FOR A RAPID AND DURABLE PLATELET RESPONSE[1,2*†]

Give your patients the Doptelet lift

The fastest-growing TPO-RA for your adult patients with thrombocytopenia in chronic immune thrombocytopenia (ITP) who had an insufficient response to a previous treatment.[1,3‡]

The American Society of Hematology (ASH) guidelines recommend limiting steroid treatment to 6 weeks or less due to potential adverse effects.[4]

IN THE PIVOTAL 6-MONTH TRIAL[1]:

CORE STUDY: Efficacy was evaluated in a 6-month, multicenter, randomized, double-blind, placebo-controlled Phase 3 study. Patients had received one or more prior chronic ITP therapies and had average screening and baseline platelet counts of <30x10⁹/L. Forty-nine patients were randomized (2:1) to receive either Doptelet (n=32) or placebo (n=17)[1]

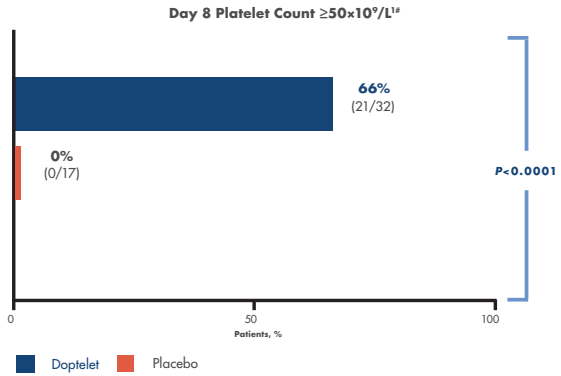
PRIMARY ENDPOINT: Patients on Doptelet maintained a **platelet response** for a median of 12.4 cumulative weeks without the need for rescue therapy[1§‖¶]

SECONDARY ENDPOINT:

66% of patients treated with Doptelet achieved a **platelet response** on Day 8[1¶]

0% of patients on placebo responded[1]

Of the 66% of patients that responded on Day 8, over half (n=12 out of 21, 37.5%) achieved a complete response during that time (post hoc)[1,5¶]

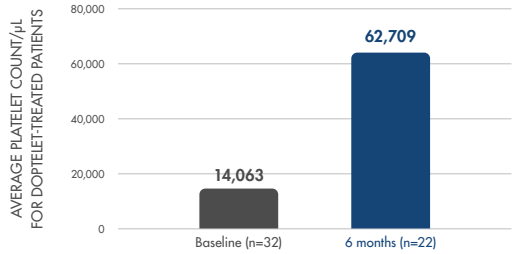


Doptelet® (avatrombopag) tablets

A DURABLE RESPONSE WAS OBSERVED[1*†]

MEAN PLATELET COUNT FROM BASELINE TO 6 MONTHS FOR DOPTELET-TREATED VS PLACEBO-TREATED PATIENTS[6]

*A durable platelet response is defined as the proportion of patients who had a platelet response for ≥6 of the last 8 weeks of treatment.[2]



Seventeen patients who received placebo entered with a mean baseline platelet count of 12,712/μL.

One placebo patient finished the core study with a mean platelet count of 31,000/μL.[6]

†The durable platelet response rate was significantly greater in avatrombopag-treated patients compared with those receiving placebo (34.4% vs 0.0%; *P*=0.009).[2]
‡Doptelet-treated patients maintained a platelet count of ≥50x10⁹/L for a median of 12.4 cumulative weeks. Sixty-six percent of Doptelet-treated patients were able to achieve a platelet count of ≥50x10⁹/L in as few as 8 days.[1]
§Throughout the core study and extension phase, 72.3% of patients were exposed to avatrombopag for at least 32 weeks. In the open-label extension phase for those patients continuing Doptelet treatment, a response was achieved at 44.2% of visits.[2,7]
‖After initiating therapy with Doptelet, assess platelet counts weekly until a stable platelet count of ≥50x10⁹/L has been achieved, and then obtain platelet counts monthly thereafter.[1]
¶Platelet response is a platelet count of ≥50,000/μL and complete response is a platelet count of ≥100,000/μL.[7]
#Baseline patient platelet counts in the Doptelet-treated group were ≤15x10⁹/L (56.3%), 15-30x10⁹/L (40.6%), and ≥30x10⁹/L (3.1%).[2]

TPO-RA=thrombopoietin receptor agonist.

INDICATION

[DOPTELET is indicated for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment.]

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Thrombotic/Thromboembolic Complications. DOPTELET is a thrombopoietin (TPO) receptor agonist and TPO receptor agonists have been associated with thrombotic complications in patients with chronic liver disease (0.4%; (1/274) in DOPTELET-treated patients) and thromboembolic complications in patients with chronic immune thrombocytopenia (7%; (9/128) in DOPTELET-treated patients). Portal vein thrombosis has been reported in patients with chronic liver disease, and thromboembolic events (arterial and venous) have been reported in patients with chronic immune thrombocytopenia treated with TPO receptor agonists.

Consider the potential increased thrombotic risk when administering DOPTELET to patients with known risk factors for thromboembolism, including genetic prothrombotic conditions and acquired risk factors.

DOPTELET should not be administered to patients with chronic liver disease or chronic immune thrombocytopenia in an attempt to normalize platelet counts. Monitor platelet counts, and for signs and symptoms of thromboembolic events and institute treatment promptly.

Serious Adverse Reactions

Serious adverse reaction that occurred more frequently in patients treated with DOPTELET (9%; 12/128) compared to placebo (5%; 1/22) was headache, occurring in 1.6% (2/128).

Please see Important Safety Information continued on back page and accompanying Full Prescribing Information for DOPTELET.

In the open-label extension:

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Open-label extension: Patients could enter the open-label extension phase if they completed the 6-month core study or if they experienced a lack of efficacy during that period. In the extension phase, all patients received titrated Doptelet once daily. Thirty-nine patients (24 Doptelet and 15 placebo) entered the 90-week maintenance period of the extension phase, in which Doptelet dose titration and downward titration of concomitant ITP medications were allowed. At the end of the extension phase, a 4-week, dose-tapering period was followed by a 30-day follow-up after the last dose of Doptelet.[2,7]

This **post hoc analysis** assessed the endpoints from the Phase 3 study and provided previously unreported data on the percentage of patients who were able to achieve a **platelet response** or **complete response** at any time during the core study and extension phase.[5]

- The **primary endpoint** of the extension study was to assess the long-term safety and efficacy of treatment with Doptelet by measuring platelet response rate, bleeding, and the use of rescue therapy[2]
- The **secondary endpoint** included the percentage of patients who achieved platelet counts ≥50,000/µL or ≥100,000/µL at any time during the core study and its extension phase. These endpoints were reported in an integrated analysis of the Phase 3 core study and extension phase data[5,7]*

DOPTELET RESPONDERS DURING THE CORE STUDY AND EXTENSION PHASE†

94% of patients achieved a **platelet response** at least once vs 6% of patients who did not achieve a platelet response[5*‡]

84% of patients achieved a **complete response** vs 16% of patients who did not achieve a complete response[5‡]

LIMITATIONS AND DISCLOSURES§

The open-label extension was not placebo-controlled; therefore, causality cannot be attributed, and hypothesis testing cannot determine whether within-arm changes were due to drug effect.

There is no comparator in the post hoc analysis, and further studies are needed to validate these results. The post hoc analysis is not included in the Doptelet Prescribing Information, and the FDA did not consider this analysis in approving Doptelet.

*In an integrated analysis of the core study and its open-label extension phase, 93.8% of patients initially randomized to Doptelet achieved a platelet count of ≥50,000/µL at any time, and 64.7% of placebo patients who rolled over to Doptelet in the open-label extension phase also reached this metric.[5,7]

†Results are comprised of patients who were initially randomized to Doptelet in the core study.[5]

‡Platelet response is a platelet count of ≥50,000/µL and complete response is a platelet count of ≥100,000/µL.[7]

§The open-label extension and post hoc analysis may not meet the FDA definition of an adequate and well-controlled study due to its design and inherent limitations. Results from this analysis may differ from those observed in clinical practice.

References: 1. DOPTELET (avatrombopag) [prescribing information]. Morrisville, NC: AkaRx, Inc; 2024. **2.** Jurczak W, Chojnowski K, Mayer J, et al. Phase 3 randomised study of avatrombopag, a novel thrombopoietin receptor agonist for the treatment of chronic immune thrombocytopenia. *Br J Haematol.* 2018;183(3):479-490. **3.** Data on file. TPO-RA market growth. 2023: Sobi, Inc. **4.** Neunert C, Terrell DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia. *Blood Adv.* 2019;3(23):3829-3866. **5.** Nagalla S, Vredenburg M, Tian W, Allen LF. Platelet response to avatrombopag in patients with chronic immune thrombocytopenia: additional analyses from a phase 3 study and its extension. *Blood.* 2019;134(suppl 1):1071. **6.** Data on file. 302 clinical study report. 2016: Sobi, Inc. **7.** Al-Samkari H, Aggarwal K, Vredenburg M, Tian W, Allen LF. Long-term response rates in patients with chronic immune thrombocytopenia treated with avatrombopag: additional analyses from a phase 3 study and its extension phase. *Blood.* 2019;134(suppl 1):2356.

IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS (continued)

Adverse Reactions

The most common adverse reactions (≥10%) in patients with chronic immune thrombocytopenia were headache, fatigue, contusion, epistaxis, upper respiratory tract infection, arthralgia, gingival bleeding, petechiae, and nasopharyngitis.

Postmarketing Experience

Following the approval of DOPTELET, hypersensitivity reactions involving the immune system, including, but not limited to, pruritus, rash, choking sensation, swollen face, and swollen tongue have been reported.

These are not all the possible risks associated with DOPTELET. Please see Full Prescribing Information for DOPTELET at www.doptelethcp.com

To report suspected adverse reactions, contact Sobi North America at 1-866-773-5274 or FDA at 1-800-FDA-1088.

For statutory pricing disclosures, visit sobi.com/usa/en/state-disclosure-requirements.

Please see Full Important Safety Information throughout and accompanying Full Prescribing Information for DOPTELET in pocket.

sobi rare strength

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