0	0	0	0	0	0	0	0
Hyperglycaemia NOS	1	0	0	0	0	0	0	0	0	0
Hyperkalaemia	0	1	0	0	0	0	0	0	0	0
Lacrimation increased	0	0	0	0	0	1	0	0	0	0
Leucopenia NOS	0	0	0	0	0	0	0	1	0	0
Musculoskeletal-Other	0	0	0	0	0	2	0	0	0	0
Myalgia	0	2	0	0	0	0	0	0	0	0
Nausea	3	0	0	0	0	6	0	1	0	0
Neutropenia	0	0	0	0	0	0	1	0	1	0
Ocular/Visual-Other	1	0	0	0	0	0	0	0	0	0
Oedema NOS	4	0	0	0	0	6	2	0	0	0
Peripheral sensory neuropathy	1	0	1	0	0	2	0	0	0	0
Platelet count decreased	1	0	0	0	0	0	0	0	0	0
Pruritus NOS	2	0	0	0	0	0	0	0	0	0
Taste disturbance	1	0	0	0	0	1	0	0	0	0
Tremor NEC	0	0	0	0	0	1	0	0	0	0
Urinary frequency	0	1	0	0	0	0	0	0	0	0
Vomiting NOS	1	0	0	0	0	0	0	0	0	0
MAXIMUM GRADE (PER PATIENT)	**4**	**5**	**1**	**0**	**0**	**11**	**2**	**1**	**1**	**0**

1. Only those Adverse Events possibly, probably or definitely related to study intervention are reported

2. For each patient the maximum grade per adverse event is reported