JYNARQUE® (tolvaptan) REMS PATIENT ENROLLMENT FORM

Fax#: 1-866-750-6820

JYNARQUE is available only through the JYNARQUE REMS, a restricted distribution program. Only prescribers, pharmacies, and patients enrolled in the program can prescribe, dispense, and receive JYNARQUE. Your certified healthcare provider will help you complete this form and provide you with a copy. Fields marked * are required.

Prescribers and Patients: Please complete this form online at www.JYNARQUErems.com or once completed, fax it to the REMS at 1-866-750-6820.

**Indicates required field*

Patient Information

First Name*: _____ Middle Initial: _____ Last Name*: _____

Birthdate*: _____ Sex*: ☐ Male ☐ Female

Race*: ☐ White ☐ Black or African American ☐ American Indian or Alaska Native
☐ Asian ☐ Native Hawaiian or Other Pacific Islander ☐ Other, Specify _____

Ethnicity*: ☐ Hispanic or Latino ☐ Not Hispanic or Latino

Address Line 1*: _____

Address Line 2: _____

City*: _____ State*: _____ Zip code*: _____

Phone*: _____ Mobile Phone*: _____ Email*: _____

Medical History

The information in this section is only collected to help determine if there are reasons why some people have elevations in their liver function tests and others do not.

Alcohol Classification*: ☐ Never Drank ☐ Ex-Drinker (stopped drinking at least 1 month ago) ☐ Current Drinker

Typical Alcohol Consumption (required for Current Drinker):

- ☐ Occasional (drink alcohol less than once each week)
- ☐ Light (1-2 beers, 1-2 glasses of wine, or 1-2 liquor drinks each week)
- ☐ Moderate (3-7 beers, 3-7 glasses of wine, or 3-7 liquor drinks each week)
- ☐ Heavy (more than 7 beers, more than 7 glasses of wine, or more than 7 liquor drinks each week)

Previously Treated with Tolvaptan Prior to REMS Enrollment*: ☐ Yes ☐ No

If yes, how long did you take tolvaptan? _____ years _____ months _____ days

Was this part of a clinical trial? ☐ Yes ☐ No

If yes, please provide clinical trial number/patient ID: _____

Prescriber Information

First Name*: _____ Last Name*: _____

NPI No.*: _____

Practice/Facility Name (where you see this patient): Mayo Clinic

Address Line 1: 200 First Street SW

City: Rochester State: MN Zip code: 55905

Phone*: _____ Fax: (507) 284-9374 Email: _____

Prescriber Agreement

*Has the patient's liver function been assessed by evaluating ALT, AST, and bilirubin prior to enrolling this patient in the REMS?

☑ Yes ☐ No

If the answer is No, you must assess the patient's liver function by evaluating ALT, AST, and bilirubin prior to submitting this form to the REMS.

I have reviewed and discussed the risks of JYNARQUE and the requirements of the JYNARQUE REMS with this patient.

Prescriber Signature*: _____ Date*: _____

Healthcare Provider: Provide a copy of this form to the patient.

Phone: 1-866-244-9446 | www.JYNARQUErems.com | Fax: 1-866-750-6820

Healthcare providers must report cases of liver injury to the REMS Program Coordinating Center.

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Patient Agreement

Before my treatment begins, I will:

- Review the ***Patient Guide***.
- Enroll in the REMS by completing the ***Patient Enrollment Form*** with my healthcare provider. Enrollment information will be provided to the REMS.
- Get a blood test to check my liver.
- Receive counseling from my healthcare provider on the risk of serious liver problems and possibly death and requirements to get blood tests by using the ***Patient Guide***.

During treatment, I will get a blood test to check my liver:

- 2 weeks after my treatment begins,
- 4 weeks after treatment begins, and then
- every month after that for the first 18 months, and then
- every 3 months

I will contact my healthcare provider if I have any side effects, reactions, or symptoms after receiving JYNARQUE.

I understand and acknowledge that:

1. I have received, read, and understand the ***Patient Guide*** that my healthcare provider has given me.
2. JYNARQUE can cause serious side effects. It can cause serious liver problems and possibly death. This complication can be identified through monthly testing and awareness of side effects, reactions, or symptoms. My healthcare provider has reviewed with me the risks of treatment with JYNARQUE.
3. In order to receive JYNARQUE, I am required to be enrolled in the REMS, and my information will be stored in a database of all patients who receive JYNARQUE in the United States.
4. I should tell the REMS right away if I change my JYNARQUE healthcare provider, if my contact information changes, or if I discontinue JYNARQUE.
5. Otsuka Pharmaceutical Company, Ltd and its agents may contact me via phone, mail, fax, or email to support administration of the REMS.
6. Otsuka Pharmaceutical Company, Ltd and its agents may use and share my personal health information, including lab results and prescription data collected as part of the REMS for the purpose of the operations, analysis, and reporting of the REMS including enrolling me into, administering, and evaluating the REMS, coordinating the dispensing of JYNARQUE, and releasing my personal health information to the Food and Drug Administration (FDA), as necessary.

Patient or Legal Guardian Signature*: _____

Date*: _____

Printed Patient/Legal Guardian Name: _____

Healthcare Provider: Provide a copy of this form to the patient.

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Otsuka

Otsuka America Pharmaceutical, Inc.

Manufactured by Otsuka Pharmaceutical Co., Ltd., Tokyo, 101-8535 Japan.
Distributed and marketed by Otsuka America Pharmaceutical, Inc., Rockville, MD 20850 USA.
JYNARQUE is a registered trademark of Otsuka Pharmaceutical Co., Ltd., Tokyo, 101-8535 Japan.

 April 2020 OPSUS20EBP0036

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THE OTSUKA PATIENT EXPERIENCE PROGRAM ENROLLMENT FORM

FAX: 1-240-514-3999 EMAIL: pelconsent@otsuka-us.com

Please send this form back via fax to 1-240-514-3999 or email to pelconsent@otsuka-us.com.

Remember, you are not alone. Our support team is here to help you. If you have any questions, please call 1-833-468-7852.

The Otsuka Patient Experience Program is designed to support you on your treatment journey. Through the Otsuka Patient Support services, you will have access to the programs and services listed below. Enroll today by completing and faxing or emailing this form:

- Personal support from a licensed healthcare professional
- Information about copay assistance
- Other information and resources available through Otsuka

To enroll online, please scan or visit PatientExperienceProgram.com

All fields with an * are required.

CONTACT INFORMATION

☐ Mobile Phone ☐ Home Phone

*Name (First, Last) *Contact Number

*Street Address *City *State *ZIP Code

*Date of Birth (MM/DD/YYYY) Email Address Preferred Language

Specialty Pharmacy (Optional) ☐ AllianceRx ☐ Optum ☐ PANTHERx ☐ I am not sure

*"WHERE ARE YOU IN YOUR TREATMENT JOURNEY?"

- ☐ I have started treatment within the last 3 months
- ☐ I am currently on treatment and have been receiving refills for over 3 months
- ☐ I have been recommended to start treatment and I intend to start

*TELEPHONE COMMUNICATION, TEXT MESSAGES, AND EMAIL CONSENT

PLEASE READ THE FOLLOWING CAREFULLY AND CHECK THE INDICATED BOX

☐ ***I consent to receive ☐ calls and/or ☐ texts and/or ☐ emails** from and on behalf of Otsuka America Pharmaceutical, Inc. and Otsuka Precision Health Inc. (OPH Inc.) and confirm that I am the primary user for the phone number(s) provided above. I understand that my consent to receive calls, texts, and/or emails is not required or a condition of the program. The number of messages will vary based on my program selections. **By consenting to text or email messages, I understand that every effort is made to protect information, SMS/Text and Email messages may not be secure.** Message and data rates may apply. For additional information, see the Otsuka America Pharmaceutical Privacy Policy at: https://www.otsuka-us.com/privacy-policy. Text STOP to opt out and HELP for help.

See page 2 and 3 to complete required information.

Otsuka Patient Support™

OTSUKA PATIENT EXPERIENCE ENROLLMENT FORM

Please send this form back via fax to 1-240-514-3999 or email to pelconsent@otsuka-us.com.

OTSUKA PATIENT SUPPORT™ HEALTH INFORMATION USE AND DISCLOSURE AUTHORIZATION ("AUTHORIZATION")

Permission to Use and Disclose Health Information: This Authorization relates to the Otsuka Patient Experience Program and patient experience team. The Program provides services relating to drugs and devices ("Products") of OPH Inc. and its affiliates and successors ("Otsuka"). Your "Providers," for purposes of this Authorization, include any physician, pharmacy, care center, clinic, or other healthcare facilities and professionals, as well as any discount plan, health plan, or other payors that may have information related to the Products you use. By signing this Authorization, you (or your personal representative on your behalf) allow your Providers and Otsuka, along with the Recipients defined below, to use and disclose some of your Protected Health Information as defined below ("PHI") and as described in this Authorization.

PHI Recipients: Your Providers may give your PHI to Otsuka and any Program operators, manufacturers and distributors of the Product, and contractors ("Recipients"). The Recipients can also re-disclose your information to their contractors, vendors, and third parties that may take over the Program in the future. For example, Otsuka may give your information to vendors, advocacy organizations, patient assistance programs, patient access centers, data aggregators, laboratories, safety program administrators, Otsuka Precision Health, other business partners, website tracking tool vendors, and personnel of these third parties. For purposes of this Authorization, "Recipients" include Otsuka and all of these other third parties. "Recipients" also include any legal representatives, caregivers or other contacts listed in this Authorization.

PHI to be Used and Disclosed: PHI includes any and all health information related to the following:

- Your name, address, patient ID number, and other demographic data, date of birth, and information you provide on any forms related to the Products
- Healthcare records related to your eligibility for and use of the Products, such as dates of treatment, dosage, and dispensing
- The healthcare condition for which the Products were or may be prescribed, or your condition while taking or after stopping the Products. You understand that this may include sensitive PHI such as your mental health information
- Your experience with the Products, including whether you take them as prescribed
- Healthcare coverage, financial, payment, and claim information related to the Product or your ability to pay
- Information to help support your transition of care, such as getting discharged from a hospital

Purposes: The Recipients may use, share, and re-disclose your PHI, in electronic or any other form or format, for the following purposes:

- Determining if you qualify for and contacting you about the Program and Product-related services
- Providing assistance to you regarding the Product, facilitating access to the Product, determining health plan coverage requirements, and communicating with you and the Providers regarding the Product, your treatment, or payment for the Product
- Internal data collection, research, and reporting, including reviewing utilization, trends, and future needs of patients and providers
- Data analysis including de-identifying the PHI, creating limited data sets, or combining it with other information, and monetizing de-identified data as permitted by law
- Establishing your treatment profile, tracking coverage, and determining cost sharing
- Examining the effectiveness and operation of the Program
- Analysis to help evaluate and improve the Program and create new programs
- Consistent with applicable law and any applicable standards of ethical conduct, contacting your healthcare provider(s), law enforcement, emergency services, a family member, or any other person reasonably able to assist if a Recipient has a good faith belief that such action is necessary to prevent or lessen a threat to your health or safety, or to the health and safety of others
- Fulfilling the Recipients' legal obligations
- Using tracking tools on websites and applications to examine your interaction and experience with Program-related or Product-related platforms and to help the websites and applications function
- Proper management and administration of the Recipients and the Program, including re-disclosures to other Recipients, Providers, payors, and service providers as needed to operate the Program

Revocation: You may revoke and cancel this Authorization by calling 1-833-468-7852, emailing connect@otsuka-us.com, or sending a written notice to Otsuka Patient Support™, 508 Carnegie Center Drive, Princeton, NJ 08540. If you have questions about the Program, you can talk to your Provider and/or call Otsuka Patient Support™ at that number. If a Provider is disclosing PHI for the Program on an ongoing basis, your revocation will take effect with respect to such Provider when they receive notice of your revocation. Revocation will not affect any uses or disclosures of PHI that took place before such cancellation was received. For example, if your PHI has already been shared with third parties, it will not be able to be deleted. If you revoke this Authorization you will no longer be eligible to receive Program services, but this will not affect your ability to receive the Product.

Voluntary Authorization: You do not have to sign this Authorization. Refusal to sign will not affect the start, continuation, or quality of your treatment or any other treatment, payment, enrollment in health plans, or eligibility for benefits for which you qualify. Your Providers may not condition treatment, payment, enrollment, or eligibility for benefits on whether you sign this Authorization.

See page 3 to complete required information.

Otsuka Patient Support™

OTSUKA PATIENT EXPERIENCE ENROLLMENT FORM

Please send this form back via fax to 1-240-514-3999 or email to pelconsent@otsuka-us.com.

Re-Disclosure: Once your PHI is disclosed as allowed in this Authorization, it may be re-disclosed by the Recipients and will no longer be protected by the Health Insurance Portability and Accountability Act (HIPAA). Additionally, it may no longer be protected by certain other state and federal privacy and security laws.

Expiration: This Authorization will remain in effect for one (1) year from the date of the signature(s) below or until it is revoked, whichever is earlier.

Copy of Authorization: You have a right to receive a copy of this authorization.

By signing this Authorization, you acknowledge that you have read, understand, and agree to this Authorization and **expressly authorize** the uses and disclosures of PHI referenced in this Authorization.

Alternate Contacts: By completing the contact information below, you agree that PHI may be shared with the person(s) named below and that they have agreed that the Program can contact them about you and give them the option to receive texts about you. If you no longer want us to share your PHI with these people, you must contact us using the information above.

☐ Mobile Phone ☐ Home Phone

*Care Partner/Contact Name (First, Last) *Care Partner/Alternate Contact Number

☐ Mobile Phone ☐ Home Phone

*Additional Care Partner/Contact Name (First, Last) *Care Partner/Alternate Contact Number

Consent: By signing this Authorization, I acknowledge and confirm that I have read, understand, and agree to this Authorization and **expressly authorize** the uses and disclosures of PHI referenced in this Authorization.

☐ **I expressly authorize the uses and disclosures of PHI referenced in this Authorization.**

☐ **I consent to participate in the Otsuka Patient Experience Program.**

SIGN HERE*

PATIENT/LEGAL GUARDIAN SIGNATURE (I have read, understand, and agree to the Authorization) — If legal guardian, please state the relationship to the patient

***Date** (MM/DD/YYYY)

Legal Representative Name (First, Last)

Legal Representative Relationship

Please visit Otsukapatientsupport.com for more information on Otsuka products.

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Otsuka America Pharmaceutical, Inc.

Otsuka Patient Support™

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