# Application for Tolvaptan in ADPKD

## Fax Cover Sheet

BCRenal
Provincial Health Services Authority

| | | |
|---|---|---|
| To: Coordinator, Tolvaptan Adjudication Team | | From: |
| Fax: | 604-875-7366 | Fax: |
| Phone: | 604-875-7340 | Phone: |
| Subject: | Application for Tolvaptan in ADPKD | Date: |

**Please include the following forms. This is a mandatory requirement for review and approval of this application:**

- ☐ Tolvaptan Application Form
- ☐ Patient-Prescriber Agreement Form (PPAF)
- ☐ Copy of Imaging Report
- ☐ Copy of GFR Report - (if GFR decline is being used as a criterion for tolvaptan approval)
- ☐ Any Other Supporting Documentation

**Ensure all items listed as mandatory on the application form are included.**

**Comments:** _____

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Add HA/hospital logo

**PATIENT INFORMATION LABEL**

**Name:** _____

**Address:** _____

**Phone:** _____

**Date of Birth (MM/DD/YYYY):** _____

**PHN:** _____

# Application for Tolvaptan in ADPKD

Rev: March 2024

**Instructions:**

- Ensure the patient is registered in PROMIS, with a diagnosis of ADPKD
- Complete the information below, fax this form along with the PPAF/Tolvaptan consent for monitoring and any supporting documentation (e.g., imaging reports) to BC Renal at 604-875-7366

***Indicates Mandatory field**

**The following information is required for approval:**

*Confirmed diagnosis of ADPKD: ☐ Yes ☐ No

Tolvaptan is only indicated for use in ADPKD and not in any other renal cystic disease.

**Current patient characteristics:**

*Current age: _____ years *Most recent BP: _____/_____ mmHg
*Patient height: _____ cm Mayo Class (if known) _____

**Imaging:**

To interpret these results please provide confirmation of typical morphology of ADPKD ***and*** renal sizes. 'Typical morphology' is defined as diffuse, bilateral cystic involvement of the kidneys (i.e., not atypical morphology which includes asymmetric, unilateral or segmental cystic involvement)

*Typical morphology? Yes _____ No _____ Unknown _____

***Current renal size** - At least one of these measurements must be included. If both are available, include TKV. Ultrasound is not sufficiently accurate to assess TKV and should be used for kidney length only, if TKV is not available.

TKV _____mL ☐ CT ☐ MRI Date _____
Ultrasound kidney length: R _____ cm L _____ cm Date _____

☐ ***Attach a copy of the imaging report along with this application.**

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# Application for Tolvaptan in ADPKD

Rev: March 2024

**Evidence of disease progression**

Demonstration of disease progression may assist with determining candidacy; this would include evidence of GFR decline or rapidly increasing kidney volume over the course of the last ≥2 years.

**GFR** - If using GFR decline as a criterion for tolvaptan approval, please include historical GFR values over at least the last 3 years. If not, only the current GFR is required.

| **GFR*** | | | **Date** |
|---|---|---|---|
| Current | | mL/min/1.73m$^2$ | |
| Previous | | mL/min/1.73m$^2$ | |
| Previous | | mL/min/1.73m$^2$ | |

**Historical TKV values** - If available, provide values at least 1 year apart to determine rate of growth.

| **Previous TKV** | **CT** | **MRI** | **Date** |
|---|---|---|---|
| 1. | ☐ | ☐ | |
| 2. | ☐ | ☐ | |
| 3. | ☐ | ☐ | |

Please list any other clinical criteria not listed above that may impact patient's candidacy:

**Please attach all supporting documents along with this application.**

## Criteria for tolvaptan use in ADPKD

Potential candidates for treatment with tolvaptan are those with ADPKD and more rapidly progressing disease. These criteria are based on evidence from clinical trials[1,2], and the Updated Canadian Expert Consensus on Assessing Risk of Disease Progression and Pharmacological Management of Autosomal Dominant Polycystic Kidney Disease[3].

Please indicate which group (**1, 2 or 3**) best reflects your patient's characteristics, as well as which criteria within that group are met.

☐ **Group 1**: Patients 18-55 years old who are similar to those in clinical trials[1,2]:

eGFR >25 mL/min/1.73 $m^2$ **AND** Evidence of renal enlargement

Renal enlargement can be documented as any of:

- ☐ TKV >750 mL in those with eGFR >45 mL/min/1.73$m^2$
- ☐ Class 1C, 1D or 1E on the Mayo Clinic Classification

Although not a criterion in the REPRISE trials, documentation of renal enlargement has been included here as a criterion. In those patients with advanced or rapidly progressive CKD without enlarged kidneys, an alternate diagnosis for CKD should be investigated.

☐ **Group 2**: Patients 55-65 years old who would have met criteria for the REPRISE trial[2], and who also have evidence of rapid disease progression. **All three of these criteria must be met:**

- ☐ eGFR of 25 to 44 mL/min/1.73 $m^2$

**AND**

- ☐ Historical evidence of a decline in eGFR >2.0 mL/min/1.73 $m^2$/year

**AND**

- ☐ Class 1D or 1E on the Mayo Clinic Classification

Although not a criterion in the REPRISE trial, documentation of renal enlargement has been included here as a criterion to ensure that only the more rapidly progressing patients are chosen for tolvaptan treatment. In those patients with advanced or rapidly progressive CKD without enlarged kidneys, an alternate diagnosis for CKD should be investigated.

☐ **Group 3**: Patients ≥ 18 years of age with eGFR ≥ 25 mL/min/1.73 $m^2$ who do not otherwise fit into the criteria above may also be considered if they display other clear markers of renal progression related to their ADPKD. This includes, but is not limited to the factors below. Also note that not all factors in this group in isolation would meet criteria for tolvaptan treatment but are examples of criteria to consider. **If applying to group 3, please also explain your rationale for tolvaptan treatment on page 2 of this application.**

- ☐ Annual decrease in eGFR of >2.5 mL/min/1.73 $m^2$ in the setting of substantial renal expansion from ADPKD, and alternate diagnoses for eGFR decline have been excluded
- ☐ Documented Increase in TKV of >5% per year as determined by serial MRI or CT kidney volumes
- ☐ Mayo Clinic Classification groups 1D or 1E
- ☐ If available, predicted rapid progression based on genetic information such as, PKD 1 protein truncating mutation or high risk classification via the PROPKD risk score (7-9 points)
- ☐ MRI or CT cannot be done to assess TKV and patient has large kidney lengths (e.g. >20cm) on ultrasound at a young age. Ultrasounds are not as strong of a predictor of progression as total kidney volume and should only be considered if it is not possible to obtain TKV
- ☐ Consideration can be given to patients with high symptom burden related to renal expansion that is refractory to all other treatment strategies

# JINARC Patient-Prescriber Agreement Form (PPAF)

Please return this completed and signed PPAF by fax to: **1-844-3JINARC (354-6272).**

**PRESCRIBER SECTION**

Pr JINARC® (tolvaptan) is available in Canada. **JINARC can only be prescribed to patients who have completed and signed this form with their prescriber**.

The purpose of this Patient-Prescriber Agreement Form (PPAF) is to document the fully-considered engagement of both the patient and the prescriber to the treatment of autosomal dominant polycystic kidney disease (ADPKD) with JINARC ("Product"). In accordance with Health Canada requirements, the manufacturer of JINARC has implemented a safety monitoring initiative with regard to use of and access to JINARC. This initial step will also serve to confirm the patient enrollment into the JINARC Controlled Hepatic Safety Monitoring and Distribution Programme ("Programme"). The manufacturer of JINARC is Otsuka Canada Pharmaceutical Inc. ("Otsuka"). Otsuka is responsible for the Programme and may administer, in whole or in part with a designated third-party service provider, the Programme.

JINARC is indicated to slow the progression of kidney enlargement and kidney function decline in patients with ADPKD. In ADPKD, kidney enlargement reflects renal cyst burden.

Careful consideration and discussion of the appropriateness of JINARC treatment should be undertaken between the prescriber and patient before initiation of treatment, taking into account the potential benefits and risks of treatment, appropriate patient selection, and the need for mandatory ongoing hepatic function monitoring.

Following mutual agreement to undertake treatment with JINARC, both the patient and their prescriber must complete, sign, and date this PPAF in person, together at the same time. The patient and prescriber must read each statement of their respective section(s) of this PPAF thoroughly, **add their initials before each statement** confirming that he/she understands the benefits and risks of treatment with JINARC and agrees to comply with the conditions for use prior to initiating JINARC.

**Please return all pages of this completed and signed PPAF by fax to: 1-844-3JINARC (354-6272).** Incomplete information will result in delay. Please call **1-844-2JINARC (254-6272)** if you have any questions regarding the Programme. A Programme nurse will contact the patient to acknowledge and confirm enrollment if the patient provides the required consent as specifically set out herein.

JINARC is only distributed to pharmacies through a unique distributor who will verify with the Programme that there is a signed and valid PPAF on file prior to distributing JINARC. **To allow the Programme specialty pharmacy to dispense JINARC, the prescriber should complete the prescription information section on this form.**

Both the patient and prescriber should keep a copy of the executed PPAF for their records. Should the patient's attending prescriber change, this PPAF will need to be renewed. In the event that there are material changes to the Programme, this PPAF or the Product Monograph for JINARC, the prescriber and the patient will be contacted and informed of such changes. The PPAF is specific to JINARC and cannot be used for any other product.

| PRESCRIBER INITIALS | **As the PRESCRIBER of JINARC for the undersigned patient, I acknowledge that:** |
|---|---|
| | ◯ I am a nephrologist or,<br>◯ I am a specialist experienced in the management of autosomal dominant polycystic kidney disease (ADPKD).<br>Please provide a brief description of your experience/training: _____ |
| | I understand that JINARC is indicated to slow the progression of kidney enlargement and kidney function decline in patients with ADPKD. In ADPKD, kidney enlargement reflects renal cyst burden. |
| | I understand that JINARC is contraindicated in patients: who have been asked to permanently discontinue tolvaptan in the past; with known or suspected hypersensitivity to tolvaptan, benzazepine or benzazepine derivatives (e.g., mirtazapine) or any of the excipients; with hypovolemia; with hypernatremia; with anuria; who do not have access to fluids or who cannot respond to the physiologic sensation of thirst; with a history, signs or symptoms of significant liver impairment or injury, excluding uncomplicated polycystic liver disease; who are using strong CYP3A inhibitors; who are pregnant or nursing; or who have one of the following rare hereditary diseases: Galactose intolerance, Lapp lactase deficiency or Glucose-galactose malabsorption. |
| | I understand that JINARC has not been studied in pediatric patients (<18 years of age) with ADPKD. Its use is therefore not recommended in this patient population. Also, patients who are at, or approaching, end-stage renal disease, would not be expected to benefit from JINARC treatment. |
| | I understand that the patients most likely to benefit from JINARC treatment according to the TEMPO 3:4 trial, appear to be those with rapidly progressive ADPKD, or at a stage of incipient rapid progression, but before widespread destruction of renal architecture has occurred. Patients who are also likely to benefit from JINARC according to the REPRISE trial, appear to be those at high risk of progressive eGFR decline based on renal function for age (18 to 65 years of age with baseline eGFR between 25 and 65 mL/min/1.73m$^2$). I will comply with patient selection criteria as outlined in the totality of the JINARC Product Monograph. |
| | I have reviewed and understood the risks and potential benefits of JINARC, as well as the requirements of the Hepatic Safety Monitoring and Distribution Programme. |
| | I have counselled my patient about the potential risks and benefits of JINARC, the criteria for selecting him/her for this treatment, the appropriate use of JINARC, as well as the need for mandatory ongoing hepatic function testing. |
| | I have provided and reviewed the mandatory JINARC patient educational material with my patient. |
| | I understand the Hepatic Safety Monitoring and Distribution Programme will send me a liver function status report form for every liver function test required of the patient. I further understand that I, or my delegate(s), must complete, sign and return this report to the Programme in order to ensure that the patient's pharmacy can continue to order and dispense JINARC to my patient. I acknowledge that failure to do so may lead to JINARC supply interruptions for this patient. I understand the Programme may contact me by phone, fax or by email after sending the liver function status report form to follow up on the availability of pending results for a given month or to provide me with information on the Programme. |
| | Prior to initiating and prescribing JINARC, I will confirm that my patient's liver function test (i.e., ALT and AST) levels are less than three (3) times the upper limit of normal, and total bilirubin has been assessed. |
| | I have reviewed the "Prescriber Privacy and Consent Declaration" on this form and I agree to its terms and conditions. |

## Prescriber Information

Prescriber Stamp

First name: _____

Last name: _____

Medical license #: _____

Email address: _____

Telephone number: _____

Fax number: _____

Street address: _____

City: _____

Province: _____ Postal code: _____

Primary office contact person name (if different):

_____

Telephone number: _____

## Prescription Information

Patient first name: _____

Patient last name: _____

**JINARC oral tablets:**

◯ 45+15 mg (60 mg)
◯ 60+30 mg (90 mg)
◯ 90+30 mg (120 mg)

One _____ mg tablet p.o. AM and one _____ mg tablet 8 hours later

Disp: _____ weekly blister packs (14 tabs per pack)

Refill x _____

This original prescription constitutes a legal prescription for the patient for JINARC. The original copy of this prescription will be kept in my files and will not be re-used. Completion of this section is required for medication to be dispensed.

Signature: X _____

Date: _____
DD/MM/YYYY

Version 3 – May 2021

# PRESCRIBER Privacy and Consent Declaration

The Programme is provided by Otsuka Canada Pharmaceutical Inc. ("Otsuka") and may be administered, in whole or in part by Otsuka and a designated third-party service provider, McKesson Canada Corporation acting on its behalf and on behalf of its Specialty Health Division (collectively referred to as "McKesson Canada"). Otsuka and McKesson Canada ("Program Administrator") respect all applicable privacy laws and as such have agreed that identifiable patient information will only be accessible by employees of the Program Administrator directly involved in the provision of the services and support to the Programme ("Programme Support Team") or to any other third party if required by law or for safety information reporting unless specific consent has been obtained.

The Programme will limit data collection to information required for Programme administration. Generally accepted industry standards shall be used to store and protect confidential data, and access will be limited to the Programme Support Team.

The Program Administrator shall comply with and abide by all applicable privacy legislation in the jurisdictions in which the services for the Programme are to be provided and where the Programme information is stored. The Programme is only intended to provide support to your patients, to you (the Prescriber), and your treatment team so that you can best support patients that, in your professional judgement, would benefit from [Pr] JINARC®. The Programme is also there to ensure that you and your team have the support and knowledge you need about JINARC. The Programme is not intended to replace your professional judgement, or the professional judgement of other healthcare professionals involved in the patient's care. As the Prescriber of JINARC, you are responsible for using your professional judgement regarding the use of the Programme tools and services.

By accepting participation in the Programme, as the Prescriber of JINARC for the undersigned patient, I understand and agree:

(1) That I have received and reviewed the Product Monograph and I will undertake to use JINARC as clinically appropriate for the purpose of the Programme.

(2) To provide cooperation and necessary information to facilitate all necessary steps for patients to be able to seek private or public coverage and ensure that any such requests are submitted in a timely fashion or are underway prior to requesting the medication supplied by the Programme.

(3) To the collection, use and disclosure of information by the Program Administrator for the Programme to support its services and to meet Health Canada requirements for the Programme.

(4) To the disclosure by the Program Administrator to Otsuka that I have enrolled to participate in the Programme.

(5) To the disclosure by the Program Administrator to Otsuka personnel, not part of the Program Support Team of de-identified patient information, or as required, aggregated de-identified patient information (depending on the nature of the information) so as to not permit the identification of the patient, specifically: liver function test monitoring status, Product shipment history under the Programme, as well as high-level summary information including, but not limited to, size of Product patient population and those covered/non-covered by public or private plans.

(6) That unless specific consent has been obtained, that email communication will not be used for the exchange of any patient personal information and/or health information.

(7) To patient personal information and/or health information and/or adverse events being collected, viewed, stored and analyzed in or outside of Canada where we have facilities or in which we use third-party service providers. In that case, personal information will be subject to the laws of the country in which they are located and may be disclosed to governments, courts or law enforcement or regulatory agencies of that other country and in accordance with the laws of that other country, but the practices of the Program Administrator regarding my personal information will at all times be governed by this privacy policy.

(8) That, should I report safety information (including adverse events) and Product quality complaints to the Programme, I acknowledge that this information will be reported by the Program Administrator to Otsuka during the course of the patient's participation in the Programme. I also agree to be consulted to provide follow-up information, until such time as I explicitly inform Otsuka, in writing, of my desire not to be consulted. I acknowledge that such adverse event reports may need to be forwarded to regulatory authorities in and outside of Canada.

(9) That in the event that Otsuka appoints a third-party service provider, other than McKesson Canada, for the administration of the Programme, in its entirety or for a specific service for or through the Programme, I agree to the transfer of this PPAF and information contained herein, or related thereto, to such third-party service provider under the same terms and conditions as set out herein.

(10) That this PPAF is only applicable for treatment with JINARC.

I hereby confirm that I have read and understood the information provided and related to the Programme, and agree to participate as a Prescriber. I understand that I may suspend my participation in the Programme at any time. To do this, I must contact the Program Administrator at the number provided. I further understand that the Programme is mandated by Health Canada and if I suspend my participation, access to the Product may be terminated. I further understand that Otsuka reserves the right in their sole discretion to modify, suspend access to, or terminate the Programme.

Otsuka



MEMBER OF INNOVATIVE MEDICINES CANADA

# JINARC Patient-Prescriber Agreement Form (PPAF)

Please return this completed and signed PPAF by fax to: **1-844-3JINARC (354-6272).**

**PATIENT SECTION**

| PATIENT INITIALS | **As the PATIENT being prescribed [Pr] JINARC®, I acknowledge that:** |
|---|---|
| | I understand that JINARC is able to slow the growth of cysts in kidneys and the decline of kidney function. This should help protect my kidneys from damage and failure. |
| | My Prescriber has given me a copy of the mandatory patient educational material about JINARC and has reviewed it with me. |
| | I understand the risks, especially for the liver, and the benefits that may occur over time when receiving treatment with JINARC, as presented by my Prescriber. |
| | I understand that I must go for blood tests to check my liver function during JINARC treatment, as prescribed by my Prescriber: monthly for the first 18 months, every 3 months for the next 12 months, and then every 3-6 months thereafter. |
| | I understand that if I do not go for my blood tests, the Programme pharmacy will no longer be able to order and dispense JINARC for me, which could lead to treatment discontinuations or interruptions. |
| | I understand I should inform my Prescriber if I have symptoms like fatigue, loss of appetite, right upper abdominal discomfort, dark urine, or jaundice (yellowing of the eyes and skin). |
| | I should take this medicine every day exactly as my Prescriber has told me in order for JINARC to better protect my kidneys. |
| | I understand that my Prescriber may be invited to participate in a Canadian JINARC Patient Outcomes Registry (C-MAJOR) to measure the impact of JINARC on my kidneys and overall health over time and that I may be invited to participate by signing a separate consent form. In the case that I agree to participate, I understand that the data collected from this Hepatic Safety Monitoring and Distribution Programme ("Programme") will be transferred to the Registry, as appropriate. |
| | I have reviewed the "Patient Privacy and Consent Declaration" and I agree to its terms and conditions which allow my healthcare providers to share my health information, as defined in this document, to the Program Administrator, for the limited purpose of managing the JINARC Hepatic Safety Monitoring and Distribution Programme. |

## Patient Information

Referred by: ◯ Nephrologist ◯ Family physician

First name: _____ Last name: _____

Date of birth: _____ (DD/MM/YYYY) Gender: ◯ Male ◯ Female Email address: _____

Mobile number: _____ Telephone number: _____

Street address: _____ City: _____ Province: _____ Postal code: _____

Name of your family physician:* _____

Telephone number: _____ Fax number: _____

Street address: _____ City: _____ Province: _____ Postal code: _____

Name of your pharmacist:* _____

Telephone number: _____ Fax number: _____

Street address: _____ City: _____ Province: _____ Postal code: _____

* By providing us with the names of your family physician and your pharmacist, you are giving the Programme consent to inform them that you have been prescribed JINARC and to provide them with information on autosomal dominant polycystic kidney disease and JINARC.

◯ I have read and agree to the Patient Privacy and Consent Declaration on this form.

◯ By checking this box, I also agree to receive a "welcome call" from the Programme nurse to confirm my enrollment in the Programme, the Programme pharmacy and to introduce me to the ORIJIN® Patient Support Program which involves support to access reimbursement from my health insurance company, financial assistance (if and where required), access to a Programme nurse for counselling and other related services as they become available. All of which shall be subject to the same privacy consent granted on this form. I understand the Program Administrator may need to disclose my Personal Information to my insurers and my healthcare providers in order to provide me with such services.

◯ By checking this box, I agree to share my email address and first name with Otsuka, the makers of JINARC, for the purpose of receiving the ORIJIN Newsletter and other electronic communications from jinarc.ca/support. I will have the opportunity to opt-out from such communications.

If you are unavailable, can the Programme leave you a message? ◯ Yes ◯ No Best time for contact: ◯ Morning ◯ Afternoon ◯ Evening ◯ No preference

Signature: X _____ Date: _____ (DD/MM/YYYY)

Version 3 – May 2021

# PATIENT Privacy and Consent Declaration

The Programme is provided by Otsuka Canada Pharmaceutical Inc. ("Otsuka") and may be administered, in whole or in part by Otsuka and a designated third-party service provider, McKesson Canada Corporation acting on its behalf and on behalf of its Specialty Health Division (collectively referred to as "McKesson Canada"). Otsuka and McKesson Canada ("Program Administrator") respect all applicable privacy laws and as such have agreed that identifiable patient information will only be accessible by employees of the Program Administrator directly involved in the provision of the services and support to the Programme ("Programme Support Team") or to any other third party if required by law or for safety information reporting unless specific consent has been obtained.

I have been informed by my healthcare provider of the Programme purpose and have been given the opportunity to discuss this Programme with my healthcare provider. I understand that it is my right to refuse to sign this consent form. By signing the consent, I acknowledge my agreement to enroll in the Programme.

I authorize my Prescriber and his/her staff, and my health insurer(s) to disclose my personal information, including information about my insurance, prescriptions, verifying or coordinating insurance coverage(s), medication delivery and compliance, medical condition and health ("Personal Information") to the Programme Support Team for the purposes of the Programme and as otherwise permitted or required under law. I am aware the Programme Support Team adheres to a strict privacy policy.

My Personal Information will be retained only as long as necessary for the fulfilment of the purposes for which it was collected and/or for which consent was received, unless otherwise required by law. My Personal Information that is no longer required to fulfil the identified purposes will be destroyed, erased or made anonymous.

I also authorize my healthcare provider to provide the Program Administrator with this completed Patient-Prescriber Agreement Form ("PPAF") on my behalf so that the Programme Support Team can contact me in connection with the Programme. I acknowledge that I am responsible for any charges by my cell phone provider, should I choose to be contacted on my cell phone.

I authorize Otsuka personnel, not part of the Programme Support Team, to collect unidentifiable aggregate data for Programme management purposes. Unidentifiable aggregate data may be used for publication relating to the Programme; however, my Personal Information will not be used or disclosed for any purpose other than as described above. All information collected will be archived by the Program Administrator. If an adverse event is disclosed by me and/or about my state of health through the Programme, such information will be conveyed to Otsuka, with my initials (and date of birth and/or gender, if known), so that Otsuka can follow up with my Prescriber appropriately. This is necessary for Otsuka to maintain the most up-to-date records as to the safety profile of its products.

I consent to my Personal Information and any information relating to adverse events reporting being collected, viewed, stored and analyzed in or outside of Canada where we have facilities or in which we use third-party service providers. In that case, my Personal Information will be subject to the laws of the country in which they are located and may be disclosed to governments, courts or law enforcement or regulatory agencies of that other country and in accordance with the laws of that other country, but the practices of the Program Administrator regarding my Personal information will at all times be governed by this privacy policy.

I understand that I have the right to revoke this consent at any time by contacting the Programme at 1-844-2JINARC (1-844-254-6272); however, information about me already collected and disclosed for the purposes of the Programme will not be destroyed, except under those exceptions specified by law. I may arrange a right of access to the information held by the Program Administrator and may rectify deficient information. I acknowledge that revocation of consent may prevent my continued participation in the Programme.

In the event that Otsuka appoints a third-party service provider, other than McKesson Canada, for the administration of the Programme in its entirety or for a specific service provided for or through the Programme, I agree to the transfer of all my Personal Information and services to such third-party service provider under the same terms and conditions as set out herein.

Since Pr JINARC® can only be sold to pharmacies by a unique distributor (McKesson Canada), I authorize the Programme pharmacy to contact if needed my pharmacy (indicated on this form or that I will have communicated to the Programme) to exchange information about the medications I take to manage possible drug interactions or to provide instructions and requirements to my pharmacy to order JINARC. I understand that the information shared between my pharmacy and the Programme will only pertain to my treatment with JINARC and participation in the Programme.

I understand that this PPAF is not applicable for any treatment other than JINARC and that Otsuka reserves the right to terminate the Programme, or any aspect thereof, at any time, in its sole discretion, without prior notice.

Otsuka



MEMBER OF INNOVATIVE MEDICINES CANADA