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Study No.: TRA102537
Title: A randomized, double-blind, placebo-controlled phase III study to evaluate the efficacy, safety and tolerability of eltrombopag olamine (SB-497115-GR), a thrombopoietin receptor agonist, administered for 6 months as oral tablets once daily in adult subjects with previously treated chronic idiopathic thrombocytopenic purpura (ITP). RAISE. R andomized placebo-controlled ITP Study with E ltrombopag
Rationale: Over a 6-month period, eltrombopag may increase the platelet count and therefore reduce bleeding and the need for rescue medications. It may also allow a reduction or cessation of co-administered steroid and other immunosuppressive or cytotoxic drug therapies that have well-known, unwanted side effects. The purpose of this study is to evaluate the 6 month safety and efficacy of eltrombopag in the treatment of previously treated subjects with chronic ITP.
Phase: III
Study Period: 22 November 2006 – 18 July 2008
Study Design: A randomized, double-blind, placebo-controlled, study to evaluate efficacy, safety and tolerability of eltrombopag, initially administered as 50 mg oral tablets once daily for 6 months in adult subjects with previously treated chronic ITP and platelet counts <30 Gi/L.
Centres: This was a multi-center study. Study sites were located in a total of 23 countries from the following continents/countries: Europe (44 Sites), North America (16 Sites), Asia (8 Sites), New Zealand (4 Sites), South America (2 Sites) and Africa (1 Site).
Indication: Previously treated chronic idiopathic thrombocytopenic purpura (ITP).
Treatment: Starting dose was either eltrombopag 50 mg or matching placebo once daily. Dose modification guidelines allowed subjects to: <ul style="list-style-type: none"> • increase the dose of study medication if platelet count elevation was insufficient (e.g. <50 Gi/L) on or after Day 22 (to a maximum of 75 mg [or matching placebo], once daily); • maintain the dose of study medication if platelet counts were between 50 and 200 Gi/L; • reduce the dose of study medication if platelet counts had risen to values between 200 and 400 Gi/L; • interrupt treatment with study medication if platelet counts exceeded 400 Gi/L and restart at a lower dose when platelet counts returned to ≤ 150 Gi/L <p>Upon completion of the first 6 weeks of treatment, concomitant ITP medications were allowed to be reduced or discontinued if a subject's platelet count was ≥ 100 Gi/L for at least 2 successive weeks.</p>
Objectives: The primary objective of this study was to determine the efficacy of oral eltrombopag, when administered once daily, for 6 months duration, to previously treated adult subjects with chronic ITP.
Primary Outcome/Efficacy Variable: Platelet count data collected was used to determine the response to therapy. The primary endpoint was the odds of achieving a platelet count ≥ 50 Gi/L and ≤ 400 Gi/L during the 6-month treatment period, for subjects receiving eltrombopag relative to placebo.

Secondary Outcome/Efficacy Variable(s): Secondary objectives were:

- To assess the ability of eltrombopag to prevent the use of rescue treatment (rescue treatment was defined as a composite of: new ITP medication, increased dose of concomitant ITP medication from baseline, platelet transfusion or splenectomy)
- To describe the pharmacodynamics and durability of eltrombopag response (maintenance of an elevated blood platelet count)
- To describe the effect of eltrombopag on reduction of concomitant ITP medications from baseline
- To assess the impact of eltrombopag on the incidence and severity of bleeding symptoms of thrombocytopenia when administered once daily for 6 months in previously treated adult subjects with chronic ITP
- To assess the impact of eltrombopag on the health related quality of life (HRQoL) and subject reported outcomes

Statistical Methods: The primary endpoint was the odds of achieving a platelet count between 50-400 Gi/L, during the 6 month treatment period, for subjects receiving eltrombopag relative to placebo. Assuming 60% and 25% positive response rates in the eltrombopag and placebo groups, respectively, 120 evaluable subjects were needed to provide $\geq 90\%$ power at the 1% (two-sided) level of significance. To ensure sufficient power for both the primary and main secondary endpoints, a 30% increase in subjects was pre-specified to compensate for potential missing data and drop-outs during the full 6 month study duration, for a total of 189 subjects (63 placebo subjects; 126 eltrombopag subjects). The primary population for analysis was comprised of all randomized subjects (Intent-To-Treat population). All safety parameters were reported using the safety population comprised of all randomized subjects who received at least one dose of study treatment. The relative difference between eltrombopag and placebo with respect to the odds of achieving a platelet count ≥ 50 and ≤ 400 Gi/L during the 6 months of treatment was assessed using a repeated measures model for binary data using generalized estimating equations methodology. This comparison was made at the 1% (2-sided) level of significance.

Study Population: Male and female subjects ≥ 18 years of age, with chronic ITP and platelet counts < 30 Gi/L on Day 1, who had received one or more prior ITP therapies were eligible for inclusion in this study.

	Eltrombopag	Placebo
Number of Subjects:		
Planned, N	126	63
Randomised, N	135	62
Completed, n (%)	112 (83)	55 (89)
Total Number Subjects Withdrawn, N (%)	23 (17)	7 (11)
Withdrawn due to Adverse Events n (%)	13 (10)	4 (6)
Withdrawn due to Subject decision n (%)	4 (3)	2 (3)
Lost to follow-up n (%)	3 (2)	0
Withdrawn due to Lack of Efficacy n (%)	1 (<1)	0
Withdrawn due to non-compliance n (%)	1 (<1)	0
Withdrawn for other reasons n (%)	1 (<1)	1 (2)
Demographics	Eltrombopag	Placebo
N (ITT)	135	62
Females: Males	93:42	43:19
Median Age, years (Min-Max)	47 (18-85)	52.5 (18-77)

White/Caucasian/European, n (%)	95 (70)	42 (68)
Primary Efficacy Results:		
Summary of Responders (ITT Population): The number and percentage of evaluable subjects who achieved a platelet response between 50-400 Gi/L at each nominal on-therapy visit is summarised below:		
Timing of Assessment	Treatment Group	
	Eltrombopag N=135	Placebo N=62
	Responders, n (%)	Responders, n (%)
Baseline	1 (1)	1 (2)
Day 8	50 (37)	4 (7)
Day 15	61 (46)	5 (8)
Day 22	68 (51)	5 (8)
Day 29	64 (49)	6 (10)
Day 36	75 (56)	5 (8)
Day 43	73 (54)	8 (14)
Week 10	56 (52)	8 (17)
Week 14	52 (46)	9 (18)
Week 18	52 (46)	8 (17)
Week 22	55 (49)	9 (19)
Week 26	68 (52)	10 (17)
1 Week Follow-up	46 (42)	8 (15)
2 Week Follow-up	26 (22)	10 (18)
4 Week Follow-up	24 (20)	8 (14)
The Primary Analysis of Responders (ITT Population) – The analysis of platelet counts using a repeated measures model for binary data and generalised estimating equation methodology to estimate regression parameters, is presented below:		
	Responders	
Odds ratio (OR) for eltrombopag/Placebo treatments	8.2	
99% CI	3.59, 18.73	
p-value (two-sided vs. Placebo)	<0.001	
Comment: For the Primary Analysis of Responders, patients who received rescue medications were considered no- responders for the duration of rescue. After ceasing rescue medication, these patients were evaluable again for response (50 to 400 Gi/L) only after platelets fell below 50 Gi/L.		
Secondary Outcome Variable(s):		
<ul style="list-style-type: none"> Summary and analysis of patients initiating rescue medication on-therapy (ITT population): 		
	Treatment Group	
Treatment	Eltrombopag N=135	Placebo N=62
Subjects Initiating Rescue Medication/Treatment, n (%)	24 (18)	25 (40)
OR eltrombopag/ Placebo	0.33	

95% CI	0.16, 0.64	
p-value (two-sided vs Placebo)	0.001	
<ul style="list-style-type: none"> The summary of median platelet counts (ITT Population) is presented below: 		
Timing of Assessment	Treatment Group	
	Eltrombopag N=135	Placebo N=62
	Median Platelet Count (Min – Max)	Median Platelet Count (Min – Max)
Baseline	16 (0 – 78)	16 (2 – 87)
Day 8	36 (1 – 593)	17.5 (3 – 354)
Day 15	54 (2 – 750)	18 (2 – 214)
Day 22	54 (1 – 507)	18.5 (1 – 271)
Day 29	53 (1 – 400)	18 (3 – 313)
Day 36	60 (1 – 952)	19 (4 – 297)
Day 43	59 (1 – 545)	20 (3 – 275)
Week 10	61.5 (1 – 433)	20 (0 – 293)
Week 14	60 (1 – 409)	17.5 (1 – 303)
Week 18	61 (3 – 363)	20.5 (2 – 281)
Week 22	72 (3 – 408)	23 (1 – 315)
Week 26	73.5 (1 – 429)	23 (2 – 315)
1 Week FU	38.5 (1 – 409)	19 (0 – 323)
2 Week FU	21 (1 – 434)	18 (1 – 340)
4 Week FU	24 (1 – 446)	18 (1 – 301)
<ul style="list-style-type: none"> Maximum continuous and cumulative weeks of platelet response (ITT Population): 		
	Treatment Group	
	Eltrombopag N=135 n (%)	Placebo N=135 n (%)
Continuous Response, n	134	60
Mean (SD)	9.5 (8.9)	2.2 (5.5)
Median (Min – Max)	8.1 (1 – 26)	0 (0 – 25)
Cumulative Response, n	134	60
Mean (SD)	11.3 (9.5)	2.4 (5.9)
Median (Min – Max)	10.9 (0 – 26)	0 (0 – 25)
<ul style="list-style-type: none"> The reduction in use of baseline ITP medications (ITT Population) is presented in the table below: 		
	Treatment Group	
	Eltrombopag N=135	Placebo N=62
Subjects taking an ITP medication at baseline, n (%)	63 (47)	31 (50)
Subjects who reduce or discontinue baseline ITP medications, n (%)	37 (59)	10 (32)
OR eltrombopag/Placebo	3.10	
95% CI	1.24, 7.75	
p-value (two-sided vs placebo)	0.016	

- The summary of WHO bleeding scores (ITT Population) is presented in the table below:

Visit	Bleeding Grade	Treatment Group	
		Eltrombopag N=135, n (%)	Placebo N=62, n (%)
Baseline	Grade 1-4	98 (73)	47 (77)
	Grade 2-4	30 (22)	17 (28)
Day 8	Grade 1-4	75 (56)	44 (73)
	Grade 2-4	21 (16)	12 (20)
Day 15	Grade 1-4	52 (39)	40 (68)
	Grade 2-4	11 (8)	13 (22)
Day 22	Grade 1-4	49 (38)	39 (67)
	Grade 2-4	14 (11)	12 (21)
Day 29	Grade 1-4	45 (37)	33 (56)
	Grade 2-4	12 (10)	11 (19)
Day 36	Grade 1-4	29 (23)	39 (66)
	Grade 2-4	9 (7)	11 (19)
Day 43	Grade 1-4	30 (23)	34 (59)
	Grade 2-4	7 (5)	11 (19)
Week 10	Grade 1-4	20 (22)	19 (49)
	Grade 2-4	8 (9)	5 (13)
Week 14	Grade 1-4	20 (23)	24 (57)
	Grade 2-4	4 (5)	7 (17)
Week 18	Grade 1-4	18 (22)	23 (59)
	Grade 2-4	2 (2)	7 (18)
Week 22	Grade 1-4	13 (18)	18 (46)
	Grade 2-4	6 (8)	4 (10)
Week 26	Grade 1-4	24 (22)	29 (56)
	Grade 2-4	8 (7)	8 (15)
1-Week Follow-Up	Grade 1-4	30 (28)	32 (59)
	Grade 2-4	12 (11)	11 (20)
2-Week Follow-Up	Grade 1-4	57 (50)	31 (56)
	Grade 2-4	18 (16)	10 (18)
4-Week Follow-Up	Grade 1-4	55 (46)	34 (59)
	Grade 2-4	15 (13)	12 (21)
• Analysis of Bleeding – (ITT Population):			
		Treatment Group	
		Eltrombopag N-135	Placebo N-62
Analysis of Bleeding (WHO Grades 1-4)			
OR bleeding throughout 6 months, eltrombopag/placebo		0.24	
95 % CI		0.16, 0.38	
p-value (two-sided, vs Placebo)		<0.001	
Analysis of Clinically Significant Bleeding (WHO Grades 2-4)			

OR bleeding throughout 6 months, eltrombopag/placebo		0.35			
95% CI		0.19, 0.64			
p-value (two-sided, vs placebo)		<0.001			
<ul style="list-style-type: none"> The mean HR-QoL scores for all domains and instruments at Week 6, Week 14, and Week 26 or Early Discontinuation from the Study (ITT Population) are presented in the table below: 					
Patient-Reported Outcome	Treatment Group	Baseline Mean \pm SD	Week 6 Mean \pm SD	Week 14 Mean \pm SD	Week 26/Early WD Mean \pm SD
SF-36v2					
Physical Function	Eltrombopag	73.1 \pm 26.8	78.0 \pm 24.4	78.9 \pm 22.5	80.6 \pm 21.7
	Placebo	75.0 \pm 21.7	76.5 \pm 20.8	77.6 \pm 20.0	75.8 \pm 22.6
Physical Role	Eltrombopag	64.5 \pm 30.5	73.7 \pm 27.4	72.9 \pm 24.9	73.7 \pm 25.4
	Placebo	64.5 \pm 26.7	66.9 \pm 25.4	67.2 \pm 25.8	67.5 \pm 27.1
Bodily Pain	Eltrombopag	75.2 \pm 27.8	78.5 \pm 25.4	77.6 \pm 25.8	75.7 \pm 26.6
	Placebo	70.0 \pm 23.2	69.9 \pm 25.9	68.3 \pm 24.8	68.5 \pm 25.0
General Health	Eltrombopag	56.0 \pm 21.3	59.7 \pm 21.5	59.3 \pm 20.7	57.3 \pm 23.1
	Placebo	53.7 \pm 21.8	55.9 \pm 21.4	52.8 \pm 23.2	53.3 \pm 24.9
Vitality	Eltrombopag	55.1 \pm 26.3	62.1 \pm 22.7	61.0 \pm 22.4	60.0 \pm 23.3
	Placebo	56.7 \pm 20.2	59.0 \pm 20.0	56.8 \pm 22.3	57.5 \pm 22.4
Social Function	Eltrombopag	72.7 \pm 28.3	77.6 \pm 26.2	78.4 \pm 22.6	79.0 \pm 24.2
	Placebo	76.1 \pm 21.7	78.0 \pm 21.4	73.4 \pm 25.8	75.0 \pm 25.8
Emotional Role	Eltrombopag	69.1 \pm 30.9	77.5 \pm 25.9	74.1 \pm 25.2	76.9 \pm 25.4
	Placebo	73.4 \pm 25.4	73.1 \pm 24.6	73.3 \pm 22.9	71.5 \pm 26.5
Mental Health	Eltrombopag	68.0 \pm 21.0	71.8 \pm 19.0	70.6 \pm 19.3	70.2 \pm 21.6
	Placebo	70.3 \pm 18.7	71.7 \pm 18.3	68.6 \pm 20.4	68.6 \pm 22.8
Physical Component Summary ^a	Eltrombopag	46.9 \pm 9.7	48.7 \pm 9.0	49.0 \pm 8.1	48.7 \pm 8.6
	Placebo	45.6 \pm 8.3	46.2 \pm 8.3	46.3 \pm 8.3	46.2 \pm 8.1

Mental Component Summary ^b	Eltrombopag	44.3 ± 12.6	47.2 ± 11.1	46.2 ± 11.3	46.5 ± 12.4
	Placebo	46.4 ± 10.1	46.8 ± 10.0	45.3 ± 11.1	45.2 ± 12.3
MEI-SF	Eltrombopag	72.7 ± 21.4	76.2 ± 19.5	76.9 ± 20.5	76.7 ± 20.2
	Placebo	71.3 ± 17.2	73.4 ± 16.4	71.1 ± 20.5	72.0 ± 21.7
FACIT-Fatigue	Eltrombopag	36.0 ± 12.2	39.2 ± 9.7	39.5 ± 9.9	39.2 ± 10.1
	Placebo	36.3 ± 9.0	38.3 ± 8.2	36.9 ± 10.2	37.0 ± 11.3
FACT-Th (6 selected items)	Eltrombopag	13.5 ± 5.8	15.9 ± 6.0	16.7 ± 5.6	16.0 ± 6.1
	Placebo	14.8 ± 5.8	15.1 ± 5.7	15.3 ± 5.4	15.3 ± 6.0
<p>Note: Analyses for each instrument include all subjects in the ITT population with a non-missing baseline assessment and at least one non-missing follow-up assessment.</p> <p>a. Physical Component Summary includes all domains but Physical Function, Physical Role, Bodily Pain and General Health contribute proportionately the most to the aggregate scores.</p> <p>b. Mental Component Summary includes all domains but Vitality, Social Function, Emotional Role and Mental Health contribute proportionately the most to the aggregate scores.</p>					
<p>• Average Effect of Eltrombopag Compared to Placebo on Instrument and Domain Score Changes from Baseline (ITT population):</p>					
		Average Effect of Eltrombopag vs. Placebo on Score Change from Baseline^a			
Patient-Reported Outcomes	Estimate	95% CI		p-value	
SF-36v2					
Physical Function	2.8	-1.1, 6.7		0.154	
Physical Role	5.4	0.5, 10.3		0.030 ^b	
Bodily Pain	5.1	-0.5, 10.6		0.074	
General Health	2.4	-1.6, 6.5		0.243	
Vitality	3.9	0.1, 7.7		0.045 ^b	
Social Function	4.1	-0.6, 8.9		0.089	
Emotional Role	5.4	0.8, 10.1		0.023 ^b	
Mental Health	2.5	-0.9, 6.0		0.154	
Physical Component Summary ^c	1.3	-0.2, 2.9		0.092	
Mental Component Summary ^d	2.1	0.2, 4.0		0.030 ^b	
MEI-SF	3.3	-0.6, 7.3		0.100	
FACIT-Fatigue	1.6	-0.2, 3.5		0.082	
FACT-Th (6 selected items)	1.5	0.5, 2.5		0.004^b	

<p>a. Note: Unadjusted models include the effects of baseline score and treatment</p> <p>b. Estimated from a longitudinal regression model for the effect of eltrombopag vs. placebo of on-therapy score changes from baseline. 95% CIs and p-values are obtained from robust variance estimates with an exchangeable working correlation structure</p> <p>a. Physical Component Summary includes all domains but Physical Function, Physical Role, Bodily Pain and General Health contribute proportionately the most to the aggregate scores</p> <p>d. Mental Component Summary includes all domains but Vitality, Social Function, Emotional Role and Mental Health contribute proportionately the most to the aggregate scores</p>		
<p>Safety Results: All the adverse events (AEs) and serious AEs (SAEs) occurring from the day that subjects received investigational product until completion of the study (including the follow-up period) were recorded.</p>		
<p>• Summary of patients with adverse events on-therapy +1 Day (Safety Population)</p>		
	Treatment Group, n (%)	
	Eltrombopag, N=135	Eltrombopag, N=135
	n, (%)	n, (%)
Any AE	118 (87)	56 (92)
Any SAE	15 (11)	11 (18)
AEs leading to withdrawal	12 (9)	4 (7)
<p>• Summary of patients with adverse events >1 Day post-therapy (Safety Population)</p>		
	Treatment Group, n (%)	
	Eltrombopag, N=135	Placebo, N=61
Any AE	31 (23)	21 (34)
Any SAE	2 (1)	0
<p>• On-therapy + 1 Day adverse events reported by 5% or more of patients in either treatment group (Safety Population)</p>		
Preferred Term	Treatment Group, n (%)	
	Eltrombopag N=135	Placebo N=61
Subjects with Any AE	118 (87)	56 (92)
Headache	41 (30)	20 (33)
Diarrhea	17 (13)	6 (10)
Nausea	16 (12)	4 (7)
Nasopharyngitis	14 (10)	8 (13)
Upper respiratory tract infection	14 (10)	7 (11)
Fatigue	13 (10)	8 (13)
Pain in extremity	9 (7)	6 (10)
ALT increased	10 (7)	4 (7)
Vomiting	10 (7)	1 (2)
Urinary tract infection	9 (7)	4 (7)
Arthralgia	9 (7)	3 (5)
Pharyngolaryngeal pain	9 (7)	3 (5)
Myalgia	8 (6)	2 (3)

Pharyngitis	8 (6)	1 (2)
AST increased	7 (5)	2 (3)
Epistaxis	7 (5)	6 (10)
Back pain	7 (5)	3 (5)
Influenza	7 (5)	3 (5)
Cough	6 (4)	4 (7)
Abdominal pain upper	6 (4)	5 (8)
Constipation	6 (4)	5 (8)
Dizziness	5 (4)	6 (10)
Pruritus	4 (3)	5 (8)
Cataract	4 (3)	4 (7)
Hypertension	4 (3)	3 (5)
Edema peripheral	2 (1)	6 (10)
Dyspepsia	2 (1)	4 (7)
Ecchymosis	2 (1)	4 (7)
Insomnia	2 (1)	4 (7)
Anxiety	2 (1)	3 (5)
Conjunctival hemorrhage	2 (1)	3 (5)
Contusion	2 (1)	3 (5)
Neck pain	2 (1)	3 (5)
Non-cardiac chest pain	2 (1)	3 (5)
Abdominal distension	1 (<1)	3 (5)
Conjunctivitis	1 (<1)	4 (7)
Fall	1 (<1)	3 (5)
Swelling face	1 (<1)	3 (5)
Cellulitis	0	4 (7)
Eye swelling	0	3 (5)
<ul style="list-style-type: none"> • Summary of Serious Adverse Events Started On-Therapy + 1 Day n (%) [n considered by the investigator to be related to study medication] : Safety Population 		
Preferred Term	Eltrombopag N=135	Placebo N=61
Headache	3 (2) [2]	0
Cataract	1 (<1) [1]	2 (3) [2]
Loss of consciousness	1 (<1) [0]	0
Alanine aminotransferase increased	1 (<1) [1]	1 (2) [0]
Aspartate aminotransferase increased	1 (<1) [1]	0
Transaminases increased	1 (<1) [1]	0
Urinary tract infection	1 (<1) [0]	0
Aortic aneurysm	1 (<1) [0]	0
Deep vein thrombosis	1 (<1) [1]	0
Thrombophlebitis superficial	1 (<1) [1]	0
Duodenal ulcer hemorrhage	1 (<1) [0]	0
Spinal compression fracture	1 (<1) [0]	0
Hypokalemia	1 (<1) [0]	0
Pulmonary embolism	1 (<1) [1]	0
Pulmonary infarction	1 (<1) [1]	0

Hemorrhagic anemia	1 (<1) [0]	0
Rectosigmoid cancer	1 (<1) [0]	0
Cataract subcapsular	0	1 (2) [1]
Retinal hemorrhage	0	1 (2) [0]
Brain stem hemorrhage	0	1(2) [0]
Heart rate increased	0	1 (2) [1]
Renal function test abnormal	0	1 (2) [0]
Cellulitis	0	1 (2) [0]
Orchitis	0	1 (2) [0]
Gastrointestinal hemorrhage	0	1 (2) [0]
Hand fracture	0	1 (2) [0]
Hyperkalemia	0	1 (2) [0]
Hemorrhage urinary tract	0	1 (2) [0]
Urogenital hemorrhage	0	1 (2) [0]
Respiratory tract hemorrhage	0	1 (2) [0]
Menorrhagia	0	1 (2) [0]
<ul style="list-style-type: none"> • Summary of Serious Adverse Events Started >1 To 30 Days Post Therapy n (%) [n considered by the investigator to be related to study medication] : Safety Population 		
Preferred Term	Eltrombopag N=135	Placebo N=61
Cataract	1 (<1) [1]	0
Intra-abdominal hemorrhage	1 (<1) [0]	0
Pulmonary embolism	1 (<1) [0]	0
<ul style="list-style-type: none"> • Summary of Serious Adverse Events Started >30 Days Post Therapy n (%) [n considered by the investigator to be related to study medication] : Safety Population 		
Preferred Term	Eltrombopag N=135	Placebo N=61
Chest pain	1 (<1) [0]	0
Cerebral hemorrhage	1 (<1) [0]	0
Peritoneal hemorrhage	0	1 (2) [0]
Bronchitis	0	1 (2) [0]
Acute myeloid leukemia	0	1 (2) [0]
<ul style="list-style-type: none"> • Subjects with Fatal Adverse Events Started On-Therapy + 1 Day n (%) [n considered by the investigator to be related to study medication] : Safety Population 		
Preferred Term	Eltrombopag N=135	Placebo N=61
Brain stem hemorrhage	0	1 (2) [0]

Conclusion: ITP subjects taking eltrombopag once a day for 6 months had a statistically higher odds of responding with a platelet count of ≥ 50 to ≤ 400 Gi/L compared to subjects on placebo.

Publications: None