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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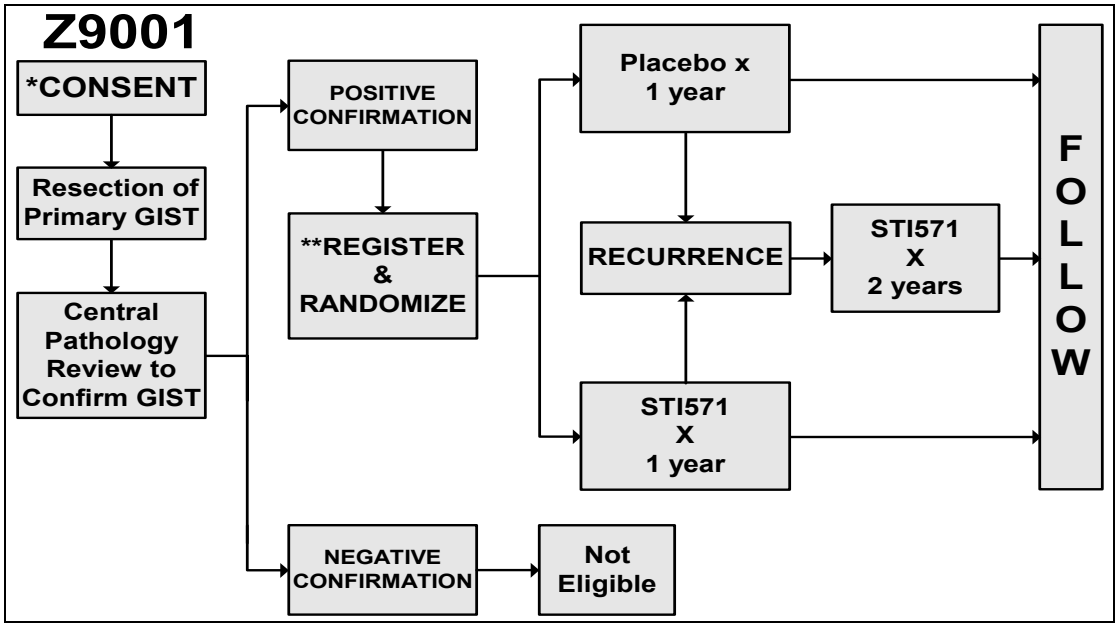

Objectives

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 5 patients having been registered through September 30, 2002 from 5 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.

Registrations by Physician Group to Study Z9001

(Data as of 30SEP02)

Physician Group	# Patients
Fong / New York, NY	1
Winchester / Evanston, IL	1
Thigpen / Lakeland, FL	1
Chao / Louisville, KY	1
VanderMeer / Sayre, PA	1
Total (5 Physician Groups)	**5**

Z9001 Patient Demographics

(Data as of 30SEP02)

n=5

	Arm A n=3		Arm B n=2	
Age				
Median	66		47	
Minimum	42		44	
Maximum	75		50	
Ethnicity				
Hispanic	0	0%	0	0%
Non-Hispanic	3	100%	2	100%
Race				
White	3	100%	1	50%
Black	0	0%	1	50%
Nat. Hawaiian/Pac. Islander	0	0%	0	0%
Asian	0	0%	0	0%
Amer. Ind/Alaska Nat.	0	0%	0	0%
Unknown	0	0%	0	0%

Note: Summaries are based on available patient data

Z9001 Adverse Events

(Data as of 30SEP02)

n=5

	Arm A n=3					**Arm B n=2**				
	Grade					**Grade**				
	1	**2**	**3**	**4**	**5**	**1**	**2**	**3**	**4**	**5**
Constipation	1	0	0	0	0	0	0	0	0	0
Dermatitis-Exfolative	1	0	0	0	0	0	0	0	0	0
Diarrhoea	1	0	0	0	0	1	0	0	0	0
Dyspepsia	1	0	0	0	0	0	0	0	0	0
Fatigue	1	0	0	0	0	1	0	0	0	0
Flatulence	2	0	0	0	0	0	0	0	0	0
Headache	2	0	0	0	0	0	0	0	0	0
Hypercalcaemia	1	0	0	0	0	0	0	0	0	0
Hyperglycaemia	1	0	0	0	0	0	0	0	0	0
Hyperkalaemia	1	0	0	0	0	0	0	0	0	0
Myalgia	1	0	0	0	0	0	0	0	0	0
Nausea	2	0	0	0	0	1	0	0	0	0
Ocular/Visual Other	1	0	0	0	0	0	0	0	0	0
Peripheral sensory neuropathy	1	0	0	0	0	0	0	0	0	0
Pruritis	1	0	0	0	0	0	0	0	0	0
Taste disturbance	1	0	0	0	0	0	0	0	0	0
Urinary frequency	0	1	0	0	0	0	0	0	0	0
MAXIMUM GRADE (PER PATIENT)	**2**	**1**	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**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