Liver Meeting of the American Association for the Study of Liver Diseases
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PHARMACEUTICALS

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Dr. Lee Allen, CMO: Introduction

- Avatrombopag is an orally administered thrombopoietin receptor agonist that mimics the effects of endogenous thrombopoietin leading to the production of platelets
- Two completed pivotal Phase 3 clinical trials, ADAPT-1 and ADAPT-2, evaluated avatrombopag for the treatment of thrombocytopenia in patients with chronic liver disease scheduled to undergo a planned medical procedure who were undergoing procedures that had an associated bleeding risk
- Based on the positive safety and efficacy data, we announced the submission of our New Drug Application to the FDA on September 21st

Dr. Norah Terrault: Bio

- Professor of Medicine at the University of California San Francisco, Division of Gastroenterology, and the Principal Investigator of our ADAPT-1 and ADAPT-2 clinical trials
- Nationally and internationally recognized for her work related to viral hepatitis in the setting of liver transplantation
- Author of more than 275 original articles, reviews and book chapters
- Served as Associate Editor for Hepatology and Deputy Editor for Liver Transplantation
- Associate Editor for Hepatology Communications
- Investigator on several NIH-funded clinical studies in hepatitis B and Non-alcoholic Fatty Liver Disease
- Investigator on several ongoing clinical trials

Superiority of Avatrombopag to Placebo for the Treatment of Chronic Liver Disease-Associated Thrombocytopenia in Patients Undergoing Scheduled Procedures:

Results of 2 Randomized, Placebo-Controlled Phase 3 Studies ADAPT-1 and ADAPT-2

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Thrombocytopenia and Chronic Liver Disease

- **Severe thrombocytopenia (platelet count <50 x 10^9/L) is common in patients with chronic liver disease**
- **Platelet transfusions are current standard of care to reduce risk of bleeding during invasive procedures**
  - *Associated with risk of transfusion reactions, infections and induction of platelet refractoriness*
- **No pharmacological treatments are currently licensed for this indication**

Avatrombopag- an oral, small molecule TPO receptor agonist being developed to provide a measured increase in platelet count as an alternative to platelet transfusions

- **It binds to a different site on the TPO receptor than endogenous TPO, so the effects of avatrombopag and TPO are additive**

Afdhal N et al. J Hepatol. 2008; 48(6): 1000-1007; Hod E and Schwartz J. Br J Haematol. 2008; 142(2): 348-360; Giannini EG. Aliment Pharmacol Ther. 2006; 23(8): 1055-1065
Meehan KR et al. Am J Hematol. 2000; 64(4): 251-256 Rebulla P. Haematologica. 2005; 90(2): 247-253

Avatrombopag Phase 3 Studies- ADAPT-1 & ADAPT-2

Two global Phase III studies of avatrombopag in patients with thrombocytopenia and chronic liver disease undergoing scheduled procedures

- Identically-designed, randomized, double-blind, placebo-controlled, parallel-group studies
- In total, **435** patients recruited from over **25** countries

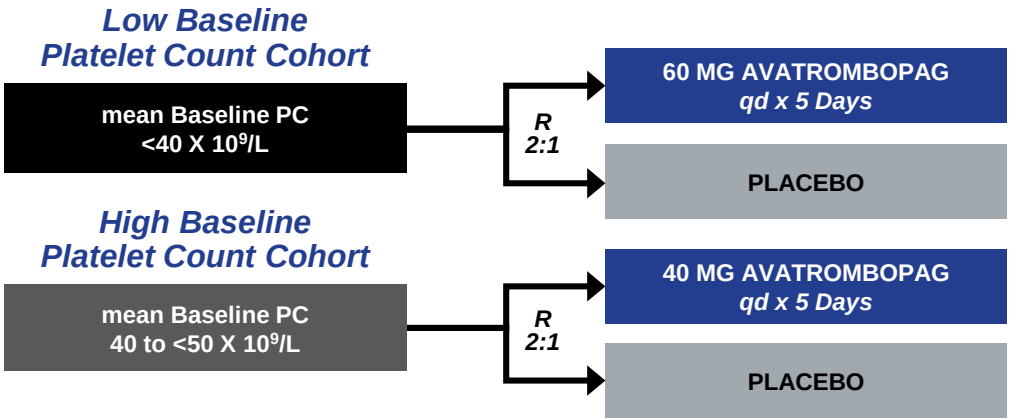
North America	21%
EU	33%
East Asia	32%
Rest of World	14%

Avatrombopag Phase 3 Study Design

ADAPT-1 & ADAPT-2

PRE-RANDOMIZATION	RANDOMIZATION (*2:1 avatrombopag:placebo*)			FOLLOW-UP	
VISIT 1	VISIT 2	VISIT 3	VISIT 4	VISIT 5	VISIT 6
Screening Period Day -14 to -1	**BASELINE** DAY 1	**TREATMENT** DAY 2–5	**PROCEDURE*** DAY 10–13	**7 DAYS POST PROCEDURE**	**DAY 35**
			5–8 days after *last dose of study drug*		***30 days after*** *last dose of study drug*

**Platelet transfusions were not mandatory*



Avatrombopag Phase 3 Study Population Criteria

ADAPT-1 & ADAPT-2

MAIN INCLUSION CRITERIA	MAIN EXCLUSION CRITERIA
Aged ≥18 years	History of arterial or venous thrombosis, hematologic disorders, or cardiovascular disease
Chronic liver disease	Known medical history of genetic pro-thrombotic syndromes
Mean Baseline platelet count <50 x 10^9/L*	Platelet transfusion or use of erythropoietin-stimulating agents within 7 days of screening
MELD score ≤24 at screening	Portal vein flow <10 cm/sec at Screening
Scheduled to undergo an invasive procedure	Hemoglobin ≤8 g/dL or ≥18 g/dL (males) or >15 g/dL (females)
	Hepatocellular carcinoma (HCC) allowed if Barcelona Clinic Liver Cancer Stage A or B

*Platelet counts were measured on 2 separate occasions: During the Screening Period and at Baseline at least 1 day apart with neither platelet count >60 x 10^9/L

ADAPT-1 & ADAPT-2: Outcome Measures

PRIMARY EFFICACY ENDPOINT:

- **Proportion of patients not requiring platelet transfusion or any bleeding rescue procedure up to 7 days post-procedure**
  - *Rescue procedures included: platelet transfusion, fresh frozen plasma (FFP), cryoprecipitate, vitamin K (phytonadione), desmopression, recombinant activated factor VII, aminocaproic acid, tranexamic acid, whole blood transfusion, packed red cell transfusion, surgical intervention or interventional radiology*

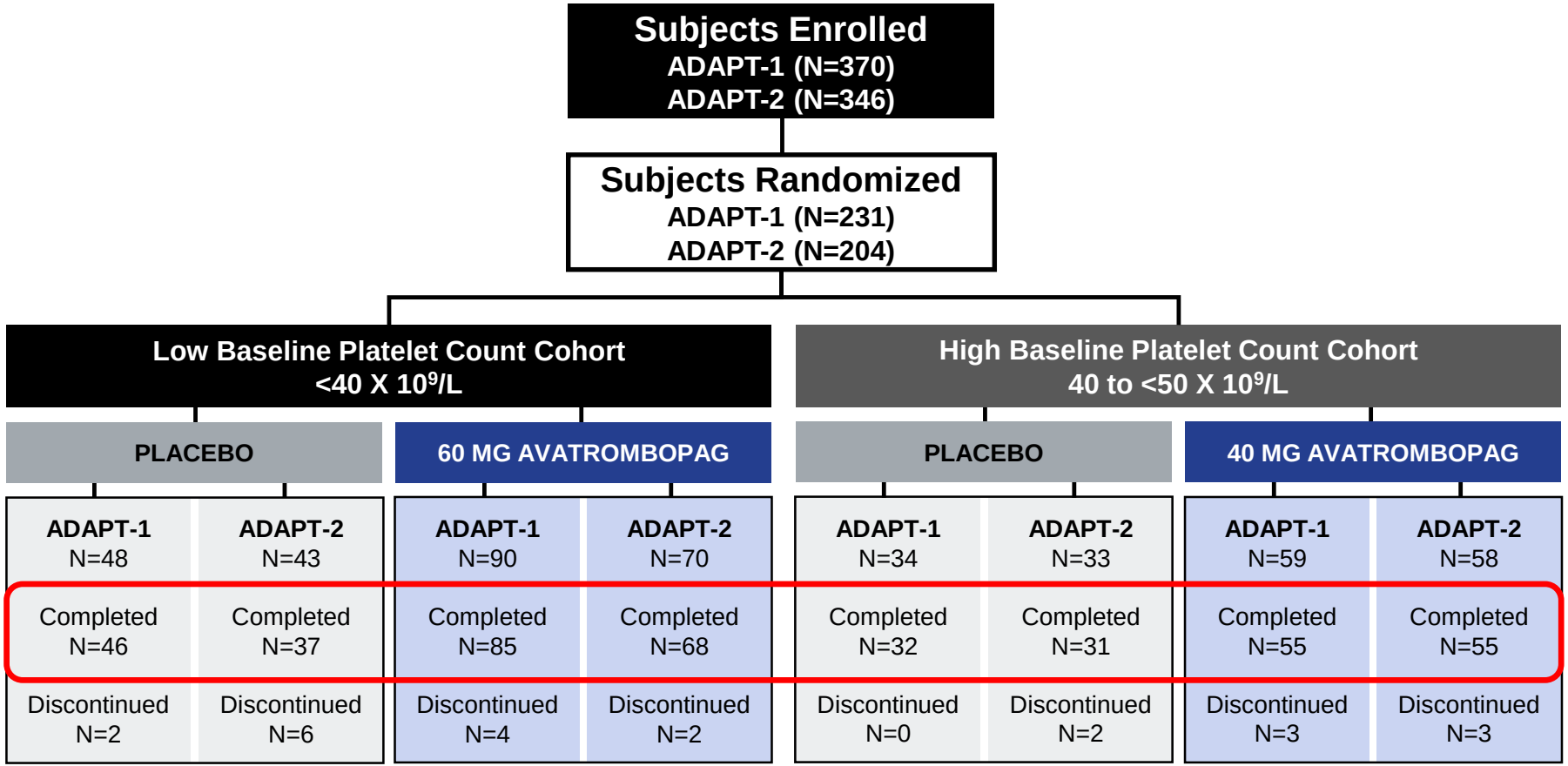
SECONDARY EFFICACY ENDPOINTS:

- **Proportion of patients achieving the target platelet count (≥50 x 10^9/L)**
- **Magnitude of change in platelet count from Baseline to Procedure Day**

SAFETY ENDPOINTS:

- **Adverse events, serious adverse events, Adverse Events of Special Interest (AESI)**

ADAPT-1 & ADAPT-2: Subject Disposition



ADAPT-1 & ADAPT-2: Patient Demographics

	ADAPT-1				ADAPT-2			
	Low Baseline Platelet Count Cohort <40 x 10^9/L		High Baseline Platelet Count Cohort 40 to <50 x 10^9/L		Low Baseline Platelet Count Cohort <40 x 10^9/L		High Baseline Platelet Count Cohort 40 to <50 x 10^9/L	
	Placebo (n=48)	Avatrombopag 60 mg (n=90)	Placebo (n=34)	Avatrombopag 40 mg (n=59)	Placebo (n=43)	Avatrombopag 60 mg (n=70)	Placebo (n=33)	Avatrombopag 40 mg (n=58)
Median Age, years	55.0	57.0	59.0	55.0	58.0	61.5	60.0	59.0
Age <65 years	85%	86%	71%	75%	70%	64%	70%	74%
Age (>=65 years)	15%	14%	29%	25%	30%	36%	30%	26%
Male, %	67%	72%	71%	63%	63%	71%	52%	57%
Weight, kg (± SD)	78 ± 23	80 ± 19	79 ± 25	78 ± 17	80 ± 21	77 ± 22	74 ± 22	78 ± 17
Race								
White	58%	58%	56%	54%	63%	57%	75%	69%
Asian	38%	37%	44%	42%	23%	36%	25%	21%
Other	4%	5%	0	4%	14%	7%	0	10%

APAPT-1 & ADAPT-2: Disease Characteristics

	ADAPT-1				ADAPT-2			
	Low Baseline Platelet Count Cohort <40 x 10^9/L		High Baseline Platelet Count Cohort 40 to <50 x 10^9/L		Low Baseline Platelet Count Cohort <40 x 10^9/L		High Baseline Platelet Count Cohort 40 to <50 x 10^9/L	
	Placebo (n=48)	Avatrombopag 60 mg (n=90)	Placebo (n=34)	Avatrombopag 40 mg (n=59)	Placebo (n=43)	Avatrombopag 60 mg (n=70)	Placebo (n=33)	Avatrombopag 40 mg (n=58)
Mean Baseline Platelet Count Cohort (± SD)	31 ± 7	31 ± 7	45 ± 3	44 ± 3	33 ± 6	33 ± 5	45 ± 3	44 ± 4
Disease Etiology, %								
Alcoholic Liver Disease	15	15	6	19	16	17	15	10
Chronic Viral Hepatitis	63	56	79	63	61	49	55	50
Nonalcoholic Steatohepatitis	8	7	0	7	12	14	15	10
Other	15	23	15	11	12	20	15	29
Hepatocellular Carcinoma, %	23	24	21	29	33	30	33	26
Mean MELD Score (SD)	11 (3)	11 (3)	10 (3)	12 (4)	11 (3)	11 (3)	11 (4)	11 (4)
Child-Turcotte-Pugh Grade, %								
Grade A	63	55	61	53	49	64	49	55
Grade B	35	43	36	38	49	29	36	38
Grade C	2	2	3	9	2	7	15	7

ADAPT-1 & ADAPT-2: Scheduled Procedures by Bleeding Risk

Bleeding Risk	ADAPT-1				ADAPT-2			
	Low Baseline Platelet Count Cohort <40 x 10^9/L		High Baseline Platelet Count Cohort 40 to <50 x 10^9/L		Low Baseline Platelet Count Cohort <40 x 10^9/L		High Baseline Platelet Count Cohort 40 to <50 x 10^9/L	
	Placebo (n=48)	Avatrombopag 60 mg (n=90)	Placebo (n=34)	Avatrombopag 40 mg (n=59)	Placebo (n=43)	Avatrombopag 60 mg (n=70)	Placebo (n=33)	Avatrombopag 40 mg (n=58)
Low %	68	67	66	59	53	60	53	58
Moderate %	20	12	9	20	23	16	28	16
High %	13	21	25	21	25	24	19	26

Low Bleeding Risk Procedures

Thoracentesis
Paracentesis
Endoscopy
Upper GI endoscopy +/- biopsy
Upper GI endoscopy +/- variceal banding, +/- sclerotherapy
Colonoscopy +/- polypectomy/biopsy

Moderate Bleeding Risk Procedures

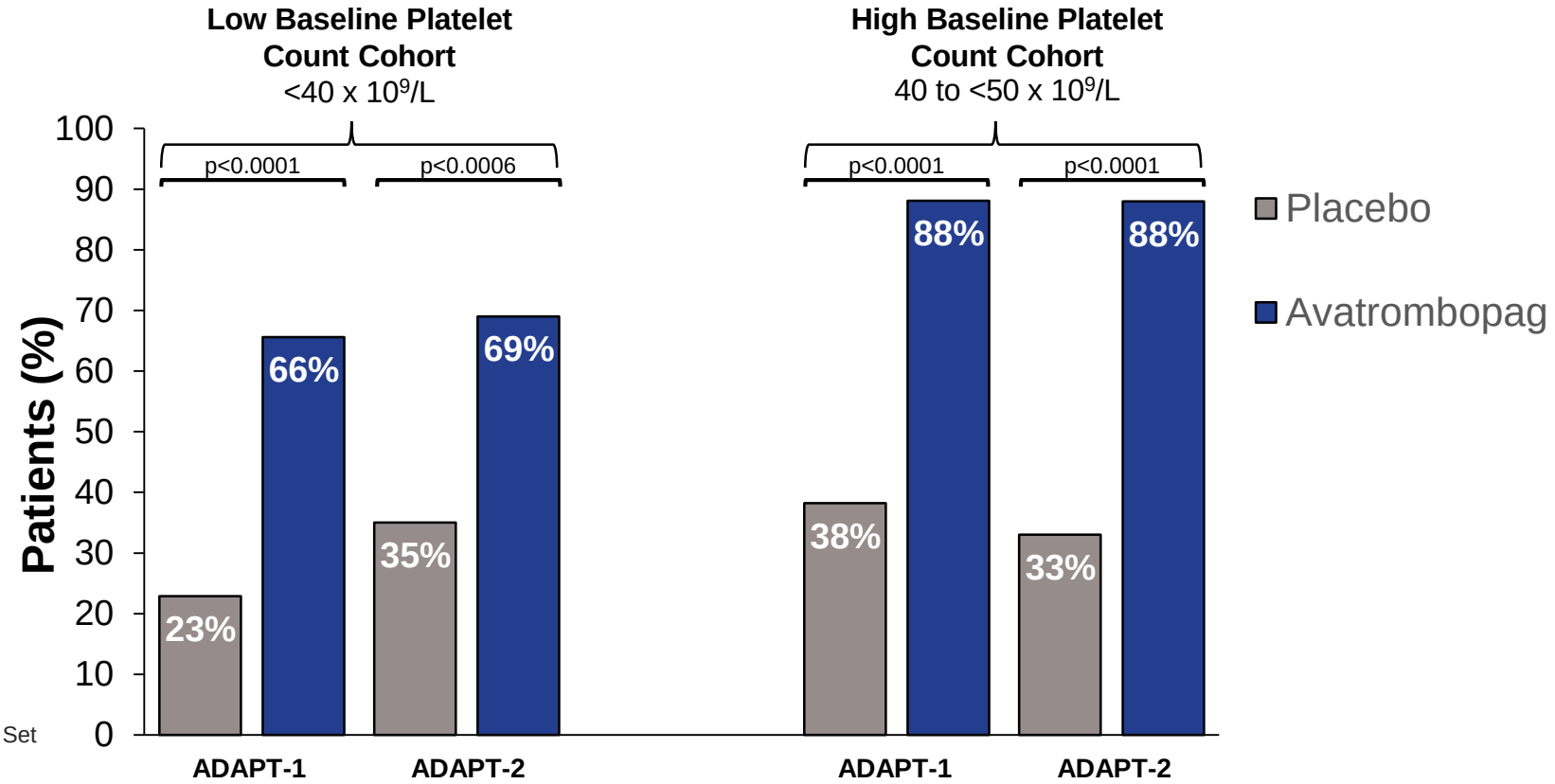
Liver biopsy
Bronchoscopy +/- biopsy
Ethanol ablation
Chemoembolization for HCC

High Bleeding Risk Procedures

Biliary interventions
Dental procedures
Transjugular intrahepatic portosystemic shunt
Laparoscopic interventions
Nephrostomy tube placement
Radiofrequency ablation
Renal biopsy
Vascular catheterization

ADAPT-1 & ADAPT-2: Primary Endpoint

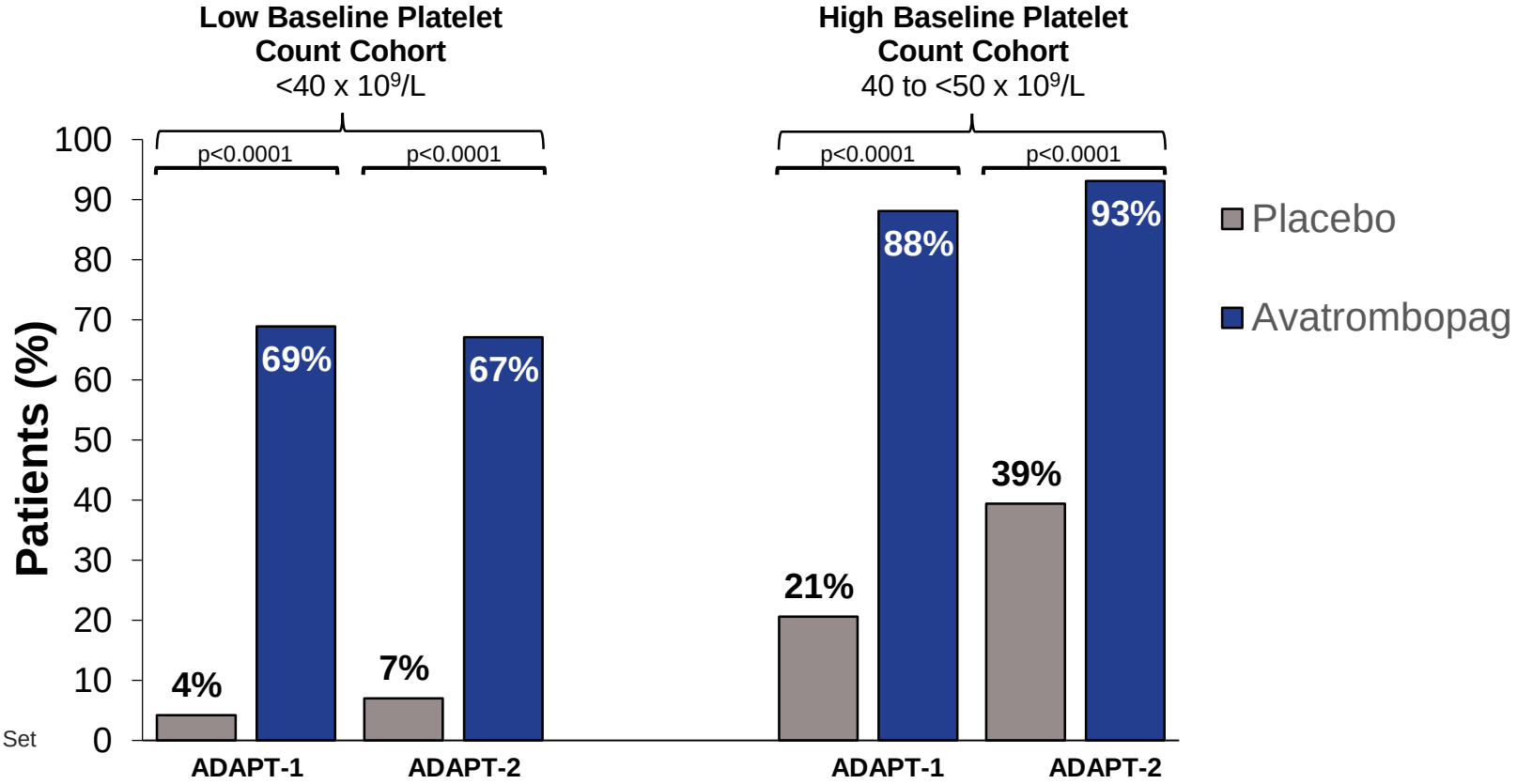
Proportion of Patients Who Did NOT Require Platelet Transfusion or Any Rescue Procedure for Bleeding*



*Full Analysis Set

ADAPT-1 & ADAPT-2: Secondary Endpoint

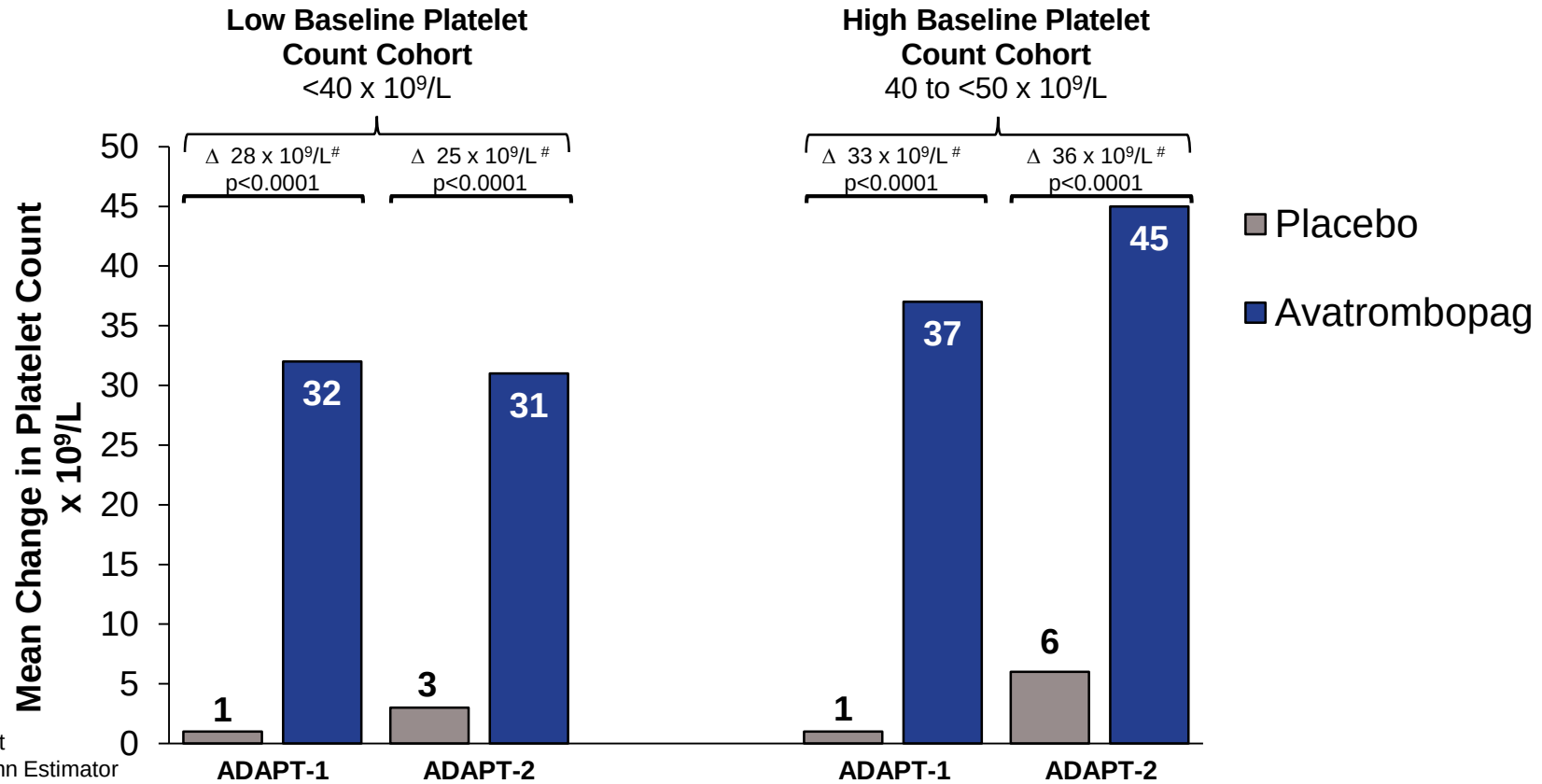
Proportion of Patients Who Achieved Platelet Counts ≥ 50 x 10^9/L on Procedure Day*



*Full Analysis Set

ADAPT-1 & ADAPT-2: Secondary Endpoint

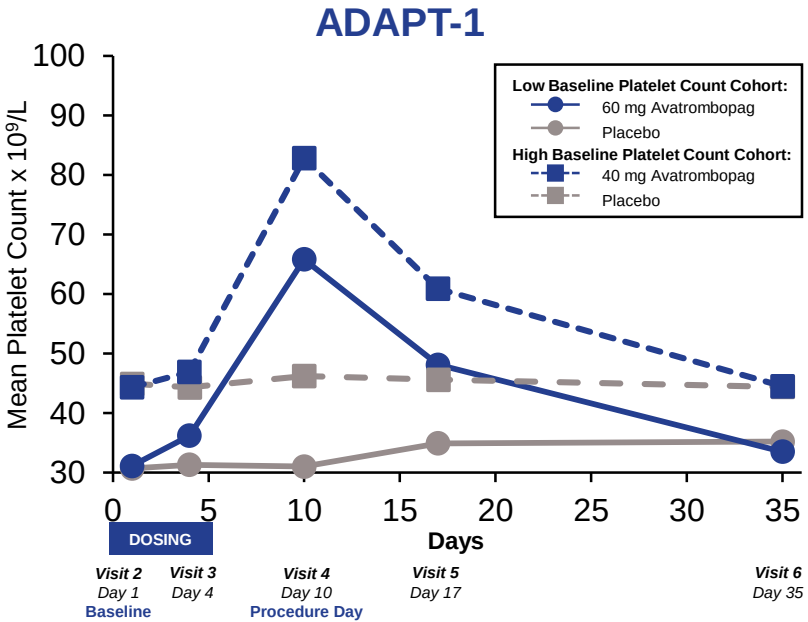
Magnitude of Change in Platelet Count from Baseline to Procedure Day*

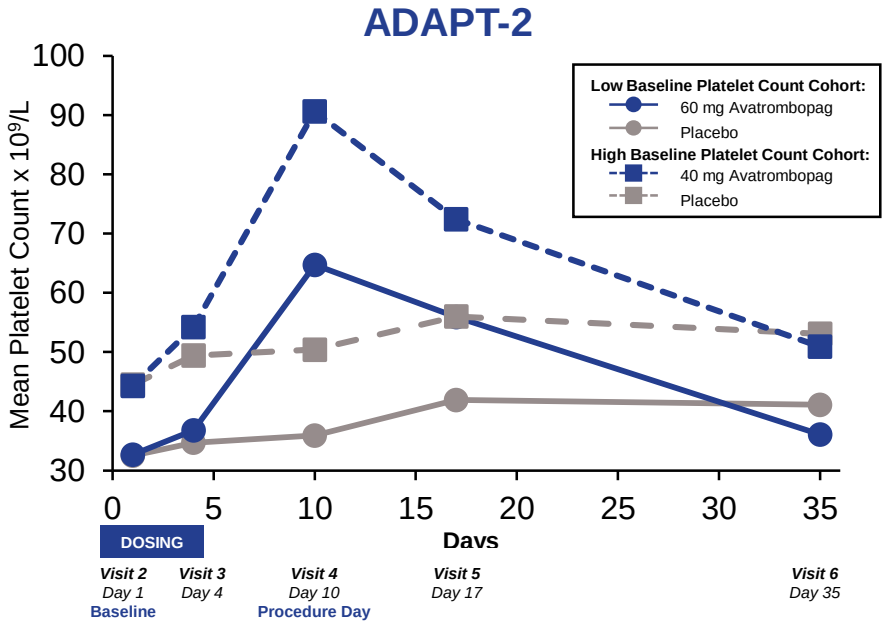


*Full Analysis Set
#Hodges-Lehmann Estimator

ADAPT-1 & ADAPT-2: Change in Platelet Count Over Time

- **Platelet counts reproducibly increased from Day 4, peaked at Day 10-13, and returned to Baseline levels by Day 35**
- **Only 3 (1.1%) avatrombopag-treated patients had platelet counts >200 x10^9/L at any time during the study**





Combined ADAPT-1 & ADAPT-2- *Safety Analysis Set* Most Frequently Reported TE-Emergent Adverse Events

ADAPT-1 and ADAPT-2 Combined Safety Data				
	Low Baseline Platelet Count Cohort <40 x 10^9/L		**High Baseline Platelet Count Cohort** 40 to <50 x 10^9/L	
	Placebo (n=91) n (%)	**Avatrombopag 60 mg** (n=159) n (%)	**Placebo** (n=65) n (%)	**Avatrombopag 40 mg** (n=115) n (%)
TEAEs, n (%)	53 (58.2)	89 (56.0)	33 (50.8)	59 (51.3)
Pyrexia (fever)	8 (8.8)	18 (11.3)	6 (9.2)	9 (7.8)
Abdominal pain	6 (6.6)	10 (6.3)	4 (6.2)	8 (7.0)
Nausea	7 (7.7)	10 (6.3)	4 (6.2)	8 (7.0)
Headache	7 (7.7)	7 (4.4)	3 (4.6)	8 (7.0)
Diarrhea	4 (4.4)	7 (4.4)	2 (3.1)	3 (2.6)
Fatigue	4 (4.4)	7 (4.4)	1 (1.5)	3 (2.6)

Safety Analysis Set- defined as all randomized subjects who received at least 1 dose of study drug and had at least 1 postdose safety assessment; Treatment-emergent Adverse Event (TEAE) an adverse event that started on or after the date of first dose of study drug, up to 30 days after the last dose of study drug. For each row category, a subject with two or more adverse events in that category is counted only once.

Combined ADAPT-1 & ADAPT-2- *Safety Analysis Set* Treatment Emergent Adverse Events

ADAPT-1 and ADAPT-2 Combined Safety Data				
	Low Baseline Platelet Count Cohort <40 x 10^9/L		**High Baseline Platelet Count Cohort** 40 to <50 x 10^9/L	
	Placebo (n=91) n (%)	**Avatrombopag 60 mg** (n=159) n (%)	**Placebo** (n=65) n (%)	**Avatrombopag 40 mg** (n=115) n (%)
Treatment-related TEAEs, n (%)	16 (17.6)	18 (11.3)	4 (6.2)	8 (7.0)
TEAE Grade ≥ 3, n (%)	12 (13.2)	13 (8.2)	4 (6.2)	17 (14.8)
Serious TEAEs	12 (13.2)	11 (6.9)	2 (3.1)	9 (7.8)
Deaths	0	0	1 (1.5)	2 (1.7)
TEAEs Leading to Discontinuation	0	2 (1.3)	0	0

Safety Analysis Set- defined as all randomized subjects who received at least 1 dose of study drug and had at least 1 postdose safety assessment; Treatment-emergent Adverse Event (TEAE) an adverse event that started on or after the date of first dose of study drug, up to 30 days after the last dose of study drug. For each row category, a subject with two or more adverse events in that category is counted only once.

ADAPT-1 & ADAPT-2:
Deaths & Adverse Events Leading to Discontinuation

TEAEs Leading to Study Drug Discontinuation

- N=2 (1.3%) in ADAPT-1 → both in the 60 mg Avatrombopag Treatment Group
  - Myalgia and anemia; possibly study drug-related
  - Pyrexia; unrelated to study drug

Deaths

- N=2 (1.7%) in ADAPT-1 → both in the 40 mg Avatrombopag Treatment Group; not considered to be study drug-related
  - 54 yo male died of multiorgan failure on study **Day 40**
  - 54 yo female died of hepatic coma on study **Day 34**
- N=1 (1.5%) in ADAPT-2 → In the Placebo Treatment Group; not considered to be study drug-related
  - 53 yo male died of acute myocardial infarction and multiple organ dysfunction on study **Day 31**

ADAPT-1 & ADAPT-2:
Adverse Events of Special Interest

Medically Significant Events

- N=1 (0.4% in avatrombopag-exposed) → TEAE of **partial portal vein thrombosis**
  - 71 yo male in the 40 mg Avatrombopag treatment group on Study **Day 18** (Visit 5), 13 days after the last dose
  - Scheduled Procedure: Upper gastrointestinal endoscopy with variceal banding
  - Platelet count **45** x10^9/L at Baseline that increased to **77** x 10^9/L on Procedure Day (study Day 11), and then decreased to **61** x 10^9/L on Day 18 and **45** x10^9/L on study Day 37
  - Event was judged as non-serious and potentially drug-related

Summary and Conclusions

- **Avatrombopag was superior to placebo in:**
  - Reducing the need for platelet transfusion or any rescue procedure for bleeding following a scheduled procedure
  - Increasing the proportion of patients achieving the target platelet count (≥50 x 10^9/L)
  - Increasing the platelet count from Baseline to Procedure Day
- **Platelet counts reproducibly increased after 4 days, peaked after 10-13 days, and returned to Baseline by Day 35**
- **Safety profile of avatrombopag was similar to placebo**

Avatrombopag offers a safe and effective alternative to platelet transfusion for patients with thrombocytopenia and chronic liver disease undergoing scheduled procedures

Questions & Answers