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Perioperative Management with Efanesoctocog Alfa in Adults, Adolescents, and Children with Severe Hemophilia A in the Phase 3 XTEND Clinical Program

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Presentation Learning Objectives

At the conclusion of this presentation, participants will be able to:

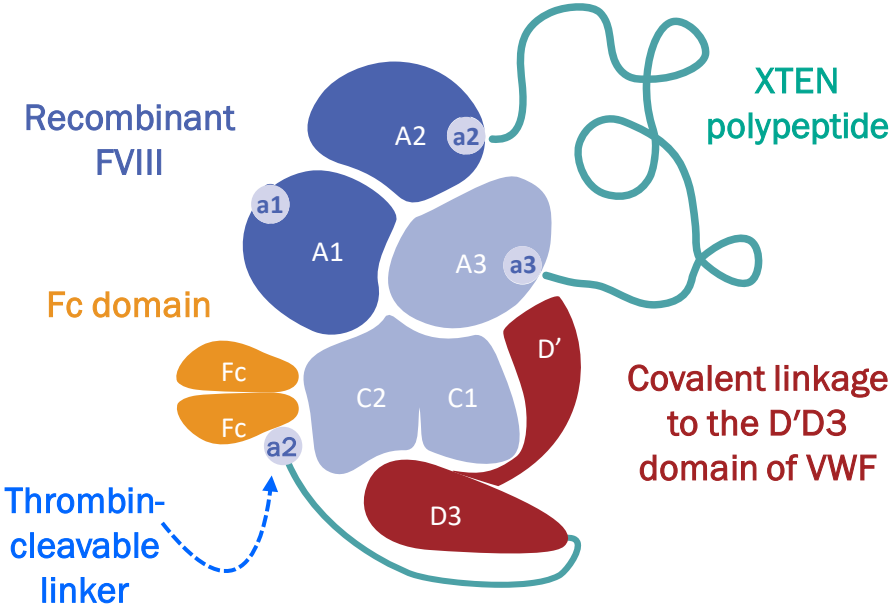
- Understand that **a single preoperative dose of efanesoctocog alfa (50 IU/kg) maintained hemostasis during major surgeries**, and that perioperative management with efanesoctocog alfa was effective and well-tolerated in adults, adolescents, and children with severe hemophilia A
- Recognize **efanesoctocog alfa** as a first-in-class, high-sustained factor VIII (HSF) replacement therapy for the treatment of hemophilia A

Efanesoctocog Alfa is a First-in-Class High-Sustained FVIII Replacement Therapy Designed to Provide Higher FVIII Activity Levels for Longer

Efanesoctocog alfa is a novel fusion protein that **overcomes the VWF-imposed half-life ceiling**[1,2]

During XTEND-1 (NCT04161495) and XTEND-Kids (NCT04759131), once-weekly efanesoctocog alfa 50 IU/kg prophylaxis provided **highly effective bleed protection** through **high-sustained factor levels** in the **normal to near-normal range** (>40%) for ~4 days in adults and adolescents and for ~3 days in children[3,4]

Efanesoctocog alfa was **efficacious** for **perioperative management across all age groups**[5,6]



FVIII, factor VIII; VWF, von Willebrand factor.

1. Chhabra ES, et al. *Blood*. 2020;135(17):1484-1496. 2. Konkle BA, et al. *N Engl J Med*. 2020;383(11):1018-1027. 3. von Drygalski A, et al. *N Engl J Med*. 2023;388(4):310-318. 4. Malec L, et al. ISTH 2023. LB Oral. 5. Klamroth R, et al. EAHAD 2023; Poster presentation PO122. 6. Chan A, et al. EAHAD 2024; Poster presentation PO050.

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Aim

Evaluate efficacy and safety of efanesoctocog alfa for perioperative management during XTEND Phase 3 clinical studies

Data cutoff: January 17, 2023.
XTEND-1: NCT04161495; XTEND-Kids: NCT04759131; XTEND-ed: NCT04644575.

Surgery in the XTEND Clinical Development Program

- Previously treated participants with severe hemophilia A (<1 IU/dL endogenous FVIII)
- Enrolled in the XTEND clinical program (XTEND-1, XTEND-Kids, and/or XTEND-ed)
- Data cutoff: January 17, 2023

- Participants undergoing surgery were to receive a preoperative loading dose of efanesoctocog alfa 50 IU/kg
- For major surgeries, postoperative doses of 30 or 50 IU/kg every 2–3 days were allowed

Surgery endpoints

- Number of injections and perioperative dose to maintain hemostasis
- Assessment of hemostatic response
- Efanesoctocog alfa consumption
- Blood loss
- Number and type of blood transfusions

FVIII, factor VIII.

Participant Demographics and Baseline Characteristics

Major surgeries

- **41 participants** underwent **49 major surgeries**
  - 9 were <18 years old

Minor surgeries

- **28 participants** underwent **32 minor surgeries**
  - 13 were <18 years old

	Participants with major surgeries (n=41)	Participants with minor surgeries (n=28)	Overall (N=63)[a]
Sex, n (%)			
Male	41 (100)	28 (100)	63 (100)
Age, years			
Mean (SD)	35.7 (18.0)	31.9 (25.0)	32.7 (20.3)
Median (range)	37.0 (3.0–72.0)	33.5 (1.4–72.0)	37.0 (1.4–72.0)
Age group, years, n (%)			
<12 years	3 (7.3)	10 (35.7)	12 (19.1)
12–17 years	6 (14.6)	3 (10.7)	9 (14.3)
18–64 years	31 (75.6)	13 (46.4)	40 (63.5)
≥65 years	1 (2.4)	2 (7.1)	2 (3.2)
Race, n (%)			
White	23 (56.1)	20 (71.4)	39 (61.9)
Black or African American	1 (2.4)	3 (10.7)	4 (6.4)
Asian	12 (29.3)	2 (7.1)	13 (20.6)
Not reported	5 (12.2)	3 (10.7)	7 (11.1)
Weight, kg			
Mean (SD)	69.6 (20.3)	59.2 (31.5)	65.6 (25.9)
Median (range)	71.7 (16.1–113.4)	63.7 (11.4–105.0)	69.2 (11.4–113.4)

Data cutoff: January 17, 2023.
[a]Six patients had both major and minor surgeries.
N, number of patients; SD, standard deviation.

Participant Demographics and Baseline Characteristics

Major surgeries

- **41 participants** underwent **49 major surgeries**
  - 9 were <18 years old
  - 32 were ≥18 years old

Minor surgeries

- **28 participants** underwent **32 minor surgeries**
  - 13 were <18 years old
  - 15 were ≥18 years old

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Major Surgeries[a]: Types of Orthopedic Surgeries Performed

Orthopedic surgeries (n=23)			
	Adults (≥18 years of age)	Children and adolescents (<18 years)	N procedures (N participants)
Unilateral knee arthroplasty	9 (8)	-	9 (8)
Unilateral elbow arthroplasty	3 (3)	-	3 (3)
Unilateral knee arthroplasty revision	1 (1)	-	1 (1)
Unilateral knee arthroplasty and cyst removal	1 (1)	-	1 (1)
Knee arthroscopy with cartilage repair, synovectomy and removal of loose body	1 (1)	-	1 (1)
Removal of implanted device from bone, left elbow	-	1 (1)	1 (1)
Unilateral hip and knee arthroplasty	1 (1)	-	1 (1)
Unilateral hip arthroplasty	1 (1)	-	1 (1)
Removal of osteosynthesis material/ankle fusion	1 (1)	-	1 (1)
Plate osteosynthesis	1 (1)	-	1 (1)
Unilateral ankle arthroplasty	1 (1)	-	1 (1)
Unilateral intramedullary nailing of tibia, right tibial coricotomy	1 (1)	-	1 (1)
Unilateral revision hip	1 (1)	-	1 (1)

The most common major orthopedic surgery was knee arthroplasty

Data cutoff: January 17, 2023.

[a]Surgeries were considered major if they were an invasive procedure that required opening a major body cavity, operating on a joint, removing an organ, dental extraction of any molar teeth or ≥3 non-molar teeth, alteration of normal anatomy, or crossing mesenchymal barriers.

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Major Surgeries[a]: Types of Non-Orthopedic Surgeries Performed

Non-orthopedic surgeries[a] (n=26)			
	Adults (≥18 years of age)	Children and adolescents (<18 years)	N procedures (N participants)
Molar tooth extraction	12 (11)	3 (3)	15 (14)
Circumcision	-	1 (1)	1 (1)
Cubital tunnel release and ulnar nerve transposition	1 (1)	-	1 (1)
Dental restorations and non-molar tooth extraction	-	1 (1)	1 (1)
Incision, drainage, and radical resection of perianal abscess	1 (1)	-	1 (1)
Laparoscopic abdomen hernia repair	1 (1)	-	1 (1)
Neurolysis of right ulnar nerve	1 (1)	-	1 (1)
Port-a-catheter replacement	-	1 (1)	1 (1)
Rhinoplasty and mentoplasty	1 (1)	-	1 (1)
Septoplasty and turbinoplasty	1 (1)	-	1 (1)
Spinal decompression and fixation	1 (1)	-	1 (1)
Vascular malformation resection	-	1 (1)	1 (1)

The most common non-orthopedic major surgery was molar tooth extraction

Data cutoff: January 17, 2023.

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Major Surgeries: Dosing Frequency and Consumption were Low

A **single preoperative 50 IU/kg dose** of efanesoctocog alfa **maintained hemostasis during surgery**

Median (range) **total number of doses per major surgery** was **4.0 (1–7) during the perioperative period** (Days −1 to 14)

Median (range) **FVIII consumption** was **162.5 (45.4–360.6) IU/kg during the perioperative period** (Days −1 to 14)

Number of doses and efanesoctocog alfa consumption

	Overall pooled major surgeries (N=49)[a]
Number of doses to maintain hemostasis during major surgery, median (range)	1.0 (1–2)
Number of doses per major surgery, median (range)[b-d]	
Day −1 to 0 (n=45)	1.0 (1–2)[e]
Day 1 to 3 (n=30)	1.0 (1–2)
Day 4 to 14 (n=47)	2.0 (1–4)
Day −1 to 14 (perioperative period) (n=49)	4.0 (1–7)
Consumption (IU/kg), median (range)[c,d,f]	
Day −1 to 0 (n=45)	50.0 (12.7–84.7)
Day 1 to 3 (n=30)	32.7 (24.3–103.0)
Day 4 to 14 (n=47)	103.3 (48.0–206.1)
Day −1 to 14 (perioperative period) (n=49)	162.5 (45.4–360.6)

Data cutoff: January 17, 2023.
FVIII, factor VIII.
[a]Analyses are based on major surgeries during the treatment period, excluding any surgery conducted after the last dose of efanesoctocog alfa. [b]Efanesoctocog alfa injections are summarized over all injections during the referenced time interval in the surgical/rehabilitation period. [c]Day 0 is defined as the surgery day; the loading dose for a surgery is the preoperative injection, administered either on the day of surgery or 1 day prior to the surgery (Day −1). [d]n is number of surgeries having surgical injections within the related interval. [e]One participant who underwent knee arthroplasty revision had 2 doses on the day of surgery, one preoperative and one postoperative. [f]Total efanesoctocog alfa consumption is summarized over all injections during the referenced time interval in the surgical/rehabilitation period.

Major Surgeries: Nearly All Surgeries Were Rated Excellent/Good

Hemostatic response[a]:

88% of surgeries (43/49) had a hemostatic response of **excellent**

- Excellent/Good: 98% (48/49)
- Fair: 2% (1/49)
- Poor: 0% (0/49)

For the 29 surgeries with data, **median (range) estimated blood loss during surgery** was **20 (0–1000) mL[b]**

For the 36 surgeries with data, **median (range) estimated blood loss postoperatively[c]** was **0 (0–660) mL**

Overall, **98% of surgeries (48/49) did not require blood transfusion**

- One participant who underwent total knee replacement with a hemostatic response rated "good" had blood loss of 250 mL during surgery and 660 mL postoperatively and received a 500 mL red blood cell transfusion

Data cutoff: January 17, 2023.
[a]Surgeon's/investigator's assessment of hemostatic response based on the International Society on Thrombosis and Haemostasis 4-point response for surgical procedures scale (excellent, good, fair, and poor). [b]Surgery with 1000 mL blood loss was knee implantation (total endoprosthesis). [c]Postoperative period refers to the day following the end of surgery to the date of hospital discharge.

Minor Surgeries: Types of Surgeries Performed

A total of **32 minor surgeries** were performed

Most common surgeries were dental procedures (n=12) or related to port-a-catheters (n=6)

	Adults (≥18 years)	Children and adolescents (<18 years)	N procedures (N participants)
Non-molar tooth extraction	2 (2)	3 (3)	5 (5)
Dental implant	4 (3)	-	4 (3)
Root canal treatment	3 (3)	-	3 (3)
Port-a-catheter removal	-	3 (3)	3 (3)
Port-a-catheter replacement	-	3 (3)	3 (3)
Cataract surgery	2 (1)	-	2 (1)
Gastroscopy with biopsy	-	2 (2)	2 (2)
Gastroscopy	-	1 (1)	1 (1)
Endoscopy with biopsy, colonoscopy	1 (1)		1 (1)
Colonoscopy with biopsy	1 (1)	-	1 (1)
Colonoscopy	1 (1)	-	1 (1)
Colonoscopy with polypectomy	1 (1)	-	1 (1)
Basal cell carcinoma excision	1 (1)	-	1 (1)
Cecostomy tube change	-	1 (1)	1 (1)
Port-a-catheter revision	-	1 (1)	1 (1)
Reposition of chin prosthesis	1 (1)	-	1 (1)
Unilateral elbow manipulation under anesthesia	1 (1)	-	1 (1)

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Gastroscopy	-	1 (1)	1 (1)
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Unilateral elbow manipulation under anesthesia	1 (1)	-	1 (1)

Data cutoff: January 17, 2023.

Minor Surgeries: Dosing and Consumption

Median (range) number of **doses per minor surgery** was **2.0 (1–6) during Days −1 to 7**

Median (range) **FVIII consumption** was **102.2 (48.1–199.2) during Days −1 to 7**

Number of doses and FVIII consumption for minor surgeries	
	Overall pooled minor surgeries (N=32)[a]
Number of doses to maintain hemostasis during minor surgery, median (range)	1.0 (1–1)
Number of doses per minor surgery, median (range)[b-d]	
Day −1 to 0 (n=27)	1.0 (1–1)
Day 1 to 3 (n=8)	1.0 (1–2)
Day 4 to 7 (n=21)	1.0 (1–3)
Day −1 to 7 (n=31)	2.0 (1–6)
Consumption (IU/kg), median (range)[c,d,e]	
Day −1 to 0 (n=27)	51.3 (32.6–58.8)
Day 1 to 3 (n=8)	50.3 (29.1–68.9)
Day 4 to 7 (n=20)	52.1 (50.0–78.6)
Day −1 to 7 (n=31)	102.2 (48.1–199.2)

Data cutoff: January 17, 2023.
FVIII, factor VIII.
[a]Analyses are based on minor surgeries during the treatment period, excluding any surgery conducted after the last dose of efanesoctocog alfa. [b]Efanesoctocog alfa injections are summarized over all injections during the referenced time interval in the surgical/rehabilitation period. [c]Day 0 is defined as the surgery day; the loading dose for a surgery is the preoperative injection, administered either on the day of surgery or 1 day prior to the surgery (Day −1). [d]n is number of surgeries having surgical injections within the related interval. [e]Total efanesoctocog alfa consumption is summarized over all injections during the referenced time interval in the surgical/rehabilitation period.

Minor Surgeries: All Hemostatic Responses Were Rated Excellent

All 25 minor surgeries with an assessment had an **excellent hemostatic response**[a]

For the 18 surgeries with data, median (range) estimated blood loss **during surgery** was **0 (0–15) mL**

No patients with minor surgeries required a blood transfusion

For the 25 surgeries with data, median (range) estimated blood loss **postoperatively**[b] was **0 (0–5) mL**

Data cutoff: January 17, 2023.
[a]Surgeon's/investigator's assessment of hemostatic response based on the International Society on Thrombosis and Haemostasis 4-point response for surgical procedures scale (excellent, good, fair, and poor). [b]Postoperative period refers to the day following the end of surgery to the date of hospital discharge.

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Conclusions

A total of 49 major and 32 minor surgeries have been safely performed with efanesoctocog alfa in the XTEND clinical development program across patients of all ages

A single preoperative dose (50 IU/kg) maintained hemostasis during major surgeries

Efanesoctocog alfa consumption for major surgeries was low (median consumption for the perioperative period: 162.5 IU/kg) and comparable to the consumption during routine efanesoctocog alfa prophylaxis

Hemostatic response to efanesoctocog alfa was rated as excellent for most (88%) major surgeries and all minor surgeries

Efanesoctocog alfa was effective and well tolerated for the perioperative management of adults, adolescents, and children who underwent both major and minor surgeries during the XTEND clinical development program

FVIII, factor VIII.

Thank you

to the study participants, their families,
and the study investigators