ALTUVIIIO®
Antihemophilic Factor (Recombinant), Fc-VWF-XTEN Fusion Protein-ehtl

Factor VIII levels at 42%, 4 days after infusion

Hypothetical patient and scenario

A first-in-class, once-weekly infusion

FACTOR UP WITH ALTUVIIIO®

SWITCH IT UP

Higher-for-longer factor levels in the near-normal to normal range (over 40%) for most of the week in adults

INDICATION

ALTUVIIIO® [antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl] is an injectable medicine that is used to control and reduce the number of bleeding episodes in people with hemophilia A (congenital Factor VIII deficiency).

Your healthcare provider may give you ALTUVIIIO when you have surgery.

SELECT IMPORTANT SAFETY INFORMATION

Who should not use ALTUVIIIO?

You should not use ALTUVIIIO if you have had an allergic reaction to it in the past.

Please see full Prescribing Information.

Getting to know ALTUVIIIO®

A once-weekly, first-in-class Factor VIII replacement therapy

ALTUVIIIO is a true factor replacement therapy:

- Proven to keep factor levels in the near-normal to normal range **(over 40%)** for most of the week, and stays **above 18%*** on average in adults
- With a **longer half-life** than other Factor VIII treatments

3-4x

Longer half-life in adults, in a separate study with EHL and SHL therapies.†

*Average trough levels were 18% for adults 18 years and older, 9% for adolescents aged 12 years to under 18 years, 17% for children aged 6 years to under 12 years, and 11% for children aged 1 year to under 6 years.

†This is information from a study that had the goal of comparing how long ALTUVIIIO, Adynovate® [Antihemophilic Factor (Recombinant), PEGylated], and Advate® [Antihemophilic Factor (Recombinant)] stayed in the body after 1 dose. Half-life was 43 hours for ALTUVIIIO, 15 hours for Adynovate, and 11 hours for Advate.

Adynovate and Advate are registered trademarks of Baxalta Incorporated, a Takeda company.

EHL=extended half-life; SHL=standard half-life.

IMPORTANT SAFETY INFORMATION (CONT'D)

What is the most important information I need to know about ALTUVIIIO?

Do not attempt to give yourself an injection unless you have been taught how by your healthcare provider or hemophilia center. You must carefully follow your healthcare provider's instructions regarding the dose and schedule for injecting ALTUVIIIO so that your treatment will work best for you.

Please see full Prescribing Information.

ALTUVIIIO is engineered to last longer

ALTUVIIIO uniquely combines 3 components to help it stay in your body longer

Fc Fusion—helps Factor VIII recirculate in your blood

XTEN Technology—shields Factor VIII from breaking down too early

vWF Fragments—keep Factor VIII in your blood for longer

vWF=von Willebrand Factor.

IMPORTANT SAFETY INFORMATION (CONT'D)

What should I tell my healthcare provider before using ALTUVIIIO?

Tell your healthcare provider if you have had any medical problems, take any medications, including prescription and non-prescription medicines, supplements, or herbal medicines, are breastfeeding, or are pregnant or planning to become pregnant.

Please see full Prescribing Information.

ALTUVIIIO®
Antihemophilic Factor (Recombinant), Fc-VWF-XTEN Fusion Protein-ehtl

Proven bleed protection with ALTUVIIIO® prophylaxis

ALTUVIIIO was studied in XTEND-1, a clinical trial of **159 adults and adolescents** with severe hemophilia A across multiple study groups.*

IN 128 PEOPLE TAKING ALTUVIIIO PROPHYLAXIS FOR 52 WEEKS

0 **Median bleeds per year†**
(median annualized bleed rate)‡

0.7 **Mean bleeds per year†**
(mean annualized bleed rate)‡
PRIMARY OUTCOME

ALTUVIIIO was studied in the XTEND-Kids study. The primary goal of the study was to determine whether or not children under 12 years of age developed inhibitors to ALTUVIIIO. Zero inhibitors were detected. Routine prophylaxis with ALTUVIIIO resulted in a mean ABR of 0.6 and a median ABR of 0.†§

*The XTEND-1 study broke patients into 2 different treatment groups: Group 1 (133 people aged 12 years and older) switched from prior prophylaxis therapy to ALTUVIIIO for 52 weeks. Efficacy of prophylaxis was studied in 128 of these patients. Group 2 (26 people aged 12 years and older) switched from prior on-demand therapy to on demand with ALTUVIIIO and later switched to ALTUVIIIO prophylaxis.

†Data based on treated bleeds, N=45.

‡The median is the middle number of all study participants' ABRs, when everyone's ABR is ordered from least to greatest; the mean is the average of all study participants' ABRs.

§XTEND-Kids enrolled 74 previously treated male patients aged 1 to <12 years of age with severe hemophilia A. Efficacy of prophylaxis was evaluated in 72 of these patients.

IMPORTANT SAFETY INFORMATION (CONT'D)

What are the possible side effects of ALTUVIIIO?

You can have an allergic reaction to ALTUVIIIO.

Please see full Prescribing Information.

Significant improvement in bleed protection with ALTUVIIIO prophylaxis

In Group 1, 133 people aged 12 years and older had **prior prophylaxis therapy** and switched to ALTUVIIIO. 78 of those people participated in a separate study to measure their ABRs on their prior prophylaxis.

Comparing the results of the 78 people who participated in both studies showed:

ON AVERAGE

People went from
3 BLEEDS
(mean ABR 3.0)

TO LESS THAN 1 BLEED A YEAR
(mean ABR 0.7)

That's a
77% REDUCTION IN YEARLY BLEEDS (MEAN)†

AND

Over 52 weeks on ALTUVIIIO prophylaxis
64% OF PEOPLE HAD ZERO BLEEDS†
vs 42% on prior prophylaxis

Improvement in joint health

PEOPLE WITH TARGET JOINTS AT THE START OF THE XTEND-1 STUDY EXPERIENCED:

100% TARGET JOINT RESOLUTION†

Target joints are 3 or more spontaneous bleeds in a major joint in a consecutive 6-month period.

Target joints were considered resolved if 2 or fewer bleeds occurred in the target joint in 12 months.

ABR=annualized bleed rate.

IMPORTANT SAFETY INFORMATION (CONT'D)

What are the possible side effects of ALTUVIIIO? (cont'd)

Call your healthcare provider or emergency department right away if you have any of the following symptoms: difficulty breathing, chest tightness, swelling of the face, rash, or hives.

Please see full Prescribing Information.

Factor Up with an established safety profile

In XTEND-1 and XTEND-Kids, people taking ALTUVIIIO® had zero inhibitors and zero serious allergic reactions

Although no inhibitors were found, and no serious allergic reactions occurred in clinical studies, inhibitors and serious allergic reactions are possible with ALTUVIIIO.

In 233 people across the clinical studies*:

- **15%** experienced headache (35 people)
- **13%** experienced joint pain (31 people)
- **4%** experienced fever (10 people)
- **4%** experienced pain in extremities (10 people)
- **4%** experienced back pain (9 people)
- **3%** experienced vomiting (7 people)

*Included participants of the XTEND-1 and XTEND-Kids studies.

Stay connected

CONTACT YOUR CoRe TODAY

Sanofi Hemophilia Community Relations and Education (CoRe) Managers provide information about ALTUVIIIO, living with hemophilia, and treatment options.

Sign up to connect and learn more!

We are committed to finding a way to help. Sanofi offers a variety of resources and financial support available to eligible patients.

QUESTIONS? CALL 1-855-MyALTUVIIIO, MONDAY THROUGH FRIDAY, 8AM TO 8PM ET

Please see full Prescribing Information.

Factor VIII levels at 42%, 4 days after infusion

Hypothetical patient and scenario

ALTUVIIIO®
Antihemophilic Factor (Recombinant), Fc-VWF-XTEN Fusion Protein-ehtl

Factor Up with ALTUVIIIO®

HIGH SUSTAINED FACTOR VIII LEVELS
Above 40% (near-normal to normal range) for most of the week in adults and for ~3 days in kids.*

48

HOUR HALF-LIFE IN ADULTS
ALTUVIIIO offers the longest half-life of any Factor VIII therapy across all age groups.†

0.7

BLEEDS PER YEAR‡
Mean ABR observed in 128 people previously treated with prophylaxis therapy.§

In adults and adolescents taking ALTUVIIIO in the XTEND-1 study, 20.1% experienced headache and 16.4% experienced joint pain. In children under 12 taking ALTUVIIIO in the XTEND-Kids study, 12.2% experienced fever.

SWITCH IT UP | Visit **ALTUVIIIO.com** to sign up and receive additional information.

*Average trough levels were 18% for adults 18 years and older, 9% for adolescents aged 12 years to under 18 years, 17% for children aged 6 years to under 12 years, and 11% for children aged 1 year to under 6 years.
†The half-life was 44.6 hours for adolescents aged 12 years to under 18 years, 42.4 hours for children aged 6 to under 12 years, and 38 hours for children aged 1 year to under 6 years.
‡Data based on treated bleeds.
§159 adults and adolescents with severe hemophilia (aged 12 years and older) were enrolled in the XTEND-1 study; 133 people were in Group 1 and switched to ALTUVIIIO prophylaxis from prior prophylaxis therapy. Efficacy of prophylaxis was evaluated in 128 of these patients. 74 previously treated male children under 12 who switched to ALTUVIIIO were studied over 1 year in the XTEND-Kids study. Efficacy was evaluated in 72 of these children.

IMPORTANT SAFETY INFORMATION (CONT'D)

What are the possible side effects of ALTUVIIIO? (cont'd)

Your body can also make antibodies called "inhibitors" against ALTUVIIIO. This can stop ALTUVIIIO from working properly. Your healthcare provider may give you blood tests to check for inhibitors.

The common side effects of ALTUVIIIO are headache and joint pain.

These are not the only possible side effects of ALTUVIIIO. Tell your healthcare provider about any side effect that bothers you or does not go away.

Please see full Prescribing Information.

sanofi

MAT-US-2209832-v3.0-05/2024