Patient Consent Form

MyPASS – My Personalized ADPKD Support Service™ (the "Program") is offered by Otsuka to help patients throughout their treatment with JYNARQUE® (tolvaptan). The Program includes commercial copay savings, no-cost medication for a limited number of months while obtaining insurance coverage, and adherence support as key components.

Patients can benefit from prescription management, support in securing reimbursement, referrals to financial patient support programs, drug shipment, and refill outreach without enrolling.

Visit j-mypass.com/sign-up to fill out this form online.

Patient Authorization

MyPASS – I authorize the Program to contact me by phone, mail, or email and to provide support for my treatment with JYNARQUE, such as:

- laboratory testing and appointment reminders
- medication and refill reminders
- potential access to no-cost medication while insurance coverage is being determined

Copay Savings – I authorize MyPASS to apply Otsuka commercial copay savings assistance to my prescription.
I understand that to be eligible for commercial copay assistance I must have commercial insurance that covers medication costs and not be enrolled in federal or state subsidized healthcare programs that cover prescription drugs, including Medicare, Medicaid, TRICARE, or any other federal or state healthcare plan, including state pharmaceutical assistance programs. I understand and agree that a benefit verification will be performed and commercial copay savings assistance will not be provided if eligibility cannot be verified.

HIPAA Disclosure – I authorize that my protected health information (PHI) be shared with MyPASS and its partners.
I authorize that my PHI may be sent to the Program by my healthcare provider and pharmacy, disclosed to and reviewed by Otsuka and its authorized representatives and vendors of Otsuka working with the Program, including Program call center staff, as necessary to provide the support available, including transition of care support. This includes sending my PHI as provided by my healthcare provider and pharmacy to my health insurers, pharmacies, advocacy organizations, and third parties such as data aggregators, copay card vendors, laboratories, safety program administrators, patient access centers, and the patient assistance program pharmacy. There is a potential for the information to be subject to re-disclosure by the recipient and no longer protected by HIPAA.

My PHI may include:

- information provided on this form
- healthcare records related to my treatment and health condition(s)
- payer-related information received from my health insurer
- prescription, fulfillment, shipment, and other information provided by pharmacies or other sites of care
- information to help support my transition of care

My authorization and notice of release will remain in effect for two (2) years from the date of my signature. I understand that I may be requested to provide my written consent on a biannual basis by the program in an effort to support continued access to prescribed treatment. I understand that my pharmacy may receive payment from the Program or Otsuka for disclosing my PHI or providing the support services outlined in this consent as authorized in this consent. Signing this consent form is voluntary. I understand that I can refuse to sign this form and it will not affect the start, continuation, or quality of my treatment from my healthcare provider.

After I have signed this consent, I may withdraw it by calling MyPASS at 1-833-J-MYPASS or by sending a written notice to My Personalized ADPKD Support Service™ c/o ASSURE Program™, Covance Market Access Services, PO Box 3040, Gaithersburg, MD 20885-3040. The withdrawal goes into effect once it has been received by the Program. If I choose to not sign this authorization or I withdraw it after signing this form, the Program will not be able to provide me with the support described above after the date of my revocation.

Patient Name _____ **DOB** _____

Signature of Patient _____ **Date** _____

Legal Representative Name _____ **Legal Representative Signature** _____

Pharmacy Selection

Has prescription information been sent to a REMS-certified specialty pharmacy already?* ☐ **Yes** ☐ **No**

Check name of selected or preferred REMS-certified specialty pharmacy below:*
Best attempt will be made to honor the pharmacy selected below. Please note that the health insurer may dictate a different preferred specialty pharmacy.

☐ **AllianceRx Walgreens Prime**
alliancerxwp.com
130 Enterprise Drive, Pittsburgh, PA 15275
Phone: (800) 480-9052 | **Fax:** (877) 231-8302
Hours (EST): M–F: 8AM–7PM, **SAT:** 9AM–1PM, **SUN:** Closed

☐ **PANTHERx**
pantherspecialty.com
24 Summit Park Drive, Pittsburgh, PA 15275
Phone: (833) 599-2245 | **Fax:** (412) 420-6242
Hours (EST): M–F: 8AM–8PM, **SAT:** 9AM–3PM, **SUN:** Closed

☐ **Avella**
avella.com
24416 N 19th Avenue, Phoenix, AZ 85085
Phone: (877) 719-6330 | **Fax:** (877) 546-5780
Hours (MST): M–F: 6AM–6PM, **SAT:** 9:30AM–12:30PM, **SUN:** Closed

Please see **IMPORTANT SAFETY INFORMATION** on page 2.

INDICATION and IMPORTANT SAFETY INFORMATION for JYNARQUE® (tolvaptan)

INDICATION:

JYNARQUE is indicated to slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD).

IMPORTANT SAFETY INFORMATION:

WARNING: RISK OF SERIOUS LIVER INJURY

- **JYNARQUE (tolvaptan) can cause serious and potentially fatal liver injury. Acute liver failure requiring liver transplantation has been reported**
- **Measure transaminases (ALT, AST) and bilirubin before initiating treatment, at 2 weeks and 4 weeks after initiation, then monthly for the first 18 months and every 3 months thereafter. Prompt action in response to laboratory abnormalities, signs, or symptoms indicative of hepatic injury can mitigate, but not eliminate, the risk of serious hepatotoxicity.**
- **Because of the risks of serious liver injury, JYNARQUE is available only through a Risk Evaluation and Mitigation Strategy program called the JYNARQUE REMS Program**

CONTRAINDICATIONS:

- History, signs or symptoms of significant liver impairment or injury. This contraindication does not apply to uncomplicated polycystic liver disease
- Taking strong CYP3A inhibitors
- With uncorrected abnormal blood sodium concentrations
- Unable to sense or respond to thirst
- Hypovolemia
- Hypersensitivity (e.g., anaphylaxis, rash) to JYNARQUE or any component of the product
- Uncorrected urinary outflow obstruction
- Anuria

Serious Liver Injury: JYNARQUE can cause serious and potentially fatal liver injury. Acute liver failure requiring liver transplantation has been reported in the post-marketing ADPKD experience. Discontinuation in response to laboratory abnormalities or signs or symptoms of liver injury (such as fatigue, anorexia, nausea, right upper abdominal discomfort, vomiting, fever, rash, pruritus, icterus, dark urine or jaundice) can reduce the risk of severe hepatotoxicity. To reduce the risk of significant or irreversible liver injury, assess ALT, AST and bilirubin prior to initiating JYNARQUE, at 2 weeks and 4 weeks after initiation, then monthly for 18 months and every 3 months thereafter.

Hypernatremia, Dehydration and Hypovolemia: JYNARQUE therapy increases free water clearance which can lead to dehydration, hypovolemia and hypernatremia. Instruct patients to drink water when thirsty, and throughout the day and night if awake. Monitor for weight loss, tachycardia and hypotension because they may signal dehydration. Ensure abnormalities in sodium concentrations are corrected before initiating therapy. If serum sodium increases above normal or the patient becomes hypovolemic or dehydrated and fluid intake cannot be increased, suspend JYNARQUE until serum sodium, hydration status and volume status parameters are within the normal range.

Inhibitors of CYP3A: Concomitant use of JYNARQUE with drugs that are moderate or strong CYP3A inhibitors (e.g., ketoconazole, itraconazole, lopinavir/ritonavir, indinavir/ritonavir, ritonavir, and conivaptan) increases tolvaptan exposure. Use with strong CYP3A inhibitors is contraindicated; dose reduction of JYNARQUE is recommended for patients taking moderate CYP3A inhibitors. Patients should avoid grapefruit juice beverages while taking JYNARQUE.

Adverse Reactions: Most common observed adverse reactions with JYNARQUE (incidence >10% and at least twice that for placebo) were thirst, polyuria, nocturia, pollakiuria and polydipsia.

Other Drug Interactions:

- **Strong CYP3A Inducers:** Co-administration with strong CYP3A inducers reduces exposure to JYNARQUE. Avoid concomitant use of JYNARQUE with strong CYP3A inducers
- **OATP1B1/3 and OAT3 Transporter Substrates:** Patients who take JYNARQUE should avoid concomitant use with OATP1B1/B3 and OAT3 substrates (e.g., statins, bosentan, glyburide, nateglinide, repaglinide, methotrexate, furosemide), as the plasma concentrations of these substrates may be increased
- **BCRP Transporter Substrates:** Tolvaptan is an inhibitor of BCRP. Patients who take JYNARQUE, should avoid concomitant use with BCRP substrates (e.g., rosuvastatin)
- **V_2-Receptor Agonist:** Tolvaptan interferes with the V_2-agonist activity of desmopressin (dDAVP). Avoid concomitant use of JYNARQUE with a V_2-agonist.

Pregnancy and Lactation: Based on animal data, JYNARQUE may cause fetal harm. In general, JYNARQUE should be discontinued during pregnancy. Advise women not to breastfeed during treatment with JYNARQUE.

To report SUSPECTED ADVERSE REACTIONS, contact Otsuka America Pharmaceutical, Inc. at 1-800-438-9927 or FDA at 1-800-FDA-1088 (www.fda.gov/medwatch).

Please see FULL PRESCRIBING INFORMATION, including **BOXED WARNING**.

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.

September 2018 10US18EBP0270