THE EHL rFVIII WITH PROVEN PROTECTION, SAFETY, AND UNIQUE STEP-WISE DOSING[1-4]

EMPOWER HIM

to step up to the challenge with Jivi®

EHL, extended half-life;
rFVIII, recombinant Factor VIII.

INDICATIONS

- Jivi antihemophilic factor (recombinant), PEGylated-aucl, is a recombinant DNA-derived, Factor VIII concentrate indicated for use in previously treated adults and adolescents (12 years of age and older) with hemophilia A (congenital Factor VIII deficiency) for:
  - On-demand treatment and control of bleeding episodes
  - Perioperative management of bleeding
  - Routine prophylaxis to reduce the frequency of bleeding episodes
- Limitations of use:
  - Jivi is not indicated for use in children less than 12 years of age due to a greater risk for hypersensitivity reactions.
  - Jivi is not indicated for use in previously untreated patients (PUPs).
  - Jivi is not indicated for the treatment of von Willebrand disease.

SELECTED IMPORTANT SAFETY INFORMATION

- Jivi is contraindicated in patients who have a history of hypersensitivity reactions to the active substance, polyethylene glycol (PEG), mouse or hamster proteins, or other constituents of the product.

For additional important risk and use information, please see full Prescribing Information.

Jivi®
antihemophilic factor
(recombinant) PEGylated-aucl

Every patient is different

Jivi® delivers...

I want effective protection from bleeds

Powerful protection from bleeds[1]

I want demonstrated safety

Up to 7 years of safety data[3,4]

I want a prophylaxis regimen with fewer infusions

Unique step-wise dosing, with the potential for fewer infusions[2,5]

SELECTED IMPORTANT SAFETY INFORMATION

- Hypersensitivity reactions, including severe allergic reactions, have occurred with Jivi. Monitor patients for hypersensitivity symptoms.
  Early signs of hypersensitivity reactions, which can progress to anaphylaxis, may include chest or throat tightness, dizziness, mild hypotension and nausea. If hypersensitivity reactions occur, immediately discontinue administration and initiate appropriate treatment.
- Jivi may contain trace amounts of mouse and hamster proteins. Patients treated with this product may develop hypersensitivity to these non-human mammalian proteins.
- Hypersensitivity reactions may also be related to antibodies against polyethylene glycol (PEG).

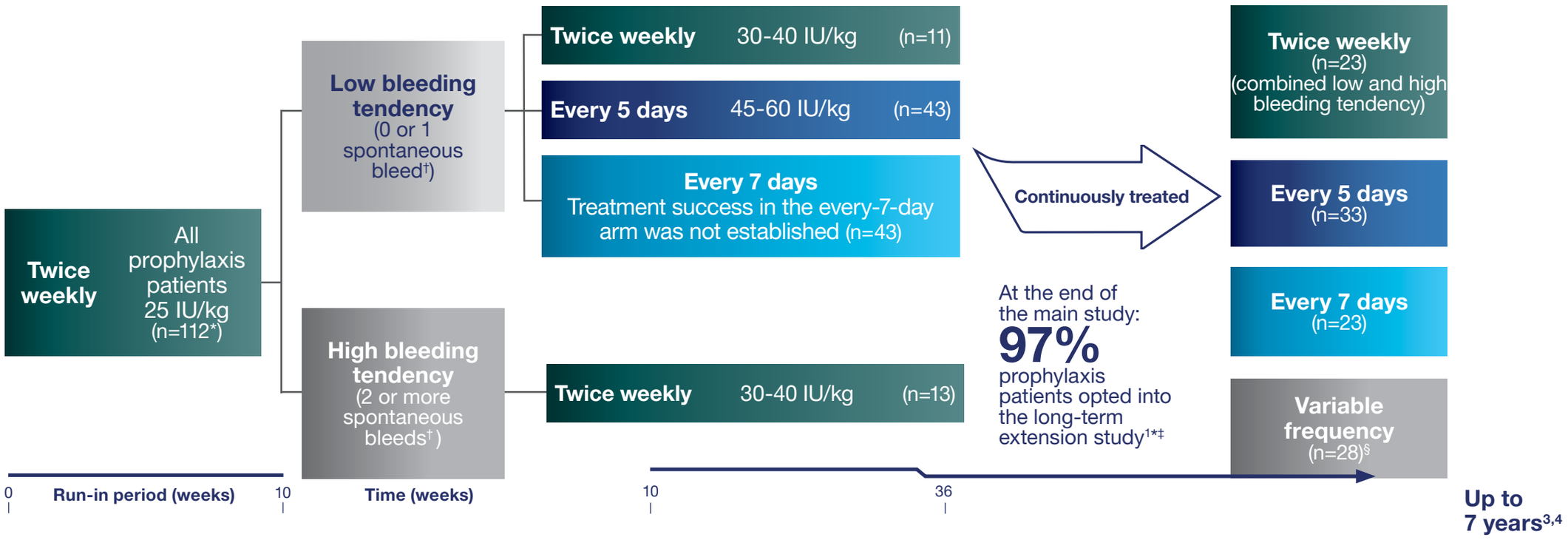
For additional important risk and use information, please see full Prescribing Information.

Jivi®
antihemophilic factor (recombinant) PEGylated-aucl

The PROTECT VIII main and extension studies were designed to reflect real-world treatment[3,4]

PROTECT VIII main study design[1]
Patients completing the PROTECT VIII main study were invited to continue on to the extension study.[4]
Patients on a prophylaxis regimen could continue their current regimen or switch to another dosing regimen on entry to the extension study and at any point during it.

Long-term extension study design[4]



SELECTED IMPORTANT SAFETY INFORMATION

- Neutralizing antibody (inhibitor) formation can occur following administration of Jivi. Carefully monitor patients for the development of Factor VIII inhibitors, using appropriate clinical observations and laboratory tests. If expected plasma Factor VIII activity levels are not attained or if bleeding is not controlled as expected with administered dose, suspect the presence of an inhibitor (neutralizing antibody).

*112 patients entered prophylactic treatment arms; an additional 20 patients entered a control arm of on-demand treatment. Two patients in the prophylactic arms left the main study prematurely during the run-in period.[1]
†Defined as joint or muscle bleeds and no identified trauma.[1,3]
‡121 of 134 patients included in the main PROTECT VIII trial continued in the extension study, receiving either on-demand treatment (n=14) or prophylaxis (n=107).[4]
§Patients who switched dosing frequency at least once after the first week of the extension study were analyzed in a separate variable-frequency group.[4]

For additional important risk and use information, please see full Prescribing Information.

Jivi®
antihemophilic factor (recombinant) PEGylated-aucl

In the PROTECT VIII main study

Effective bleed protection with Jivi®[1]

	Bleeding Tendency[1]	Total ABR		Spontaneous ABR	
		Median (Q1;Q3)[1]	Mean (SD)[1]	Median (Q1;Q3)[1]	Mean (SD)[1]
Twice weekly	LOW* (n=11)	1.9 (0.0;5.2)	2.2 (2.7)	0 (0.0;1.9)	1.2 (2.2)
	HIGH† (n=13)	4.1 (2.0;10.6)	7.2‡ (7.5)	3.9 (0.0;4.1)	3.9 (4.3)
Every 5 days	LOW* (n=43)	1.9 (0.0;4.2)	3.3 (4.3)	0 (0.0;4.0)	1.8 (2.6)

Reduced from 17.4 ABR

Treatment success in the every-7-day arm was not established

- Total ABR in all patients in the every-7-day dosing arm (n=43); median (Q1;Q3) ABR for total bleeds of 3.9 (0.0;6.5) and a mean (±SD) of 6.43 (±10.04)[3,6]
- Total ABR in patients who completed every-7-day dosing treatment (n=32); median (Q1;Q3) ABR of 1.0 (0.0;4.3) and a mean (±SD) of 2.67 (±3.82)[3,6]
- Spontaneous ABR in all patients in the every-7-day arm (n=43); median (Q1;Q3) of 1.9 (0.0;6.3) and mean (±SD) of 5.42 (±9.79)[3,6]
- Spontaneous ABR in patients who completed every-7-day dosing treatment (n=32); median (Q1;Q3) of 0.0 (0.0;2.1) and mean (±SD) of 1.65 (±2.89)[3,6]

SELECTED IMPORTANT SAFETY INFORMATION

- A clinical immune response associated with IgM anti-PEG antibodies, manifested as symptoms of acute hypersensitivity and/or loss of drug effect, has been observed primarily in patients < 6 years of age. The symptoms of the clinical immune response were transient. Anti-PEG IgM titers decreased over time to undetectable levels. No immunoglobulin class switching was observed.
- In case of clinical suspicion of loss of drug effect, conduct testing for Factor VIII inhibitors and Factor VIII recovery. A low post-infusion Factor VIII level in the absence of detectable Factor VIII inhibitors indicates that loss of drug effect is likely due to anti-PEG antibodies. Discontinue Jivi and switch patients to a previously effective Factor VIII product.
- The most frequently (≥5%) reported adverse reactions in clinical trials in previously treated patients (PTPs) ≥12 years of age were headache, cough, nausea, and fever.

*Patients with 0 or 1 spontaneous bleed (defined as a joint or muscle bleed and no identified trauma) during weeks 1-10 of the main study.[3]
†Patients with 2 or more spontaneous bleeds (defined as joint or muscle bleeds and no identified trauma) during weeks 1-10 of the main study.[3]
‡n=9/13 of these patients were on prior prophylaxis and had a mean number total ABR of 17.4 before entering the main study.[1]
ABR, annualized bleed rate.

For additional important risk and use information, please see full Prescribing Information.

Jivi®
antihemophilic factor (recombinant) PEGylated-aucl

In the PROTECT VIII long-term extension study

ABRs assessed with Jivi®[4]

While there were no predetermined efficacy objectives in the extension study, bleeding episodes were documented during the routine course of treatment

	Total ABR		Spontaneous ABR	
	Median (Q1;Q3)[4]	Mean (SD)[7]	Median (Q1;Q3)[4]	Mean (SD)[7]
Twice-weekly low and high bleeding tendencies (n=23)[4]	1.57 (0.79; 3.61)	3.82 (5.17)	0.79 (0.00; 3.09)	2.0 (2.71)
Every 5 days (n=33)[4]	1.17 (0.00; 4.57)	3.94 (6.79)	0.75 (0.00; 2.90)	2.29 (3.46)
Variable frequency* (n=28)[4]	3.1 (1.13; 5.86)	4.76 (5.28)	1.80 (0.60; 3.81)	2.98 (3.32)

Treatment success in the every-7-day arm was not established

- Total ABR in all patients in the every 7 day dosing arm at the end of the extension study (n=23); median (Q1;Q3) ABR for total bleeds of 0.65 (0.0;1.68) and a mean (±SD) of 2.18 (±4.61)[4]
- Spontaneous ABR in all patients in the every 7 day dosing arm at the end of the extension study (n=23); median (Q1;Q3) ABR for spontaneous bleeds of 0.32 (0.00; 0.78) and a mean (±SD) of 1.65 (±4.42)[4]

INDICATIONS

- Jivi antihemophilic factor (recombinant), PEGylated-aucl, is a recombinant DNA-derived, Factor VIII concentrate indicated for use in previously treated adults and adolescents (12 years of age and older) with hemophilia A (congenital Factor VIII deficiency) for:
  - On-demand treatment and control of bleeding episodes
  - Perioperative management of bleeding
  - Routine prophylaxis to reduce the frequency of bleeding episodes
- Limitations of use:
  - Jivi is not indicated for use in children less than 12 years of age due to a greater risk for hypersensitivity reactions.
  - Jivi is not indicated for use in previously untreated patients (PUPs).
  - Jivi is not indicated for the treatment of von Willebrand disease.

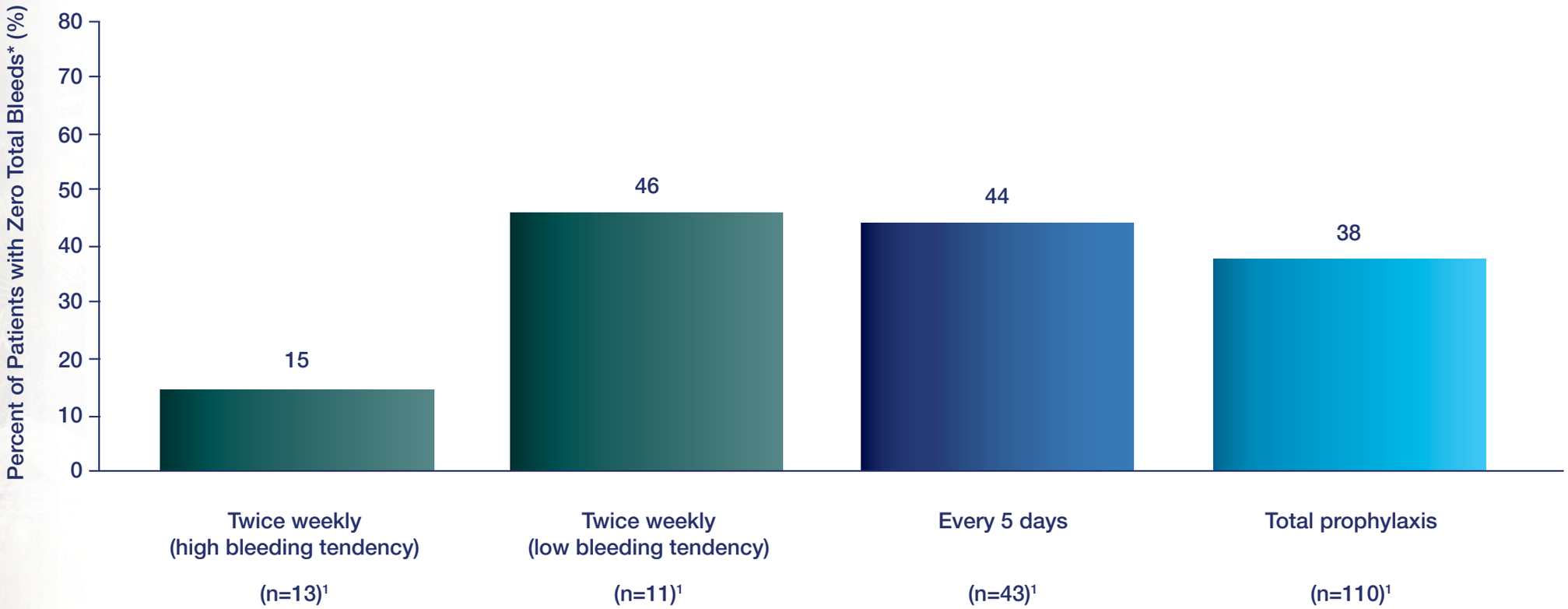
*Patients who switched dosing frequency at least once after the first week of the extension study were analyzed in a separate variable-frequency group.[4]
ABR, annualized bleed rate.

For additional important risk and use information, please see full Prescribing Information.

Jivi®
antihemophilic factor (recombinant) PEGylated-aucl

In the PROTECT VIII main study

Percent of patients with zero total bleeds in the prophylaxis arms with Jivi®[1,7]



*Total bleeds include spontaneous bleeds, trauma bleeds, and joint bleeds.

SELECTED IMPORTANT SAFETY INFORMATION

- Jivi is contraindicated in patients who have a history of hypersensitivity reactions to the active substance, polyethylene glycol (PEG), mouse or hamster proteins, or other constituents of the product.
- Hypersensitivity reactions, including severe allergic reactions, have occurred with Jivi. Monitor patients for hypersensitivity symptoms. Early signs of hypersensitivity reactions, which can progress to anaphylaxis, may include chest or throat tightness, dizziness, mild hypotension and nausea.
  If hypersensitivity reactions occur, immediately discontinue administration and initiate appropriate treatment.

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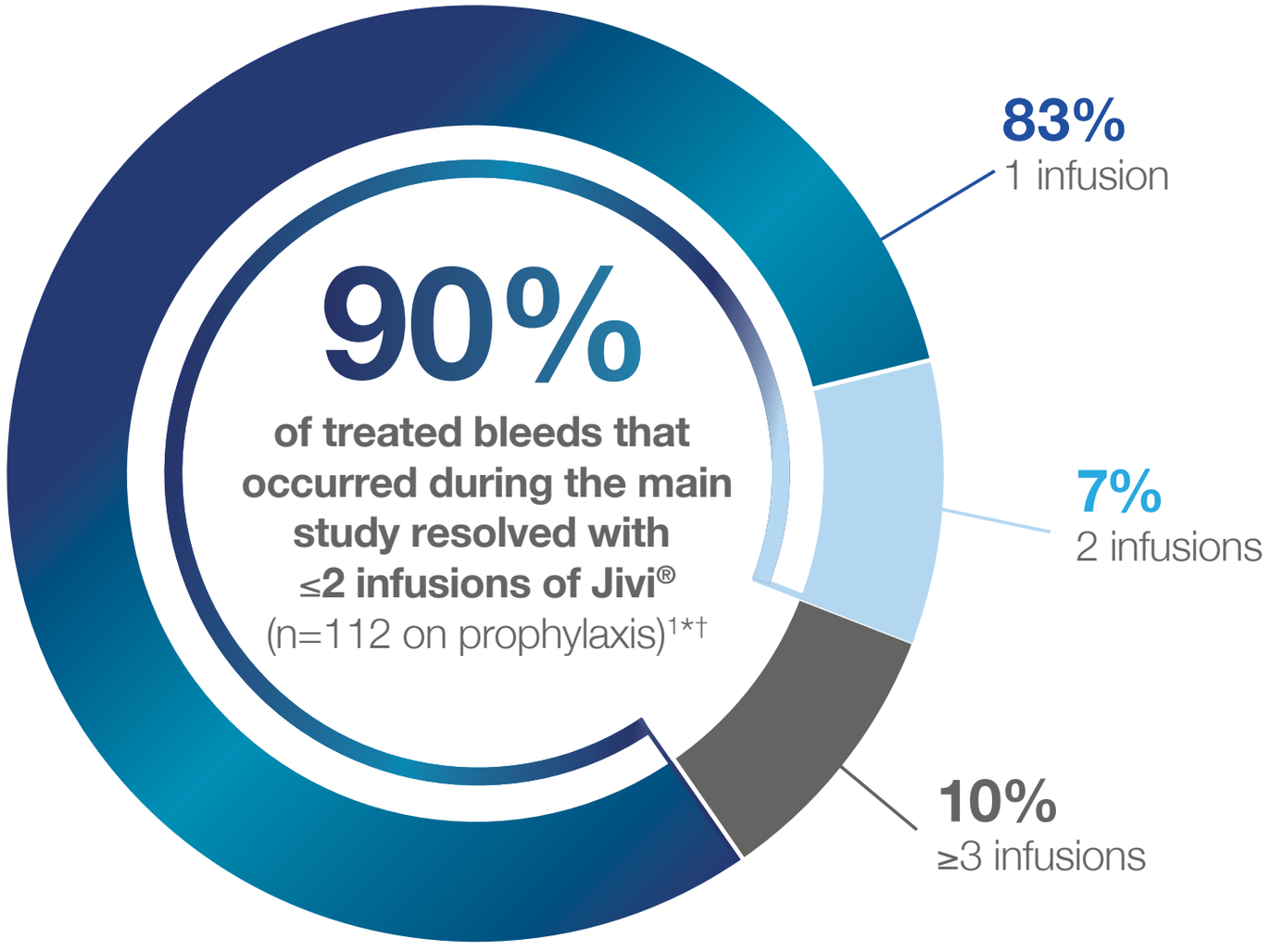
Jivi®
antihemophilic factor (recombinant) PEGylated-aucl

Jivi® provided effective treatment of bleeds[1]



SELECTED IMPORTANT SAFETY INFORMATION

- Jivi may contain trace amounts of mouse and hamster proteins. Patients treated with this product may develop hypersensitivity to these non-human mammalian proteins.
- Hypersensitivity reactions may also be related to antibodies against polyethylene glycol (PEG).

*Treatment of bleeds from week 0 through week 36.[1]
†Two patients discontinued after a single dose of Jivi and were not included in the efficacy analysis.[1]

For additional important risk and use information, please see full Prescribing Information.

Jivi®
antihemophilic factor (recombinant) PEGylated-aucl

During the PROTECT VIII main and extension studies

Target-joint resolution with Jivi®[8]

Results from a post hoc analysis of target-joint status in 82 patients in the prophylactic group from baseline through the main study and into the extension period (median time of 1421 days [range: 700-2071][8])

95%

of **historic target joints*** were resolved[8†]

107 of 113 historic target joints were resolved at time of analysis *(data cutoff 8/28/2019)*[8]

The median (IQR) target joint ABR was 0 (0-1.5) at the end of the main study and 0 (0-1.4) at the extension cutoff date *(8/28/2019)*[8]

The mean (SD) target joint ABR was 1.28 (2.14) at the end of the main study and 1.06 (2.08) at the extension cutoff date *(8/28/2019)*[9]

Analysis consisted of[8]:

- Numbers of historic target joints, as judged by the investigator, recorded at study entry
- Numbers of resolved target joints (≤2 spontaneous bleeds during last 12 months)†

SELECTED IMPORTANT SAFETY INFORMATION

- Neutralizing antibody (inhibitor) formation can occur following administration of Jivi. Carefully monitor patients for the development of Factor VIII inhibitors, using appropriate clinical observations and laboratory tests. If expected plasma Factor VIII activity levels are not attained or if bleeding is not controlled as expected with administered dose, suspect the presence of an inhibitor (neutralizing antibody).

*Patients remaining on the same prophylaxis regimen during the last 90 days of treatment. Median (Q1; Q3) joint ABRs were 0.00 (0.0,8.1) for twice-weekly and 0.00 (0.0; 4.1) for every-5-day final on-study dosing interval.[10]

†As defined by the International Society of Thrombosis and Hemostasis (ISTH).[8]

For additional important risk and use information, please see full Prescribing Information.

Jivi®
antihemophilic factor (recombinant) PEGylated-aucl

During the PROTECT VIII main and extension studies

Target-joint resolution with Jivi®[8]

Results from a post hoc analysis of target-joint status in 82 patients in the prophylactic group from baseline through the main study and into the extension period (median time of 1421 days [range: 700-2071][8])

91%

of **historic or new target joints*** were resolved[8†]

111 of 122 historic or new target joints were resolved at time of analysis *(data cutoff 8/28/2019)*[8]

The median (IQR) target joint ABR was 0 (0-1.5) at the end of the main study and 0 (0-1.4) at the extension cutoff date *(8/28/2019)*[8]

The mean (SD) target joint ABR was 1.28 (2.14) at the end of the main study and 1.06 (2.08) at the extension cutoff date *(8/28/2019)*[9]

Analysis consisted of[8]:

- Numbers of historic target joints, as judged by the investigator, recorded at study entry
- Numbers of new target joints that developed on-study (≥3 spontaneous bleeds within 6 months)†
- Numbers of resolved target joints (≤2 spontaneous bleeds during last 12 months)†

SELECTED IMPORTANT SAFETY INFORMATION

- A clinical immune response associated with IgM anti-PEG antibodies, manifested as symptoms of acute hypersensitivity and/or loss of drug effect, has been observed primarily in patients < 6 years of age. The symptoms of the clinical immune response were transient. Anti-PEG IgM titers decreased over time to undetectable levels. No immunoglobulin class switching was observed.

*Patients remaining on the same prophylaxis regimen during the last 90 days of treatment. Median (Q1; Q3) joint ABRs were 0.00 (0.0,8.1) for twice-weekly and 0.00 (0.0; 4.1) for every-5-day final on-study dosing interval.[10]

†As defined by the International Society of Thrombosis and Hemostasis (ISTH).[8]

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Jivi®
antihemophilic factor (recombinant) PEGylated-aucl

In the PROTECT VIII main study

Median Jivi® doses were within recommended label dosing[1]*

	Bleeding Tendency	Recommended Dose in Label	Median (Range) Prophylaxis Dose/Infusion
Twice weekly	LOW (n=11)[1]	30-40 IU/kg[1]	30.6 IU/kg (29-41 IU/kg)[1]
	HIGH* (n=13)[1]		39.2 IU/kg (33-42 IU/kg)[1]
Every 5 days	LOW* (n=43)[1]	45-60 IU/kg[1]	45.3 IU/kg (39-58 IU/kg)[1]

SELECTED IMPORTANT SAFETY INFORMATION

- In case of clinical suspicion of loss of drug effect, conduct testing for Factor VIII inhibitors and Factor VIII recovery. A low post-infusion Factor VIII level in the absence of detectable Factor VIII inhibitors indicates that loss of drug effect is likely due to anti-PEG antibodies. Discontinue Jivi and switch patients to a previously effective Factor VIII product.
- The most frequently (≥5%) reported adverse reactions in clinical trials in previously treated patients (PTPs) ≥12 years of age were headache, cough, nausea, and fever.

*Patients received prophylactic therapy for 26 weeks after a 10-week run-in period of twice weekly 25 IU/kg.
Patients that had high bleeding tendency (>1 breakthrough bleeds during the run-in) continued on twice-weekly 30-40 IU/kg.
Patients with ≤1 breakthrough bleeds during the run-in were randomized to less frequent dosing of every 5 days (45-60 IU/kg) or every 7 days. After randomization groups were full, remaining eligible patients continued with twice-weekly 30-40 IU/kg.[3]

For additional important risk and use information, please see full Prescribing Information.

Jivi®
antihemophilic factor (recombinant) PEGylated-aucl

In the PROTECT VIII extension study

Median Jivi® doses were within recommended label dosing[1,4]

	Bleeding Tendency	Recommended Dose in Label	Median (Range) Prophylaxis Dose/Infusion
Twice weekly	LOW and HIGH[1]* (n=23)	30-40 IU/kg[1]	36.7 IU/kg[4] (26.8 – 42.8)
Every 5 days	LOW[1] (n=33)	45-60 IU/kg[1]	44.8 IU/kg[4] (40.7 – 59.6)
Variable frequency†	Varied tendency[1] (n=28)	Varied label dose	50.7 IU/kg[4] (29.1 – 63.8)

†Patients who switched at least once after the first week of the extension study were analyzed in a separate variable frequency group.[4]

INDICATIONS

- Jivi antihemophilic factor (recombinant), PEGylated-aucl, is a recombinant DNA-derived, Factor VIII concentrate indicated for use in previously treated adults and adolescents (12 years of age and older) with hemophilia A (congenital Factor VIII deficiency) for:
  - On-demand treatment and control of bleeding episodes
  - Perioperative management of bleeding
  - Routine prophylaxis to reduce the frequency of bleeding episodes
- Limitations of use:
  - Jivi is not indicated for use in children less than 12 years of age due to a greater risk for hypersensitivity reactions.
  - Jivi is not indicated for use in previously untreated patients (PUPs).
  - Jivi is not indicated for the treatment of von Willebrand disease.

*Patients received prophylactic therapy for 26 weeks after a 10-week run-in period of twice-weekly 25 IU/kg. Patients who had high bleeding tendency (>1 breakthrough bleed during the run-in) continued on twice-weekly 30-40 IU/kg. Patients with ≤1 breakthrough bleed during the run-in were randomized to less frequent dosing of every 5 days (45-60 IU/kg or every 7 days. After randomization groups were full, remaining eligible patients continued with twice-weekly 30-40 IU/kg.[3]

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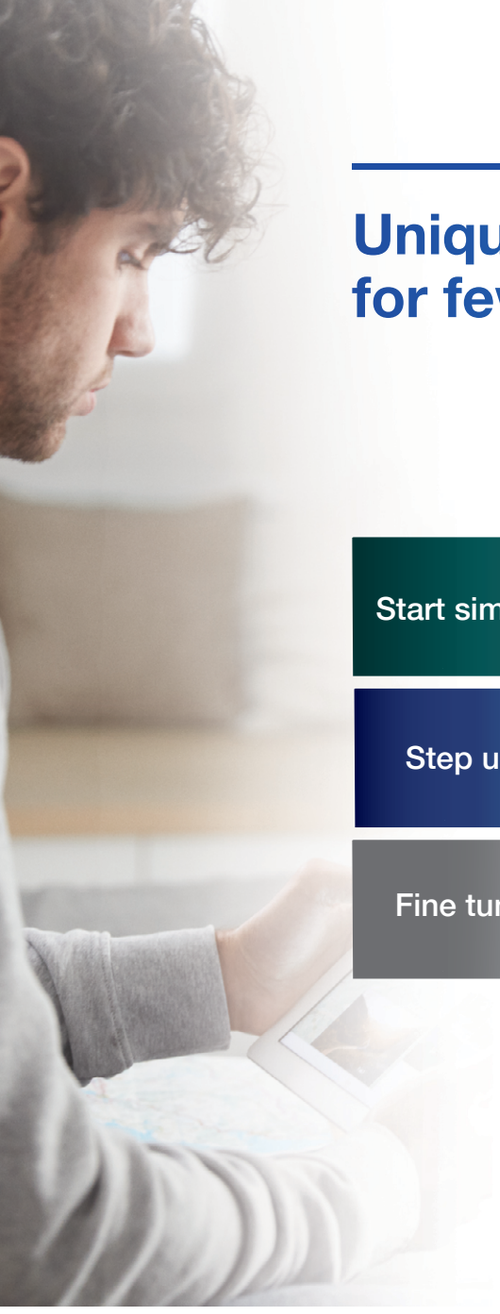
antihemophilic factor (recombinant) PEGylated-aucl



Unique step-wise dosing with Jivi®, with the potential for fewer infusions[1,2]

		For patients ≥12 years
Start simply	TWICE WEEKLY	For all prophylaxis patients: Recommended starting regimen is Jivi® twice weekly (30-40 IU/kg)[1]*
Step up	EVERY 5 DAYS	Based on bleeding episodes: Less frequent dosing of Jivi® every 5 days (45-60 IU/kg) can be used[1]*
Fine tune	↑↓	Based on bleeding episodes: The dosing frequency may be further adjusted up or down[1]

8/10 patients
in PROTECT VIII reduced dosing frequency vs their prestudy prophylaxis regimen in the main study[5†]

SELECTED IMPORTANT SAFETY INFORMATION

- Jivi is contraindicated in patients who have a history of hypersensitivity reactions to the active substance, polyethylene glycol (PEG), mouse or hamster proteins, or other constituents of the product.
- Hypersensitivity reactions, including severe allergic reactions, have occurred with Jivi. Monitor patients for hypersensitivity symptoms. Early signs of hypersensitivity reactions, which can progress to anaphylaxis, may include chest or throat tightness, dizziness, mild hypotension and nausea. If hypersensitivity reactions occur, immediately discontinue administration and initiate appropriate treatment.

*100% of patients in the every-5-days and twice-weekly dosing arms remained on the same dosing regimen for the duration of the main study.[1]
†n=40/47 patients in the every-5-days and twice-weekly dosing arms for whom prior prophylaxis dosing records were available.[5]

For additional important risk and use information, please see full Prescribing Information.

Jivi®
antihemophilic factor (recombinant) PEGylated-aucl

During the PROTECT VIII main and extension studies

Long-term safety data with Jivi®[3,4]

Up to 7 years of safety and tolerability data in previously treated adolescents and adults (N=134 in main study; N=121 in extension study)[3,4]

Most common adverse events: headache, cough, nausea, and fever[1]

Incidence of drug-related AEs/SAEs in the long-term extension study[4*]

- Drug-Related AEs: 8.3% (n=10); Drug-Related SAEs: 1.7% (n=2)

Zero FVIII inhibitors[3,4]

- No confirmed case of inhibitors against FVIII occurred[†]

No confirmed increasing plasma PEG levels over time[4,11‡]

Hypersensitivity reactions were transient (n=2/134)[3]

- Allergic reactions occurred in two patients in the PROTECT VIII main study; one was related to PEG, a component of Jivi[1,3]
- No hypersensitivity reactions were reported in the long-term extension study[4]

SELECTED IMPORTANT SAFETY INFORMATION

- Jivi may contain trace amounts of mouse and hamster proteins. Patients treated with this product may develop hypersensitivity to these non-human mammalian proteins.
- Hypersensitivity reactions may also be related to antibodies against polyethylene glycol (PEG).

*Overall AEs: 79.3% (n=96).[4]
[†]In the main study factor VIII inhibitor (1.7 BU/mL) was reported in one previously treated adult subject. Repeat testing did not confirm the presence of a Factor VIII inhibitor.[3]
[‡]A few patients had transiently detectable PEG just above the lower limit of quantitation (LLOQ). One patient had detectable PEG in plasma only at the last visit of the study, and in accordance with the study protocol, further follow-up was not allowed.[4]
AE, adverse event; PEG, polyethylene glycol; SAE, serious adverse event.

For additional important risk and use information, please see full Prescribing Information.

Jivi®
antihemophilic factor (recombinant) PEGylated-aucl

Jivi® needleless reconstitution system and storage

The Jivi® needleless reconstitution system contains[1]:

- Vial adapter with built-in 15-micrometer filter
- 2.5-mL diluent in a 5-mL syringe (500 IU, 1000 IU, 2000 IU, and 3000 IU)
- 5.0-mL diluent in a 5-mL syringe (4000 IU only)
- 25-gauge butterfly needle

Storage at room temperature (up to 77°F) for up to 6 months[1]

Store Jivi® at 36°F to 46°F for up to 24 months from the date of manufacture. Do not freeze. Within this period, Jivi® may be stored for a single period of up to 6 months at temperatures up to 77°F. Record the starting date of room temperature storage on the unopened product carton. Once stored at room temperature, do not return the product to the refrigerator. The shelf-life then expires after storage at room temperature for 6 months, or after the expiration date on the product vial, whichever is earlier. Do not use Jivi® after the expiration date indicated on the vial. Protect Jivi® from extreme exposure to light and store the vial with the lyophilized powder in the carton prior to use.

Jivi® is available in a range of vial sizes[1]

- Reconstitution with small diluent volumes

SELECTED IMPORTANT SAFETY INFORMATION

- Neutralizing antibody (inhibitor) formation can occur following administration of Jivi. Carefully monitor patients for the development of Factor VIII inhibitors, using appropriate clinical observations and laboratory tests. If expected plasma Factor VIII activity levels are not attained or if bleeding is not controlled as expected with administered dose, suspect the presence of an inhibitor (neutralizing antibody).

For additional important risk and use information, please see full Prescribing Information.

Jivi®
antihemophilic factor (recombinant) PEGylated-aucl

Empower him to step up to the challenge with Jivi®

THE EHL rFVIII WITH PROVEN PROTECTION, SAFETY, AND UNIQUE STEP-WISE DOSING[1-4]

- **Powerful protection from bleeds** with a twice-weekly starting dose; with the potential to step up to every 5 days and fine tune[1]
- Up to **7 years of safety data**[3,4]
- The potential for fewer infusions: **8/10 patients** in the PROTECT VIII main study **reduced dosing frequency** vs their pre-study prophylaxis regimen[5]

	For patients ≥12 years	
Start simply	TWICE WEEKLY	For all prophylaxis patients: Recommended starting regimen is Jivi® twice weekly (30-40 IU/kg)[1]
Step up	EVERY 5 DAYS	Based on bleeding episodes: Less frequent dosing of Jivi® every 5 days (45-60 IU/kg) can be used[1]
Fine tune	↑↓	Based on bleeding episodes: The dosing frequency may be further adjusted up or down[1]

SELECTED IMPORTANT SAFETY INFORMATION

- A clinical immune response associated with IgM anti-PEG antibodies, manifested as symptoms of acute hypersensitivity and/or loss of drug effect, has been observed primarily in patients < 6 years of age. The symptoms of the clinical immune response were transient. Anti-PEG IgM titers decreased over time to undetectable levels. No immunoglobulin class switching was observed.

References: 1. Jivi Prescribing Information. August 2018. Bayer. **2.** Data on file. Tx Review 0918. Bayer; 2018. **3.** Reding MT et al. *J Thromb Haemost* 2017;15:411-419. **4.** Reding M, et al. *Haemophilia*. 2021; 10.1111/hae.14297. **5.** Kerlin BA et al. Poster P153. Presented at the 4th Biennial Summit of the Thrombosis & Haemostasis Societies of North America. March 8-10, 2018, San Diego, California. **6.** Data on file. CSR 13024-A. Bayer; 2018. **7.** Data on file. CSR PH 40454. BAY 94-9027/13024 **8.** Reding MT et al. *Haemophilia*. 2020;26(4):e201-e204. **9.** Data on file. Jivi PROTECT VIII Extension AUG 2019 CSR Target Joint Analysis data; Bayer. **10.** Reding M et al. Poster P29. Presented at the Hemostasis and Thrombosis Research Society 2019 Scientific Symposium. 9-11 May 2019, New Orleans, Louisiana. **11.** Data on file. CSR 2.7.4. Bayer; 2018.

Jivi®
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For additional important risk and use information, please see full Prescribing Information.

You are encouraged to report negative side effects or quality complaints of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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