# FREEDOM OF CHOICE™
# Free Trial Program Enrollment Form

Adult patients with von Willebrand disease may be eligible to receive 8 free trial doses of VONVENDI® for prophylaxis use in patients with severe Type 3 von Willebrand disease receiving on-demand therapy or 3 free trial doses of VONVENDI for on-demand or surgery treatment with or without ADVATE® [Antihemophilic Factor (Recombinant)]

vonvendi
[von Willebrand factor (Recombinant)]

Fax document to: **1-866-467-7740**

**INSTRUCTIONS:**

1. Review Program Terms and confirm Eligibility criteria below.
2. Healthcare prescriber and patient to complete the enrollment form.
3. Healthcare prescriber and patient to sign the authorization and release. If patient is unable to sign this form prior to submission, Takeda will contact patient to obtain signature.
4. Fax completed form to Takeda at 1-866-467-7740.
5. Takeda will contact healthcare prescriber or patient to coordinate shipment of trial doses.

## PATIENT INFORMATION

Patient Name _____ Gender ☐ M ☐ F

☐ I certify I am 18 years of age or older Date of Birth (MM/DD/YYYY) _____ ☐ I certify I am new to VONVENDI

Address _____ Apt/Unit # _____

City _____ State _____ ZIP _____ Telephone _____

Email _____ Primary Language _____

Patient Guardian Name (if applicable) _____

Address _____ Apt/Unit # _____

City _____ State _____ ZIP _____ Telephone _____

Email _____ Primary Language _____

## PATIENT AUTHORIZATION AND RELEASE

If patient is unable to sign this form prior to submission, Takeda will contact patient to obtain signature.

I authorize any health plan, physician, healthcare professional, hospital, clinic, pharmacy provider, or other healthcare provider (collectively, "Providers") to disclose my (or Patient's) protected health information, including personal information relating to my medical condition, treatment, care management, and health insurance, as well as all information provided on this form and any prescription ("Information"), to Takeda Pharmaceutical Company Limited ("Takeda"). I understand Takeda may provide this Information to its affiliates and their representatives, agents, and contractors, as well as to a specialty pharmacy, for the purpose of facilitating my (or Patient's) participation in the Freedom of Choice free trial program. This Information may also be used for internal uses by Takeda, including data analysis.

**Patient Signature** _____ **Date** _____

**Patient Guardian Signature (if applicable)** _____ **Date** _____

## PATIENT CONSENT FOR FUTURE INFORMATION (OPTIONAL)

☐ By checking this box, I authorize the use of my Information for Takeda marketing activities and consent to receiving marketing and promotional communications from Takeda. I hereby give consent to Takeda, its affiliates, and their agents and representatives to send communications and information to me via the contact information I have provided to Takeda. I understand that this consent will be in effect until such time as I cancel such authorization.

**Please see pages 3-4 for VONVENDI and ADVATE Indications and Detailed Important Risk Information.**
**Please see VONVENDI full Prescribing Information, and please click here for ADVATE full Prescribing Information.**

Takeda

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## HEALTHCARE PRESCRIBER INFORMATION

**The following sections must be completed by the healthcare prescriber. When shipping to prescriber's office, product(s) must be addressed to the prescriber. Be sure to print all information, and sign before submitting.**

Healthcare Prescriber Name _____ Specialty _____

Facility or Healthcare Prescriber's Tax ID # _____ NPI # _____

Institution Name _____ Office Contact _____

Office Address _____ Unit # _____

City _____ State _____ ZIP _____

Direct Office Telephone _____ Email _____

ICD-10 Diagnosis Code _____ Is the patient new to VONVENDI? ☐ Yes ☐ No

Your Takeda Representative _____

Please fill out the prescription information below for VONVENDI and ADVATE, if needed, to be provided as a part of this FREEDOM OF CHOICE program.
**Ensure all dosing requirements are included.**

Patient Name _____

Address _____ Date of Birth (MM/DD/YYYY) _____

Does patient have any known allergies to ingredients in rVWF or rFVIII products? ☐ Yes ☐ No

I am prescribing VONVENDI trial doses for (check one):

☐ Prophylaxis use to treat severe Type 3 VWD patients receiving on-demand therapy (8 doses)

☐ On-demand or surgery use (3 doses)
- ☐ With rFVIII ☐ Without rFVIII
- Are you prescribing ADVATE* as the rFVIII? ☐ Yes (2 doses) ☐ No
- Type of VWD: ☐ Type 1 ☐ Type 2 ☐ Type 3
- Severity of VWD: ☐ Mild ☐ Moderate ☐ Severe

Patient Weight (kg) _____ VONVENDI Dosage (IU VWF:RCo required) _____

ADVATE Dosage (if requested) (IU) _____

Use as directed by physician.
*ADVATE alone is not indicated for the treatment of von Willebrand disease.

## HEALTHCARE PRESCRIBER AUTHORIZATION AND RELEASE (REQUIRED)

By signing this form, I certify that therapy with VONVENDI and ADVATE (as selected above) is medically necessary for the patient identified in this enrollment form ("Patient"). I have reviewed the current VONVENDI and ADVATE Prescribing Information and will be supervising Patient's treatment. I have received from Patient, or his/her personal representative, the necessary authorization to release, in accordance with applicable federal and state law regulations, referenced medical and/or other patient information relating to VONVENDI and ADVATE therapy to Takeda Pharmaceutical Company Limited, including its agents, representatives, or contractors (collectively, "Takeda"), and to the specialty pharmacy, for the purposes of enrolling the patient in the Freedom of Choice free trial program ("Program").

I certify that free trial product provided through the Program will not be exported or transferred in exchange for money, other property, or services. I further certify that no portion of the free trial will be used for reimbursement purposes, including from Medicare, Medicaid, or any third-party program that provides cost- or charge-based reimbursement to the participating institution, either directly or indirectly.

**Healthcare Prescriber Signature** _____ **Date** _____

**For more information, call Takeda at 1-888-229-8379.**

## ALTERNATIVE SHIPPING LOCATION (OPTIONAL)

Product(s) will be shipped to healthcare prescriber's office. Complete this section only if the shipping preference is to Patient's address.

Name _____ Address _____ Apt/Unit # _____

City _____ State _____ ZIP _____ Telephone _____

Email _____

Depending on the selected indication, the shipment of VONVENDI will include 8 doses for prophylaxis use -**or**- 3 doses for on-demand or surgery treatment. Each dose of VONVENDI is packaged with Sterile Water for Injection (sWFI), one MIX2VIAL® reconstitution device, one full prescribing physician insert, and one patient insert.

If requested, 2 doses of ADVATE will be shipped separately. ADVATE is available as a lyophilized powder in single-use vials containing nominally 250, 500, 1000, 1500, 2000, 3000, or 4000 International Units (IU) per vial. The 250-1500 IU strengths come with 2 mL sWFI; the 2000-4000 IU strengths come with 5 mL of sWFI.

**Please see pages 3-4 for VONVENDI and ADVATE Indications and Detailed Important Risk Information.**
**Please see VONVENDI full Prescribing Information, and please click here for ADVATE full Prescribing Information.**



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## PROGRAM TERMS AND ELIGIBILITY

To be eligible, patients must be ≥18 years with a valid prescription and have a confirmed diagnosis of von Willebrand disease.

**TERMS AND CONDITIONS:**

1. This free trial offer is solely intended to allow new patients to try VONVENDI® [von Willebrand factor (Recombinant)] with or without ADVATE® [Antihemophilic Factor (Recombinant)] if clinically necessary, and to determine with their healthcare provider whether VONVENDI is right for them. There is no obligation to continue use of VONVENDI after the free trial has been completed.
2. This free trial prescription is valid for one time only with no refills. For any future use, the patient must obtain a new prescription for VONVENDI with or without rFVIII.
3. Free trial of VONVENDI with or without rFVIII may only be delivered to the patient's home or to the healthcare prescriber's address listed on this enrollment form (no PO boxes).
4. Free trial of VONVENDI with or without rFVIII cannot be exported or transferred in exchange for money, other property, or services.
5. No portion of this free trial may be submitted for reimbursement to any third-party payer, including Medicare or Medicaid, either directly or indirectly.
6. This program is valid only for residents of the United States.
7. Takeda reserves the right to change or discontinue this program at any time without notice.
8. This is not a financial assistance or cost-savings program.
9. Initiation of this free trial program requires certain processing time. It is not intended to provide Factor product(s) to address an active or ongoing bleed at the time of enrollment.

## VONVENDI [VON WILLEBRAND FACTOR (RECOMBINANT)] IMPORTANT INFORMATION

### Indications

VONVENDI [von Willebrand factor (recombinant)] is a recombinant von Willebrand factor (rVWF) indicated for use in adults (age 18 and older) diagnosed with von Willebrand disease (VWD) for:

- On-demand treatment and control of bleeding episodes
- Perioperative management of bleeding
- Routine prophylaxis to reduce the frequency of bleeding episodes in patients with severe Type 3 von Willebrand disease receiving on-demand therapy

### Detailed Important Risk Information

#### CONTRAINDICATIONS

Do not use in patients who have had life-threatening hypersensitivity reactions to VONVENDI or its components (tri-sodium citrate-dihydrate, glycine, mannitol, trehalose-dihydrate, polysorbate 80, and hamster or mouse proteins).

#### WARNINGS AND PRECAUTIONS

**Embolism and Thrombosis**

Thromboembolic reactions, including disseminated intravascular coagulation, venous thrombosis, pulmonary embolism, myocardial infarction, and stroke can occur, particularly in patients with known risk factors for thrombosis, including low ADAMTS13 levels. Monitor for early signs and symptoms of thrombosis such as pain, swelling, discoloration, dyspnea, cough, hemoptysis, and syncope, and institute prophylaxis measures against thromboembolism based on current recommendations.

In patients requiring frequent doses of VONVENDI in combination with recombinant factor VIII, monitor plasma levels for FVIII:C activity because sustained excessive factor VIII plasma levels can increase the risk of thromboembolic events.

One out of 100 subjects treated with VONVENDI in clinical trials developed proximal deep vein thrombosis in perioperative period after total hip replacement surgery.

**Hypersensitivity Reactions**

Hypersensitivity reactions have occurred with VONVENDI. These reactions can include anaphylactic shock, generalized urticaria, angioedema, chest tightness, hypotension, shock, lethargy, nausea, vomiting, paresthesia, pruritus, restlessness, blurred vision, wheezing and/or acute respiratory distress. Discontinue VONVENDI if hypersensitivity symptoms occur and administer appropriate emergency treatment.

**Neutralizing Antibodies (Inhibitors)**

Inhibitors to VWF and/or factor VIII can occur. If the expected plasma levels of VWF activity (VWF:RCo) are not attained, perform an appropriate assay to determine if anti-VWF or anti-factor VIII inhibitors are present. Consider other therapeutic options and direct the patient to a physician with experience in the care of either VWD or hemophilia A.

In patients with high levels of inhibitors to VWF or factor VIII, VONVENDI therapy may not be effective and infusion of this protein may lead to severe hypersensitivity reactions. Since inhibitor antibodies can occur concomitantly with anaphylactic reactions, evaluate patients experiencing an anaphylactic reaction for the presence of inhibitors.

#### ADVERSE REACTIONS

In clinical trials, the most common adverse reactions observed in ≥2% of subjects (n=100) were headache, vomiting, nausea, dizziness, arthralgia, joint injury, vertigo, ALT increased and generalized pruritus.

One subject treated with VONVENDI in perioperative setting developed deep vein thrombosis after total hip replacement surgery.

**Please see VONVENDI full Prescribing Information.**

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vonvendi
[von Willebrand factor (Recombinant)]

## ADVATE® [ANTIHEMOPHILIC FACTOR (RECOMBINANT)] IMPORTANT INFORMATION

### Indications

ADVATE is a recombinant antihemophilic factor indicated for use in children and adults with hemophilia A (congenital factor VIII deficiency) for:

- Control and prevention of bleeding episodes.
- Perioperative management.
- Routine prophylaxis to prevent or reduce the frequency of bleeding episodes.

ADVATE is not indicated for the treatment of von Willebrand disease.

### Detailed Important Risk Information

### CONTRAINDICATIONS

Patients who have life-threatening hypersensitivity reactions, including anaphylaxis, to mouse or hamster protein or other constituents of the product.

### WARNINGS & PRECAUTIONS

**Hypersensitivity Reactions**

Allergic-type hypersensitivity reactions, including anaphylaxis, have been reported with ADVATE. Symptoms include dizziness, paresthesia, rash, flushing, facial swelling, urticaria, dyspnea, pruritus, and vomiting. Discontinue ADVATE if hypersensitivity symptoms occur and administer appropriate emergency treatment.

**Neutralizing Antibodies**

Neutralizing antibodies (inhibitors) have been reported following administration of ADVATE predominantly in previously untreated patients (PUPs) and previously minimally treated patients (MTPs). Monitor all patients for the development of factor VIII inhibitors by appropriate clinical observation and laboratory testing. If expected plasma factor VIII activity levels are not attained, or if bleeding is not controlled with an expected dose, perform an assay that measures factor VIII inhibitor concentration.

### ADVERSE REACTIONS

- Serious adverse reactions seen with ADVATE are hypersensitivity reactions, including anaphylaxis, and the development of high-titer inhibitors necessitating alternative treatments to factor VIII.
- The most common adverse reactions observed in clinical trials (>5% of subjects) were pyrexia, headache, cough, nasopharyngitis, arthralgia, vomiting, upper respiratory tract infection, limb injury, nasal congestion, and diarrhea.

**Please click here for ADVATE full Prescribing Information.**


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