Doptelet®
(avatrombopag) tablets

For adults with thrombocytopenia in chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.

LIFT PLATELETS. NO SWEAT.

Doptelet is the only oral TPO-RA with no food-type restrictions, no liver monitoring, and no injections.[1-3*†]

*Food required.

†Platelet monitoring required. 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.

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.

Please see Important Safety Information throughout and Full Prescribing Information for Doptelet at doptelethcp.com

About ITP

Identifying and treating ITP

ITP is an immune disorder characterized by low platelet counts (<100×10^9/L). The mechanisms of ITP can involve both increased platelet destruction and impaired platelet production.[4]

Approximately

9.5 PER **100,000**

adults are living with ITP[4]

Common symptoms include[5]:

Bruising

Petechiae

Bleeding

Fatigue

ITP=immune thrombocytopenia; IVIG=intravenous immunoglobulin; TPO-RA=thrombopoietin receptor agonist.

About patient preferences

Patient preferences can include method of administration and drug-food interactions[6]

The TRAPeze study included patients taking TPO-RAs. Avatrombopag was not evaluated.*

Results showed:

7× more patients prefer **oral administration** vs injections

4× more patients prefer treatments **without food restrictions**

* From the Thrombopoietin-Receptor Agonist Patient experience survey (TRAPeze), which virtually evaluated treatment preferences in adults with ITP in the UK and Ireland (N=32).[6]

The American Society of Hematology (ASH) guidelines recommend[7]:

- Corticosteroid therapy is a first-line treatment option. Steroids are not recommended for prolonged use due to the increased risk of adverse events.[7]
  - Shorter course of corticosteroids—no more than 6 weeks
- TPO-RAs as a second-line therapy
- TPO-RAs before rituximab
- Selection of second-line therapy in adults with chronic ITP should be individualized based on duration of disease and patient needs and preferences
- Patient education and shared decision-making is encouraged

ITP: ABOUT DOPTELET

Doptelet acts fast and lasts[1,8*]

In the 6-month core study:

50K

Raise and maintain

With Doptelet, keep platelet counts lifted at 50,000/μL (primary endpoint).[1*]

12.4 WEEKS

Keep platelet counts lifted

Patients on Doptelet reached target platelet counts of 50,000/μL for a median of 12.4 cumulative weeks.

8DAYS

Lift platelet counts quickly

In as few as 8 days, 66% of Doptelet patients reached 50,000/μL (secondary endpoint).[1]

In the pivotal trial and open-label extension:

94%

Reach target levels

94% of patients reached 50,000 platelets/μL at least once during the pivotal trial or open-label extension.[9]

The study was not placebo-controlled; therefore, causality cannot be attributed, and hypothesis testing cannot determine whether within-arm changes were due to drug effect. The Extension Study may not meet the FDA definition of an adequate and well-controlled study due to its study design.

* 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.[8,10]

Study design:

Core Study: Efficacy was evaluated in a 6-month, multicenter, randomized, double-blind, placebo-controlled Phase 3 study. Patients had previously received one or more prior chronic ITP therapies and had average screening and baseline platelet counts of <30×10⁹/L. Forty-nine patients were randomized (2:1) to receive either Doptelet (n=32) or placebo (n=17).[1]

- The **primary efficacy endpoint** was the cumulative number of weeks of platelet response, defined as a platelet count ≥50×10⁹/L in the absence of rescue therapy, over 6 months of once-daily treatment in adults with chronic ITP. Doptelet-treated patients had a median duration of 12.4 cumulative weeks vs 0 weeks for placebo
- A **secondary efficacy endpoint** was the proportion of patients with a platelet response (platelet counts ≥50×10⁹/L) at Day 8. 66% (n=21/32) of Doptelet-treated patients had platelet counts of ≥50,000/μL at Day 8 compared to placebo (n=0/17)

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.[8,10]

- 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[8]
- **Exploratory endpoints** 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. In an integrated analysis of the core study and its extension phase, 93.8% of patients initially randomized to Doptelet and who continued to be treated with Doptelet during the extension phase achieved a platelet count of ≥50,000/μL at any time, compared to 64.7% of placebo patients who rolled-over to Doptelet[9,10]

IMPORTANT SAFETY INFORMATION

Thrombotic/Thromboembolic Complications (continued)
Consider the potential increased thrombotic risk when administering DOPTELET to patients with known risk factors for thromboembolism, including genetic prothrombotic conditions.

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.

ITP: ABOUT DOPTELET

Doptelet® (avatrombopag) tablets

With Doptelet, compliance comes with convenience

Doptelet is the only oral TPO-RA of its kind that your patients can take anytime, with any food, on a consistent schedule.[1-3]

No food-type restrictions

Patients can take Doptelet with any food (food required); no administration concerns with minerals like calcium or magnesium.[1]

No liver monitoring

Doptelet does not require additional liver-function monitoring; no significant hepatotoxicity seen in Doptelet clinical trials.[1,8]

No injections

Doptelet can be taken anytime, anywhere, without adding trips to the doctor for administration.[1]

Remember to monitor patients and dose adjust as needed based on platelet response and drug interactions.*

* After initiating therapy with Doptelet, assess platelet counts weekly until a stable platelet count of ≥50 x10⁹/L has been achieved, and then obtain platelet counts monthly thereafter.[1]

IMPORTANT SAFETY INFORMATION

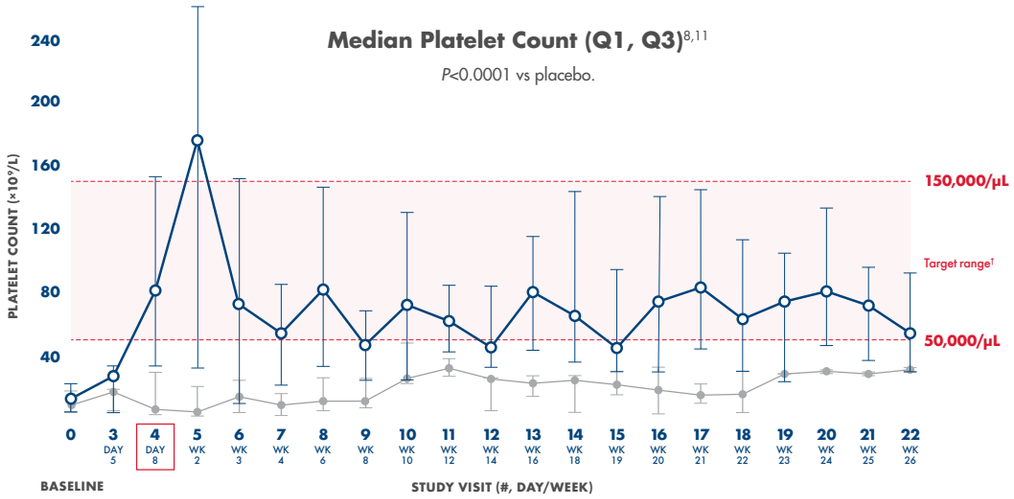
Serious Adverse Reactions
Serious adverse reaction that occurred more frequently in patients treated with DOPTELET (9%; 12/128) compared to placebo (5%; 1/22) was headache, occurring in 1.6% (2/128).

Please see Full Important Safety Information throughout and accompanying Full Prescribing Information for Doptelet at doptelethcp.com

ITP: EFFICACY — PRIMARY ENDPOINT

Rapid and durable response[1]*

Patients on Doptelet reached target platelet counts of 50,000/µL for a median of 12.4 cumulative weeks.[1]



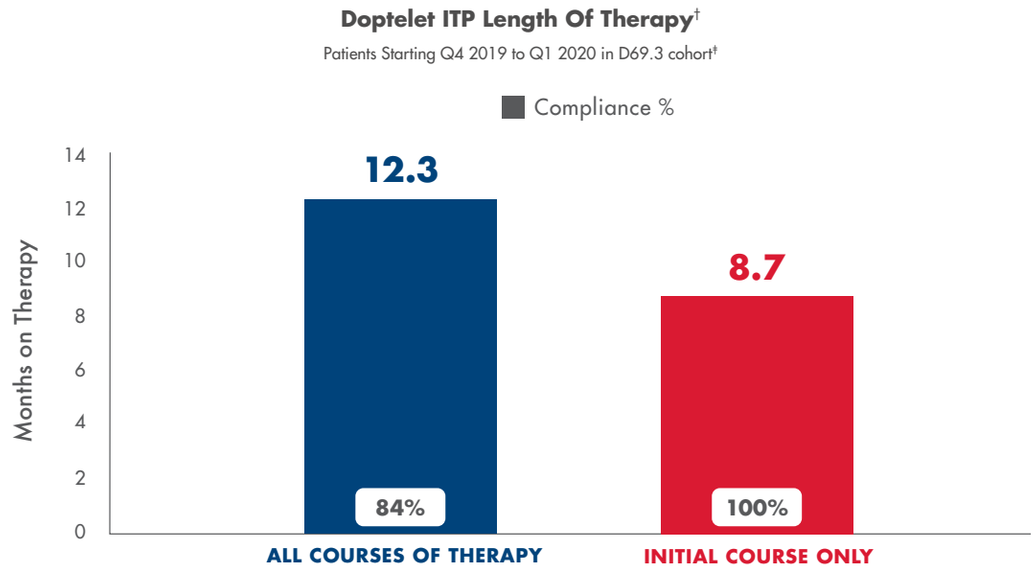
- Patients treated with Doptelet in clinical trials had a mean baseline platelet count of 14.1x10⁹/L, and mean platelet count of 62.7x10⁹/L at Week 26[11]
- **In as few as 8 days, 66% of Doptelet patients reached 50,000 platelets/µL[1]**
- **38% of patients reached a complete response by Day 8 of 100,000 platelets/µL (N=32)[9]**

* ASH guidelines define a durable response as platelet count ≥30x10⁹/L and at least doubling of the baseline count at 6 months.
† Target platelet count window in pivotal trial was ≥50×10⁹/L to ≤150×10⁹/L.[8]

ITP: EFFICACY — PERSISTENCE

Patients maintained treatment for over a year[12]

- Patients maintained treatment with Doptelet for up to 12.3 months since launch
- Compliance rate was high at 84%*



Course of Therapy: a set of shipments with no gap between shipments larger than days supply +60 days.

This analysis was conducted using dispensing data that were collected post-market approval. Results from this analysis may differ from those observed in clinical practice. The analysis is not included in the Doptelet Prescribing Information, and the FDA did not consider this analysis in approving Doptelet.

* Compliance percentage equals total days supply from shipments divided by length of therapy.
† Length of therapy calculated as an average of each patient's days on therapy (days on therapy = latest shipment date + days supply – initial shipment date).
† D69.3 cohort defined as only patients who have ever had an ICD-10 diagnosis code of D69.3 (immune thrombocytopenic purpura) or D69.49 (other primary thrombocytopenia) on a shipment.[13]

ITP: SAFETY

Safety and Tolerability[1]

Thrombotic/Thromboembolic Complications

- In clinical trials in patients with chronic ITP, 7% (9/128) of patients treated with Doptelet developed a thromboembolic event

Serious Adverse Reactions

- Serious adverse reactions that occurred more frequently in patients with chronic ITP treated with Doptelet (9%; 12/128) compared to placebo (5%; 1/22) included headache, occurring in 1.6% (2/128)[1,8]
- Adverse reactions resulting in discontinuation of Doptelet that were reported in more than 1 patient included headache, occurring in 1.6% (2/128)

IMPORTANT SAFETY INFORMATION

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.

ITP: SAFETY

Doptelet® (avatrombopag) tablets

Adverse reactions with a frequency ≥10% in patients with chronic ITP treated with Doptelet—
pooled data from clinical trials.[1*]

Adverse Reaction	Doptelet (N=128) (%)	Placebo (N=22) (%)
Headache	**31**	14
Fatigue	**28**	9
Contusion	**26**	18
Epistaxis	**19**	18
Upper Respiratory Tract Infection	**15**	5
Arthralgia	**13**	0
Gingival Bleeding	**13**	0
Petechiae	**11**	9
Nasopharyngitis	**10**	0

* The safety of Doptelet in adults with chronic ITP was evaluated in 2 Phase 3 trials (1 randomized, double-blind, placebo-controlled trial, and 1 randomized, double-blind, active-controlled trial) and 2 Phase 2 trials (1 randomized, double-blind, placebo-controlled, dose-ranging trial, and 1 open-label extension trial) in 161 patients with chronic ITP. Analysis included 128 patients who received 2.5 to 40 mg of Doptelet once daily for a median exposure of 29.1 weeks, and 22 patients who received placebo for a median exposure of 5.9 weeks.[1,14]

IMPORTANT SAFETY INFORMATION

Thrombotic/Thromboembolic Complications (continued)
Consider the potential increased thrombotic risk when administering DOPTELET to patients with known risk factors for thromboembolism, including genetic prothrombotic conditions.

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.

Please see Full Important Safety Information throughout and accompanying Full Prescribing Information for Doptelet at doptelethcp.com

ITP: DOSING

One pill. One strength.

Titrate on your terms[1]

Start patients with a recommended starting dosage strength of 20 mg once daily with food and dose adjust as needed.

Dose adjustments may be needed based on platelet response and for patients taking moderate or strong dual inducers or inhibitors of CYP2C9 and CYP3A4.*

Recommended starting dose:

20 mg

ONE PILL ONCE DAILY*

Taken on their terms[1-3]

Doptelet is the only oral TPO-RA of its kind that your patients can take anytime, with any food. Patients should take Doptelet with food and on a consistent schedule.††

Set treatment goals from the start

- One goal of chronic ITP treatment is to increase and maintain a stable platelet count
- Additional factors to consider when discussing treatment goals with your patients may include duration of ITP, frequency of bleeding episodes, increased risk factors for thromboembolism, comorbidities, age, medication adherence, support networks, patient preference, cost, and availability

ITP=immune thrombocytopenia; TPO-RA=thrombopoietin receptor agonist.

IMPORTANT SAFETY INFORMATION

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).

ITP: DOSING

Doptelet® (avatrombopag) tablets

Target the right response

RECOMMENDED STARTING DOSE: ONE PILL 20 mg ONCE DAILY[1*‡]

Platelet Count (x 10⁹/L)

BELOW GOAL	AT GOAL	ABOVE GOAL	ABOVE GOAL
IF <50 AFTER 2 WEEKS, TITRATE UP TO 20 mg 20 mg 3x weekly **AND** 20 mg other 4 days *Wait 2 weeks to assess the effects of this regimen*	**IF 50–200, MAINTAIN** 20 mg once daily	**IF 200–400 AFTER 2 WEEKS, TITRATE DOWN TO** 20 mg 3x weekly *Wait 2 weeks to assess the effects of this regimen*	**IF >400, STOP TREATMENT** Increase platelet monitoring to 2x weekly When platelet count is **<150**, **REINITIATE THERAPY AT** 20 mg 3x weekly
IF <50, TITRATE UP TO 20 mg 20 mg once daily *Wait 2 weeks to assess the effects of this regimen*		**IF 200–400, TITRATE DOWN TO** 20 mg 20 mg once weekly§ *Wait 2 weeks to assess the effects of this regimen*	**IF >400, STOP TREATMENT** Increase platelet monitoring to 2x weekly When platelet count is **<150**, **REINITIATE THERAPY AT** 20 mg 20 mg once weekly§
IF <50 AFTER >4 WEEKS, DISCONTINUE DOPTELET		**IF 200–400, TITRATE DOWN TO** 20 mg once weekly *Wait 2 weeks to assess the effects of this regimen*	**IF >400, STOP TREATMENT** Increase platelet monitoring to 2x weekly When platelet count is **<150**, **REINITIATE THERAPY AT** 20 mg once weekly
			IF >400 AFTER 2 WEEKS OF 1 TABLET WEEKLY, DISCONTINUE DOPTELET

* Start patients taking moderate or strong dual inhibitors of CYP2C9 and CYP3A4 with 20 mg 3 times a week; start patients taking moderate or strong dual inducers of CYP2C9 and CYP3A4 with 40 mg once daily. **Please see Full Prescribing Information for additional information on dose adjustments**.
† Patients may require dose adjustments based on platelet count response and drug interactions.
‡ After initiating therapy with Doptelet, assess platelet counts weekly until a stable platelet count of ≥50 x 10⁹/L has been achieved, and then obtain platelet counts monthly thereafter. Obtain platelet counts weekly for at least 4 weeks following discontinuation of Doptelet.
§ Alternative dosing: 1 tablet twice weekly.

IMPORTANT SAFETY INFORMATION

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.

Please see Full Important Safety Information throughout and accompanying Full Prescribing Information for Doptelet at doptelethcp.com

ACCESS & SUPPORT

Doptelet is broadly available* and covered for 95% of commercial lives[15]

Coverage and reimbursement information is provided for your information only and is subject to change. For specific information, please contact the patient's insurer. Third-party payment for prescription drugs is affected by numerous factors, and Sobi makes no representation or guarantee concerning reimbursement or coverage for Doptelet or any other service or item.

Doptelet® connect

Doptelet Connect is just one of the ways to help your eligible patients navigate access at any point through the fulfillment process

Patient Case Managers can assist with:

Evaluating a patient's prescription coverage, including benefits investigation, prior authorization, claims, and appeal assistance support

Answering logistical questions and providing education and coordination around the specialty pharmacy fulfillment process.

Providing financial assistance information for eligible patients.

For more information and to access enrollment forms, visit DopteletConnectHCP.com.

* Broadly available: covered for over 50% of patients on plan.

ACCESS & SUPPORT

Doptelet® (avatrombopag) tablets

The Doptelet Copay Assistance Program* is for eligible patients who have commercial prescription insurance. The Program parameters are as follows:

- Patients may pay as little as $0 per prescription
- Patients will be enrolled in the Program for a 12-month period
- Patients may save up to a maximum of $15,000 per calendar year
- Patients must be 18 years or older
- There are no income requirements

Three Ways to Enroll in the Doptelet Copay Assistance Program

- Patients can call 1-833-368-2663 for assistance enrolling
- Patients can enroll online at DopteletConnect.com
- HCPs or Specialty Pharmacies can enroll a patient at DopteletConnectHCP.com

For more information or help enrolling in the Doptelet Copay Assistance Program, please call **1-833-368-2663**, Monday–Friday 8 AM to 8 PM EST.

* In order to participate in the Doptelet Copay Assistance Program (Program), a patient must be 18 year or older and have commercial prescription insurance for Doptelet. The Program is not valid for patients whose prescriptions claims are reimbursed, in whole or in part, by any state or federal government program, including, but not limited to Medicaid, Medicare, Medigap Department of Defense (DoD), Veterans Affairs (VA), TRICARE, Puerto Rico Government Insurance, or any state patient or pharmaceutical assistance program. This offer is not valid for cash paying patients. The Program is void where prohibited by law. Certain rules and restrictions apply. Sobi reserves the right to revoke, rescind, or amend this offer without notice. This Program is not insurance.

LIFT PLATELETS. NO SWEAT.

Doptelet® (avatrombopag) tablets

Lift platelet counts quickly

Most patients reached 50,000 platelets/μL in as few as **8 days** with Doptelet.[1]

No food-type restrictions, no liver monitoring, and no injections*†

Doptelet is the only oral TPO-RA of its kind that your patients can take anytime, with any food. Patients should take Doptelet with food and on a consistent schedule.[1-3*†]

If steroids or other first-line treatments have failed to manage low blood platelet counts in your adult patients with chronic ITP, consider Doptelet[7]

TPO-RAs have been associated with thrombotic and thromboembolic complications.
* Food required.[1]
† After initiating therapy with Doptelet, assess platelet counts weekly until a stable platelet count of ≥50×10⁹/L has been achieved, and then obtain platelet counts monthly thereafter.[1]
‡ Patients may require dose adjustments based on platelet count response and drug interactions.

IMPORTANT SAFETY INFORMATION

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.

Please see Full Important Safety Information throughout and accompanying Full Prescribing Information for Doptelet at doptelethcp.com

References: 1. DOPTELET [package insert]. Durham, NC: AkaRx, Inc. **2.** Promacta [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp. **3.** Nplate [prescribing information]. Thousand Oaks, CA: Amgen. **4.** Lambert MP, Gernsheimer TB. Clinical updates in adult immune thrombocytopenia. *Blood*. 2017;129(21):2829-2835. **5.** NORD (National Organization for Rare Disorders) website: immune thrombocytopenia. Available at: https://rarediseases.org/rarediseases/immune-thrombocytopenia/. Accessed May 12, 2021. **6.** McDonald V, Newland A, Morgan M, et al. Patient preferences and experiences regarding thrombopoietin-receptor agonists for immune thrombocytopenia in the United Kingdom and Ireland (TRAPeze UK & IE study). *Hematology*. 2021;26(1):799-808. **7.** Neunert C, Terrell DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia. *Blood Adv*. 2019;3(23):3829-3866. **8.** 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. **9.** 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. **10.** 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. **11.** Data on file. Summary of local platelet count. 2014: Sobi, Inc. **12.** Data on file. Length of therapy. Sobi, Inc. **13.** Centers for Medicare & Medicaid Services. ICD-10-CM tabular list of diseases and injuries. Accessed March 18, 2022. https://www.cms.gov/medicare/icd-10/2022-icd-10-cm. **14.** Data on file. Extent of exposure. 2022: Sobi, Inc. **15.** Data on file. Coverage. 2022: Sobi, Inc.

Join the team at LetsGoDoptelet.com

Learn more

sobi rare strength

PP-15593 07/22