Jivi®: The EHL rFVIII with proven protection, safety, and unique step-wise dosing in patients 12 years of age and older[1-4]

Flexible Dosing Schedule for Your Patients

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

INDICATION

- JIVI® is a recombinant DNA-derived, Factor VIII concentrate indicated for use in previously treated adults and pediatric patients 7 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 <7 years of age due to a greater risk for hypersensitivity reactions and/or loss of efficacy.
  - Previously untreated patients (PUPs).
  - 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

For your patients 12 years of age and older, 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.

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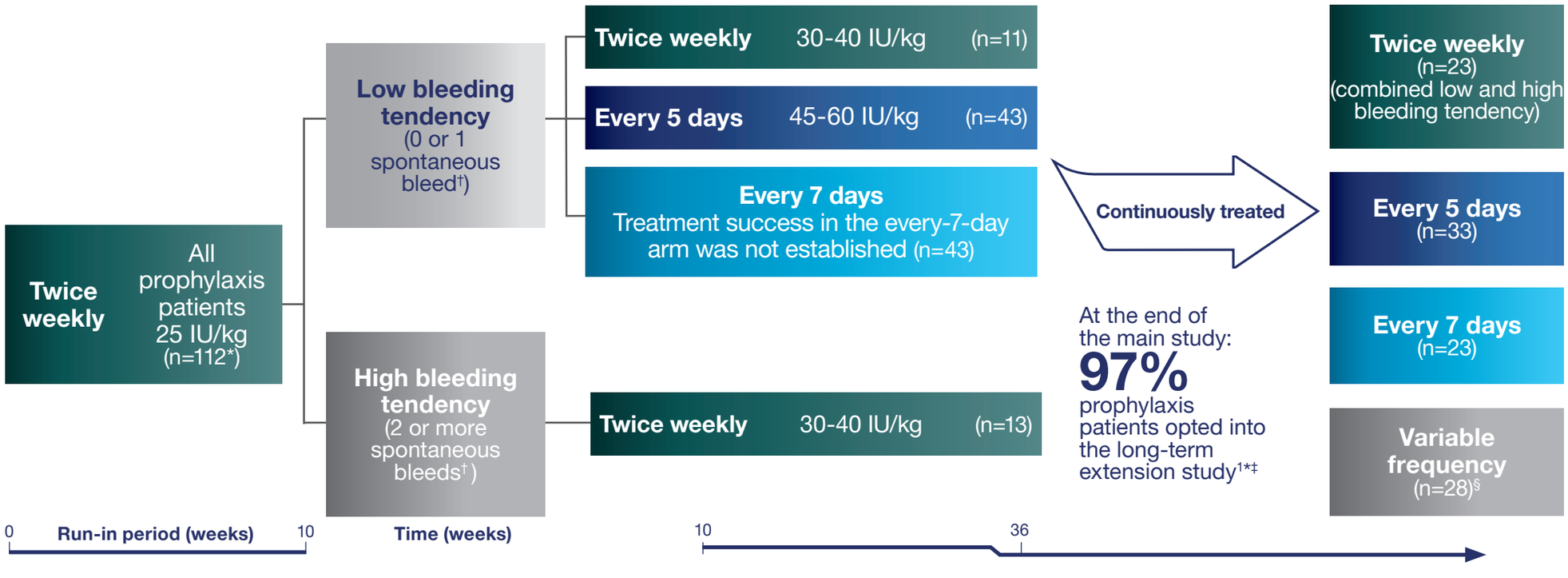
The PROTECT VIII main and extension studies were designed to reflect real-world treatment in patients 12 years of age and older[3,4]

(n=112, Adolescents and Adults)

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 has occurred following administration of JIVI. Carefully monitor patients for 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.

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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

- An immune response associated with IgM anti-PEG antibodies, manifested as symptoms of acute hypersensitivity and/or loss of drug effect, has occurred with JIVI administration. In the clinical trials, the IgM anti-PEG antibodies disappeared within 4-6 weeks. No immunoglobulin class switching from IgM to IgG has been observed.
- A low post-infusion Factor VIII level, in absence of detectable Factor VIII inhibitors, may be due to loss of treatment effect related to high titers of anti-PEG IgM antibodies. In these cases, discontinue JIVI and switch patients to a different anti-hemophilic product.
- A reduced recovery of Factor VIII after start of JIVI treatment may be due to transient low titers of anti-PEG IgM antibodies. In these cases, increase the dose of JIVI until recovery of Factor VIII returns to expected levels.
- The most common (incidence ≥5%) adverse reactions in clinical trials in previously treated patients (PTPs) ≥7 years of age were headache, fever, cough, and abdominal pain.

*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.

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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]

INDICATION

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  - 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 <7 years of age due to a greater risk for hypersensitivity reactions and/or loss of efficacy.
  - Previously untreated patients (PUPs).
  - 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.

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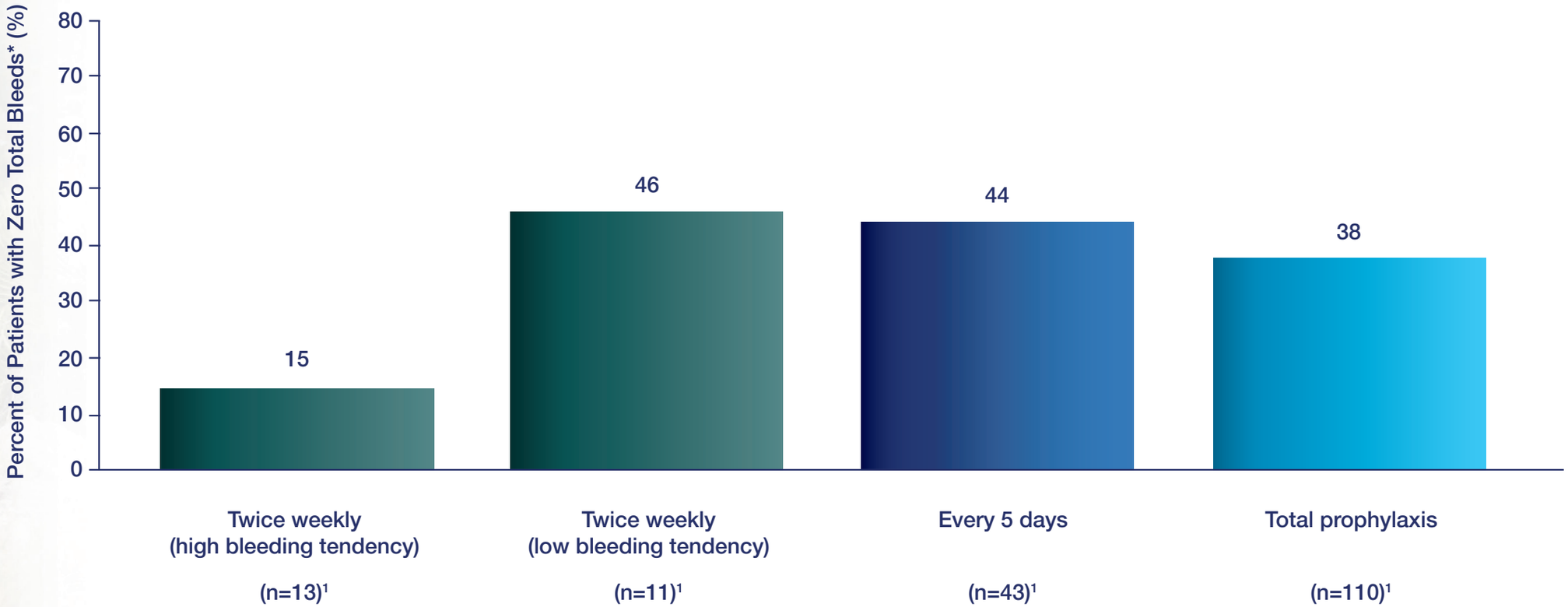
In the PROTECT VIII main study

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



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.
- JIVI may contain trace amounts of mouse and hamster proteins. Patients treated with this product may develop hypersensitivity to these non-human mammalian proteins.

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

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

Jivi®
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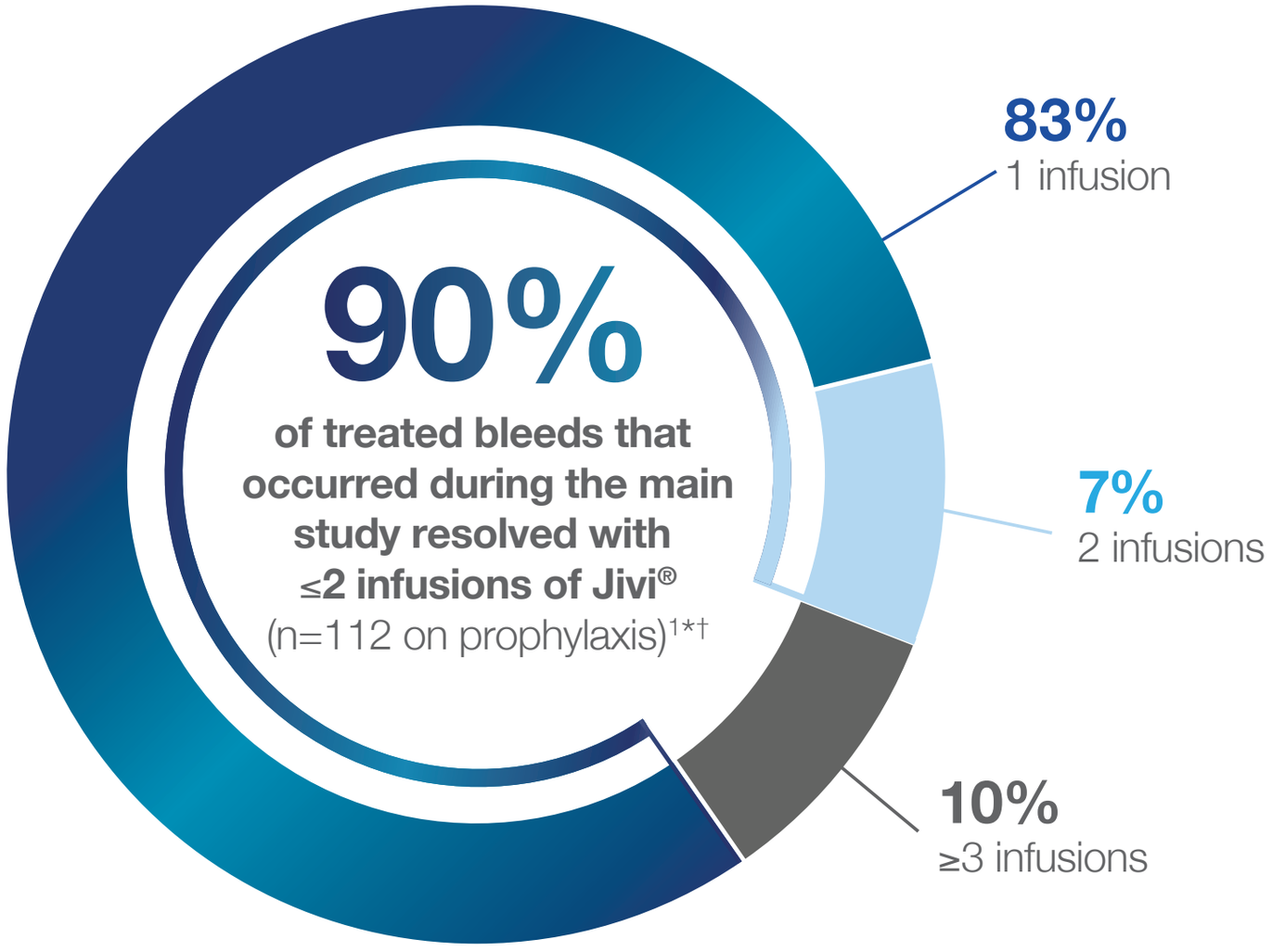
Jivi® provided effective treatment of bleeds[1]



SELECTED IMPORTANT SAFETY INFORMATION

- 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®
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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 ≥12 years of age 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 has occurred following administration of JIVI. Carefully monitor patients for 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]

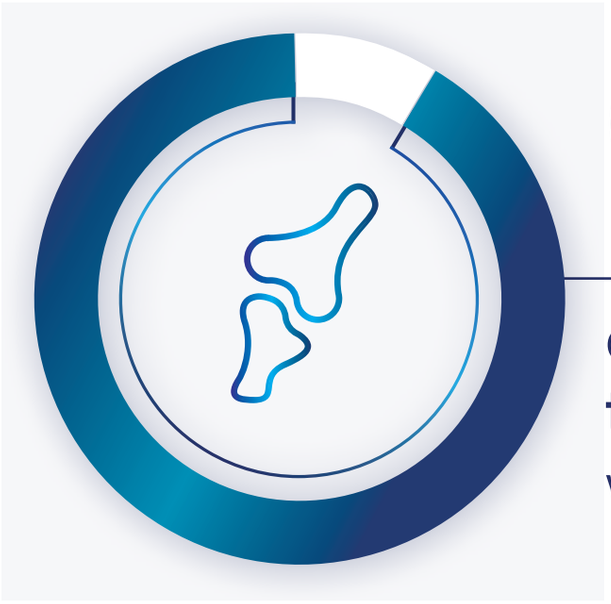
For additional important risk and use information, please see full Prescribing Information.

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 ≥12 years of age 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

- An immune response associated with IgM anti-PEG antibodies, manifested as symptoms of acute hypersensitivity and/or loss of drug effect, has occurred with JIVI administration. In the clinical trials, the IgM anti-PEG antibodies disappeared within 4-6 weeks. No immunoglobulin class switching from IgM to IgG has been 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]

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

Jivi®
antihemophilic factor (recombinant) PEGylated-aucl

In the PROTECT VIII main study

Median Jivi® doses were within recommended label dosing for adults and adolescents[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

- A low post-infusion Factor VIII level, in absence of detectable Factor VIII inhibitors, may be due to loss of treatment effect related to high titers of anti-PEG IgM antibodies. In these cases, discontinue JIVI and switch patients to a different anti-hemophilic product.
- A reduced recovery of Factor VIII after start of JIVI treatment may be due to transient low titers of anti-PEG IgM antibodies. In these cases, increase the dose of JIVI until recovery of Factor VIII returns to expected levels.
- The most common (incidence ≥5%) adverse reactions in clinical trials in previously treated patients (PTPs) ≥7 years of age were headache, fever, cough, and abdominal pain.

*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 for adults and adolescents[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)**

INDICATION

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  - Perioperative management of bleeding.
  - Routine prophylaxis to reduce the frequency of bleeding episodes.

- Limitations of use
  JIVI is not indicated for use in:
  - Children <7 years of age due to a greater risk for hypersensitivity reactions and/or loss of efficacy.
  - Previously untreated patients (PUPs).
  - 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]

†Patients who switched 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

Jivi® dosing frequency can be adjusted based on bleeding episodes

		For patients ≥12 years
Start simply	**TWICE WEEKLY**	Recommended starting regimen for Jivi is twice weekly (30-40 IU/kg) for all prophylaxis patients.[1*]
Adjust	**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 regimen	**UP OR DOWN**	From there, you have the flexibility to adjust your patient's dosing frequency up or down as needed, based on bleeding episodes.[1]

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

Learn about dosing information for patients 7 to <12 years of age at www.jivihcp.com or refer to the full Prescribing Information.

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.
- JIVI may contain trace amounts of mouse and hamster proteins. Patients treated with this product may develop hypersensitivity to these non-human mammalian proteins.

*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®
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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]

4 most common side effects*,[12]: Headache, Cough, Nausea and Fever

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

- Hypersensitivity reactions may also be related to antibodies against polyethylene glycol (PEG).
- Neutralizing antibody (inhibitor) formation has occurred following administration of JIVI. Carefully monitor patients for 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).
- An immune response associated with IgM anti-PEG antibodies, manifested as symptoms of acute hypersensitivity and/or loss of drug effect, has occurred with JIVI administration. In the clinical trials, the IgM anti-PEG antibodies disappeared within 4-6 weeks. No immunoglobulin class switching from IgM to IgG has been observed.

*In at least 5% of patients, ages 12 and over (n=148).[12]
†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]:

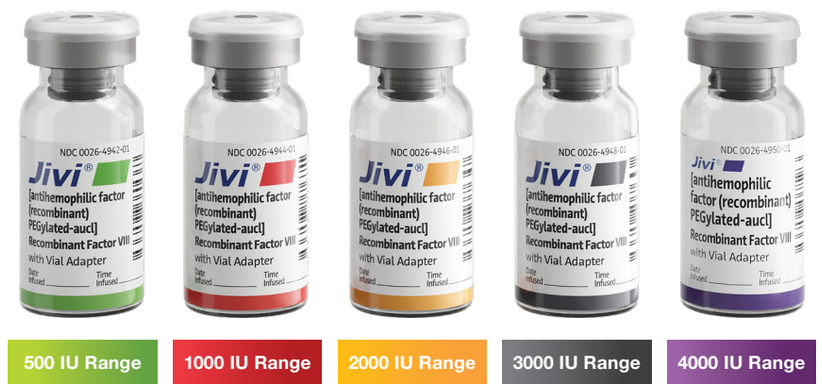
- Vial adapter with built-in 15-micrometer filter
- 2.5-mL diluent in a 5-mL syringe (500 IU, 1000 IU, 2000 IU, and 3000 IU)
- 5.0-mL diluent in a 5-mL syringe (4000 IU only)
- 25-gauge butterfly needle

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

- A low post-infusion Factor VIII level, in absence of detectable Factor VIII inhibitors, may be due to loss of treatment effect related to high titers of anti-PEG IgM antibodies. In these cases, discontinue JIVI and switch patients to a different anti-hemophilic product.

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

Jivi®
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Empower him to step up to the challenge with Jivi®

- **Powerful protection from bleeds** with a twice-weekly starting dose; with the potential to step up to every 5 days and fine tune, for patients 12 years of age and older[1]
- Up to **7 years of safety data for adults and adolescents**[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]

Dosing for Children 7 to <12 Years of Age

Start Simply	Twice Weekly	**For all prophylaxis patients 7 to <12 years of age:** Recommended starting regimen is Jivi twice weekly (60 IU/kg) Adjust the dose based on the patient's clinical response and/or recovery[1]

Unique Step-Wise Dosing for Patients ≥12 Years of Age

Start Simply	Twice Weekly	**For all prophylaxis patients ≥12 years of age:** Recommended starting regimen is Jivi twice weekly (30-40 IU/kg)[1]
Adjust	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 Regimen	⇅	**Based on bleeding episodes:** The dosing frequency may be further **adjusted up or down**[1]

SELECTED IMPORTANT SAFETY INFORMATION

- A reduced recovery of Factor VIII after start of JIVI treatment may be due to transient low titers of anti-PEG IgM antibodies. In these cases, increase the dose of JIVI until recovery of Factor VIII returns to expected levels.
- The most common (incidence ≥5%) adverse reactions in clinical trials in previously treated patients (PTPs) ≥7 years of age were headache, fever, cough, and abdominal pain.

References: 1. Jivi® Prescribing Information. Whippany, NJ: Bayer LLC; May 2025. **2.** Data on file. Tx Review 0918. Bayer; 2018. **3.** Reding MT, et al. *J Thromb Haemost*. 2017;15(3):411-419. **4.** Reding MT, et al. *Haemophilia*. 2021;27(3):e347-e356. **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. May 9-11, 2019; New Orleans, Louisiana. **11.** Data on file. CSR 2.7.4. Bayer; 2018. **12.** Data on file. Expanded Company Core Data Sheet Jivi. Version 02. Bayer, 2020.

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

You are encouraged to report 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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