Jivi®
antihemophilic factor
(recombinant) PEGylated-aucl

HEM-POWR

A Real-World Evidence (RWE) Study of Jivi®

INDICATION

- 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 the full Prescribing Information.

BAYER

PROTECT VIII Study Design (N=112)[1]

112 previously treated patients (PTPs) on a prophylaxis treatment regimen entered a 10-week run-in period where they received 25 IU/kg twice weekly of Jivi®. Of the 112 patients who entered the study, 110 patients completed the 10-week run-in period.[1]*

Following the run-in period, patients were assigned or randomized to a treatment arm based on bleeding tendency. These patients were treated for 26 weeks.[1]

Among 97 patients with low bleeding tendencies:
- 11 received 30-40 IU/kg twice weekly
- 43 patients received 45-60 IU/kg every 5 days
- 43 patients were randomized into the every-7-day treatment arm†

The 13 patients with high bleeding tendencies received 30-40 IU/kg twice weekly for 26 weeks.[1]

*An additional 20 previously treated patients entered a control arm of on-demand treatment with Jivi.
†Treatment success in the every-7-day arm was not established.

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- 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).
- 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).
- 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.

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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)[2,3]
- 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)[2,3]
- 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)[2,3]
- 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)[2,3]

*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.[2]
†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.[2]
‡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.

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- 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.

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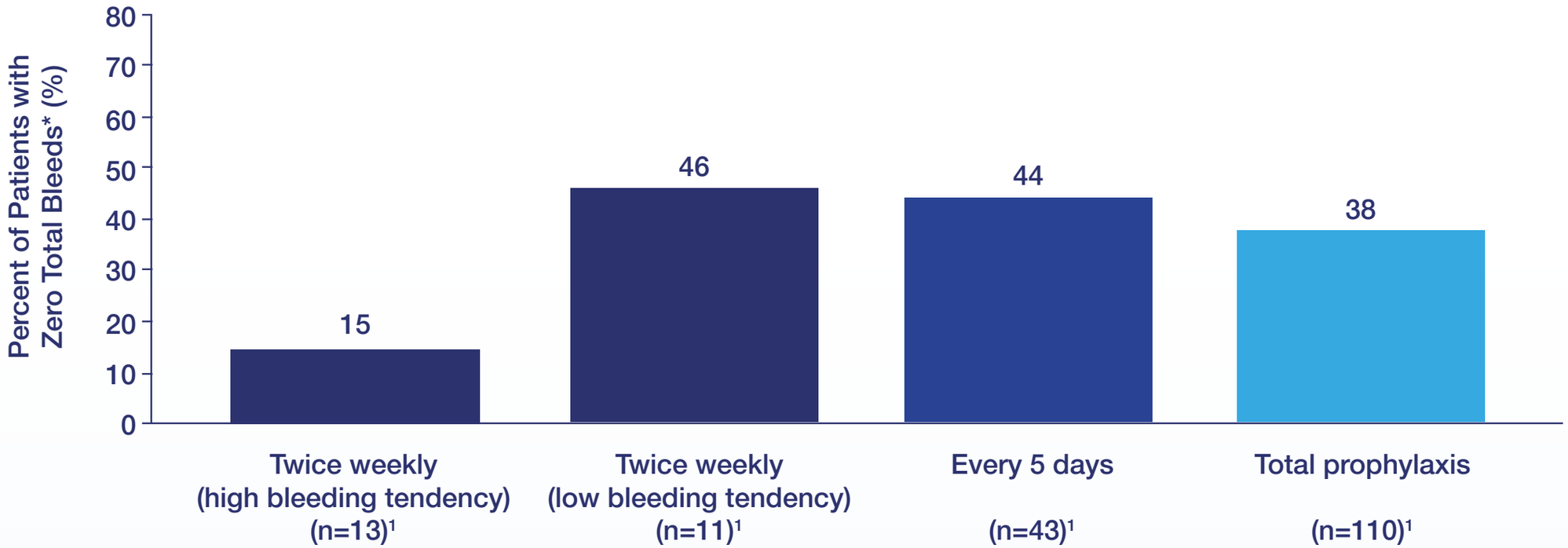
In the PROTECT VIII main study:

Percent of patients with zero total bleeds in the prophylaxis arms with Jivi®[1,4]



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

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In the PROTECT VIII main study:
Jivi® safety and tolerability in previously treated adolescents and adults[1]

Demonstrated safety profile for Jivi in the main study

2/134 previously treated patients

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

- Allergic reactions occurred in two patients. In one patient the allergic reaction was related to polyethylene glycol (PEG), a component of Jivi[1,2]

0

Zero FVIII inhibitors[2]

- No confirmed case of inhibitors against FVIII occurred[2*]

Four most common side effects: headache, cough, nausea and fever[1]

*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.[1]

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HEM-POWR Real-World Evidence (RWE) Study Design (severe subgroup, N=190)[5]

HEM-POWR is a multinational, open-label, prospective, non-interventional, multicenter cohort study of Jivi® in previously treated patients with hemophilia A in a real-world clinical setting.[5]

As of the database cut-off, August 1, 2023, 339 patients were enrolled in the study. A fourth interim analysis was conducted using the following groups: Full Analysis Set: 227 patients* & Safety Analysis Set: 332 patients.[5†]

Previously treated patients ≥12 years of age with a diagnosis of Hemophilia A, without previous history of inhibitors, and starting or currently receiving Jivi with any kind of treatment modality (ie, on-demand, prophylaxis, or intermittent prophylaxis) were eligible for enrollment into the study.

Data points were collected from patient e-diaries and physician records, and ethical approval was obtained at all sites. Statistical analyses were descriptive and explorative in nature.

This real-world study included patients that had mild or moderate disease and female patients. These patients are not included in the Jivi label and the results presented from the Full Analysis Set include only those for male patients with severe hemophilia.

In the severe subgroup, the prescribed treatment modality at baseline was: Prophylaxis [98.9%] or On-Demand [1.1%]. Of the 190 severe patients, 159 (84%) were pre-treated with Jivi.[5]

Limitations: Real-World Evidence studies may not use randomization and have treatment variables that are not under the control of the investigators. The lack of randomization and investigator control increases the potential for bias and confounding variables that could impact the study outcomes. Findings from this study may be subject to bias, such as patient selection and bleeding event recall bias, and limitations to availability of historical medical data.

*227 previously treated patients were included in the Full Analysis Set. 33 mild and moderate patients were excluded from this analysis as these populations were not studied in the PROTECT VIII pivotal trial. An additional 4 patients, (including 2 female patients) were excluded from this analysis because their severity was not defined. A total of 112/339 patients were excluded from the FAS because the date of first dose of Jivi in the study was not documented (20), infusions were not documented in their patient diary (111) or a violation of the inclusion/exclusion criteria was later detected (1).

†332/339 patients were included in the Safety Analysis Set. One patient under 12 was included in the Safety Analysis Set. The seven patients excluded from the Safety Analysis Set did not receive at least one dose of Jivi during the observation period.

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).
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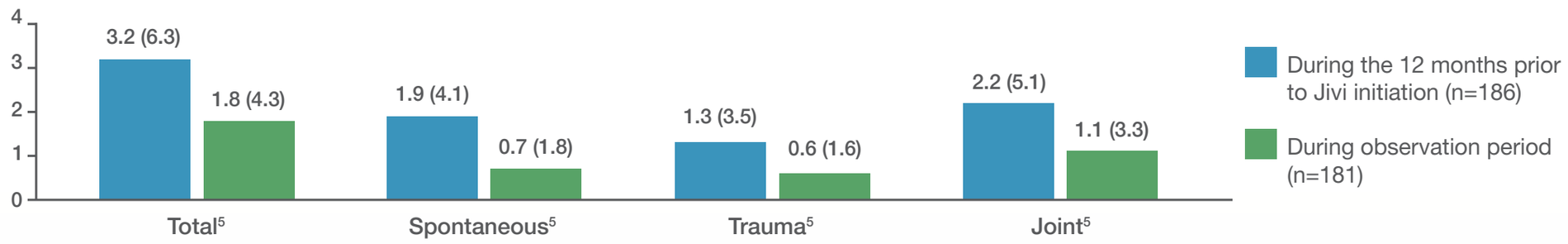
In the HEM-POWR RWE Study (4th Interim Analysis) (severe subgroup, N=190)[5]

Mean (SD) ABR during 12 months prior to Jivi® initiation* and during observation period†[5]



Median (Q1,Q3) ABR during 12 months prior to Jivi initiation* and during observation period†[5]

Median ABR (Q1, Q3)[5]	Total[5]	Spontaneous[5]	Trauma[5]	Joint[5]
12 months prior to Jivi initiation (n=186)	1.0 (0.0, 4.0)	0.0 (0.0, 2.0)	0.0 (0.0, 1.0)	0.0 (0.0, 2.0)
During observation period (n=181)	0.5 (0.0, 1.6)	0.0 (0.0, 0.7)	0.0 (0.0, 0.5)	0.0 (0.0, 0.9)

*159 of 190 patients were pre-treated with Jivi before study enrollment. 12 months of their bleeding history was captured retrospectively before starting Jivi.
†Each patient in the study will be followed during a 36-month period that begins with their first study visit receiving Jivi. As of the fourth interim analysis cutoff date, the median study time completed by patients was 2 years.

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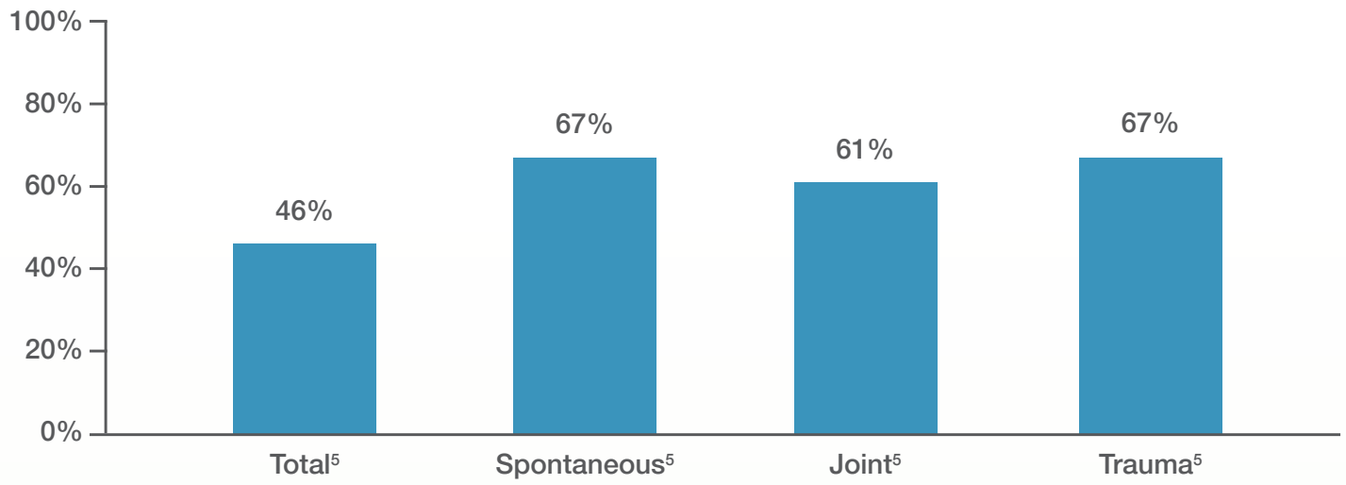
In the HEM-POWR RWE Study (4th Interim Analysis) (severe subgroup, N=190)[5]

Percent of patients with zero bleeds by bleed type during the observation period* (N=190)[5]



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In the HEM-POWR RWE Study (4th Interim Analysis) (severe subgroup, N=190)[5]

Percent of patients by dosing frequency (n=188)[5]*

Twice weekly (n=101)[5]	Every 5 days (n=34)[5]	Less frequently than every 5 days (n=22)[5]	Other† (n=31)[5]
54%	18%	12%	16%

*Two patients within the severe subgroup were treated using an on-demand dosing schedule.
†Every day (2%) and every two days (14%)

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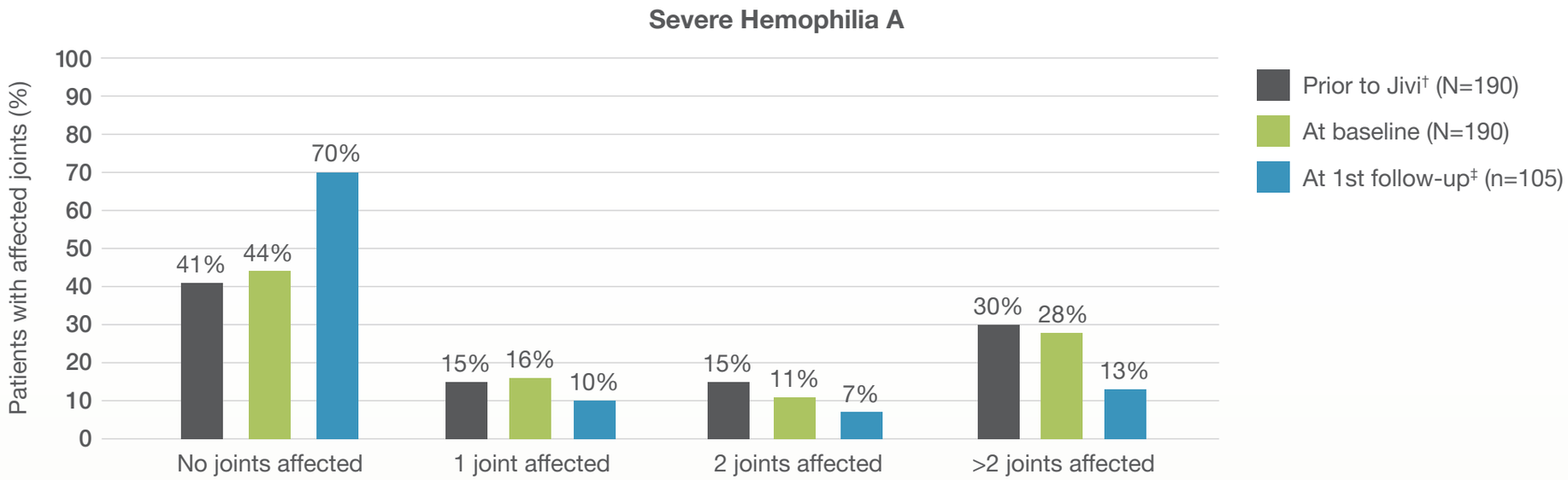
In the HEM-POWR RWE Study (4th Interim Analysis) (severe subgroup, N=190)[5]

Percent of patients with affected joints* prior to Jivi® initiation, at baseline and at first follow-up



*Affected joints are determined on an individual basis per investigator's clinical judgment based on the health status of the patient's joint, irrespective of the number of joint bleeds that occurred over a certain period of time.
†Follow-up windows defined as 180-day interval (±90 days) from initial visit. The initial visit (baseline) was the first visit in the study.
‡The first follow-up window occurred between days 90 – <270 in the study.

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In the HEM-POWR RWE Study (4th Interim Analysis) (Safety Analysis Set*, N=332)[7†]

Jivi® safety and tolerability

Incidence of patients with adverse events/serious adverse events in the study[7]:

- Drug-related Treatment Emergent Adverse Events (TEAE): 0.60% (n=2)[7‡]
- Drug-related serious TEAEs: 0.30% (n=1)[7]
  - One patient tested positive for an Anti-factor VIII antibody. This was a low titer transient inhibitor to Factor VIII that resolved within four months[7]
- There was one non-drug related TEAE (tendonitis) that led to the discontinuation of Jivi[7]
- No AE was classified as common (≥5%)[7]

As a Real-World Evidence study, there were no regularly scheduled assessments of drug tolerability. Patients participating in HEM-POWR were not required to visit study sites for efficacy or safety assessments. Patients may have visited sites as routine clinical care visits and/or may have reported adverse events to investigators who were then required to document and report the events to the study sponsor.

Limitations: Real-World Evidence studies may not use randomization and have treatment variables that are not under the control of the investigators. The lack of randomization and investigator control increases the potential for bias and confounding variables that could impact the study outcomes. Findings from this study may be subject to bias, such as patient selection and bleeding event recall bias, and limitations to availability of historical medical data.

*Patients had the option to report side effects at any time or during their follow up visit. 47% of patients did not have an on-site follow up visit as of the database cutoff (8/2023).[6]

†332/339 patients were included in the Safety Analysis Set. One patient under 12 was included in the Safety Analysis Set. The seven patients excluded from the Safety Analysis Set did not receive at least one dose of Jivi during the observation period.

‡ The two drug-related AEs experienced were related to a product needle issue (1) and a positive anti Factor VIII antibody (1).[6]

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Unique step-wise dosing with Jivi®, with the potential for fewer infusions[1,8]

The EHL rFVIII with proven protection, safety, and unique step-wise dosing[1,2,8,10]

		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 pre-study prophylaxis regimen in the main study[9†]

EHL, extended half-life;
rFVIII, recombinant Factor VIII.
*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.[9]

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References: 1. Jivi Prescribing Information. August 2018. Bayer. **2.** Reding MT et al. J Thromb Haemost 2017;15:411-419 **3.** Data on file. CSR 13024-A. Bayer; 2018. **4.** Data on file. CSR PH 40454. BAY 94-9027/13024. **5.** Enviza, Cerner. HEM-POWR Fourth Interim Analysis results. Final 1.0. Full analysis set (FAS). BAY 94-9027. **6.** Bayer Data on File, May 2023. Post-Authorization Safety Study (PASS) Third Interim Analysis Report: RD-SOP-1216. **7.** Enviza, Cerner. HEM-POWR Fourth Interim Analysis results. Final 1.0. Safety analysis set (SAF). BAY 94-9027. **8.** Data on file. Tx Review 0918. Bayer; 2018. **9.** 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. **10.** Reding M, et al. Haemophilia. 2021; 10.1111/hae.14297.

For additional important risk and use information, please see the 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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