

## TERMS AND ELIGIBILITY CRITERIA – THE NITYR™ (NITISINONE) TABLETS FREE TRIAL

### (THE “FREE TRIAL ELIGIBILITY CRITERIA”)

#### 1 About this Free Trial Eligibility Criteria

- 1.1 This Free Trial Eligibility Criteria set out how, and on what basis, you may qualify as a Free Trial Eligible Patient (as defined below) in order to participate in a 21-day free trial of NITYR™ (nitisinone) tablets (such 21-day free trial being the “**Free Trial**”).
- 1.2 You should read this Free Trial Eligibility Criteria carefully. References to “**we**”, “**us**” and “**our**” mean Cycle Pharmaceuticals Ltd.
- 1.3 By accessing or using our website to read this Free Trial Eligibility Criteria or otherwise indicating your consent, you agree to be bound by the [terms and conditions](#) of our website and also agree to comply with our [acceptable use policy](#) and [privacy policy](#). If you do not agree with and accept all of the terms of each of the aforementioned, you should stop using our website immediately.

#### 2 Eligibility criteria

- 2.1 You are only eligible to participate in the Free Trial if you are a “**Free Trial Eligible Patient**”. For the purposes of this Free Trial Eligibility Criteria (and subject always to, in particular (but not limited to) clauses 2.3 and 4 of this Free Trial Eligibility Criteria), a Free Trial Eligible Patient is a person who satisfies, in our discretion, all of the following criteria:
  - 2.1.1 a person who has a valid prescription for NITYR™ (nitisinone) tablets issued by his or her physician or other health care professional;
  - 2.1.2 a person who is;
    - (a) either insured in whole or part by commercial insurance or is enrolled in any state or federally funded prescription insurance program (which includes but is not limited to Medicare Part D, Medicaid, Medigap, Children’s Health Insurance Program, the Department of Veterans Affairs health network, the Indian Health Service, Maternal and Child Health Services Block Grant Program, Department of Defense programs and TriCare) (being a “**Federal or State Insurance Program**”). Furthermore, any person who is Medicare eligible and who is enrolled on any employer-sponsored group waiver health plan or government-subsidized prescription drug benefit program for retirees will also be considered by us to be enrolled in a Federal or State Insurance Program; or
    - (b) neither insured in whole or part by commercial insurance nor is enrolled in a Federal or State Insurance Program, but where the person in question is responsible in full for the cost of his or her own prescriptions;
  - 2.1.3 a person who, through their physician or other health care professional, has successfully enrolled in the Free Trial by completing and submitting to the NITYR patient support program (“**the PSP**”) (who provide non-commercial pharmacy services for us and on our behalf) an enrolment form and who the PSP otherwise confirm have satisfied all patient benefit investigations, checks and similar. A copy of the Free Trial enrolment form can be found at [www.nityr.us/free-trial](http://www.nityr.us/free-trial); and

- 2.1.4 a person who is resident in the United States of America. Also, please see paragraph 2.3 of this Free Trial Eligibility Criteria.
- 2.2 Subject to, amongst other things:
- 2.2.1 verification by the PSP;
- 2.2.2 applicable law; and
- 2.2.3 the remaining terms of this Free Trial Eligibility Criteria,
- caregivers of Free Trial Eligible Patients (a “**Caregiver**”) will be permitted to participate in the Free Trial for and on behalf of such Free Trial Eligible Patients (and this Free Trial Eligibility Criteria will be construed accordingly). Also, please see paragraph 2.4 of this Free Trial Eligibility Criteria.
- 2.3 This offer is restricted to residents of the United States of America. If you are not resident in the United States of America, you will not be eligible to participate in the Free Trial or otherwise qualify as a Free Trial Eligible Patient.
- 2.4 If you are a Free Trial Eligible Patient under the age of 18 years of age a Caregiver must act for and on your behalf. If you are a Caregiver acting for and on behalf of a Free Trial Eligible Patient, you must be 18 years of age or older.
- 2.5 If you are in any doubt about whether or not you constitute a Free Trial Eligible Patient, please contact the PSP on: 1-800-847-8714 (Monday to Fridays 9 am to 5 pm EST)

### **3 Terms applicable to the Free Trial**

- 3.1 The Free Trial is subject to applicable law and, in particular (but not limited to), the provisions of clause 4 of this Free Trial Eligibility Criteria.
- 3.2 If you are a Free Trial Eligible Patient and have been enrolled on a Free Trial you will:
- 3.2.1 be entitled to be sent and to receive from the PSP 21 days’ worth of free NITYR™ (nitisinone) tablets;
- 3.2.2 be sent a patient initiation document for NITYR™ (nitisinone) tablets; and
- 3.2.3 be contacted by the PSP regarding, amongst other things, the commencement, operation and conclusion of the Free Trial.
- 3.3 Free Trial Eligible Patients may also be eligible to participate in our “Diet and Low-Protein Foods Program” run in conjunction with Ajinomoto Cambrooke, Inc (“**Cambrooke**” and such program being the “**Diet Food Program**”) in which eligible persons will be entitled to receive a coupon and/or contribution(s) towards, and only redeemable against, the face value of Cambrooke’s diet and low-protein food products. Eligibility criteria and terms apply and can be found [here](#). The Diet Food Program is subject to applicable federal and state law. Accordingly, not all Free Trial Eligible Patients will be eligible to participate in the Diet Food Program.
- 3.4 For clarity, once enrolled in a Free Trial there is no obligation or requirement on any Free Trial Eligible Patient to:
- 3.4.1 use (or continue to use) NITYR™ (nitisinone) tablets;
- 3.4.2 participate in the Diet Food Program; or
- 3.4.3 to enrol in any patient support program run by us (including for clarity the NITYR™ Patient Support Program),

at any stage.

- 3.5 Participation in the Free Trial by a Free Trial Eligible Patient is non-transferable and is exclusive to each Free Trial Eligible Patient. Participation in the Free Trial is limited to one Free Trial per Free Trial Eligible Patient.

#### **4 Other terms**

- 4.1 We reserve the right to rescind, revoke, or amend the Free Trial, this Free Trial Eligibility Criteria or any other terms applicable to the Free Trial at our sole discretion and at any time without notice. Following any such rescission, revocation or amendment, you agree to be bound by the same. It is your responsibility to check this Free Trial Eligibility Criteria from time to time.
- 4.2 No person (including for clarity any Free Trial Eligible Patients, Caregivers and any prescribers of Free Trial Eligible Patients) may seek reimbursement from any health insurance (including commercial insurance and/or any Federal or State Insurance Program) or any third party for all or any part of any NITYR™ (nitisinone) tablets supplied pursuant to the Free Trial and/or any other benefit (including the Diet Food Program) received through the Free Trial.
- 4.3 If you have any questions regarding the Free Trial or the Free Trial please contact the PSP on: 1-800-847-8714 (Monday to Friday from 9 am to 5 pm EST).

#### **5 Intellectual property rights**

- 5.1 **The term “intellectual property rights”** means rights such as: copyright, trademarks, domain names, design rights, database rights, patents and all other intellectual property rights of any kind whether or not they are registered or unregistered (anywhere in the world). We retain and reserve all of our respective rights in any intellectual property in connection with NITYR™ (nitisinone) tablets, the Free Trial and this Free Trial Eligibility Criteria.
- 5.2 You agree not to adjust to try to circumvent or delete any provisions of this Free Trial Eligibility Criteria.
- 5.3 The trademarks: “NITYR™” and “Cycle®” are our trademarks. Other trademarks and trade names may also be used on our website and in this Free Trial Eligibility Criteria. The use of any of our trade marks is strictly prohibited unless you have our prior written permission and the use of any of third-party trademarks is strictly prohibited unless you the written permission of the relevant third party.

#### **6 Accuracy of information**

None of the information set out in this Free Trial Eligibility Criteria constitutes technical, financial, medical or legal advice or any other type of advice and should not be relied on for any purpose(s).

#### **7 Limitation on our liability**

Except for any legal responsibility that we cannot exclude in law, we are not legally responsible, or otherwise liable, for any direct, indirect, incidental, consequential or special damages or injuries resulting from the reliance on this Free Trial Eligibility Criteria or the Free Trial.

For full prescribing information please visit: [www.nityr.us/PI](http://www.nityr.us/PI)

# TERMS AND ELIBILITY CRITERIA – THE DIET FOOD PROGRAM

## (THE “DIET FOOD ELIBILITY CRITERIA”)

### 1 About this Diet Food Eligibility Criteria

1.1 This Diet Food Eligibility Criteria set outs, subject to its remaining terms, how, and on what basis, you may qualify as an Eligible Patient (as defined in clause 2 below) in order to receive:

1.1.1 if you are successfully enroled in and otherwise constitute a “Free Trial Eligible Patient” under our 21-day free trial of NITYR™ (nitisinone) tablets (the “**Free Trial**”), a \$200 free coupon (a “**Coupon**”) redeemable with Ajinomoto Cambrooke, Inc (“**Cambrooke**”) against the face value of Cambrooke’s low protein food products (being “**Cambrooke Products**”); or

1.1.2 if you are successfully enroled in an Eligible Program (as defined in clause 2.1.3 below), an entitlement to receive a \$200 per month contribution (a “**Contribution**”) towards, and redeemable only against, the face value of Cambrooke Products,

and both of the above being together the “**Diet Food Program**”.

1.2 You should read this Diet Food Eligibility Criteria carefully. References to “**we**”, “**us**” and “**our**” mean Cycle Pharmaceuticals Ltd and references to “**Cambrooke**” mean Cambrooke Therapeutics, Inc.

1.3 By accessing or using our website to read this Diet Food Eligibility Criteria or otherwise indicating your consent, you agree to be bound by the [terms and conditions](#) of our website and also agree to comply with our [acceptable use policy](#) and [privacy policy](#). If you do not agree with or accept all of the terms of the aforementioned, you should stop using our website immediately.

### 2 Eligibility criteria

2.1 You are only eligible to participate in the Diet Food Program if you are an “**Eligible Patient**”. For the purposes of this Diet Food Eligibility Criteria (and subject always to, in particular (but not limited to) clauses 2.3, 2.4, 3 and 4 below), an Eligible Patient is a person who fulfils all of the following criteria:

2.1.1 a person who has a valid prescription for NITYR™ (nitisinone) tablets issued by his or her physician or other health care professional;

2.1.2 a person who is either;

(a) insured in whole or part by commercial insurance; or

(b) not insured by commercial insurance but where the person in question is responsible in full for the cost of his or her own prescriptions;

2.1.3 a person who is either:

(a) successfully enroled in the “NITYR™ Patient Support Program” (being the “**NITYR™ Patient Support Program**”); or

(b) successfully enroled in a patient support program under which such person is eligible to be dispensed NITYR™ (nitisinone) tablets by a pharmacy operated and run by, or on behalf of, that person’s commercial insurance provider (an “**Alternative Patient Support Program**” and the NITYR™ Patient Support Program and any Alternative Patient Support Program together being an “**Eligible Program**”); or

(c) successfully enrolled in the Free Trial (in accordance with, and subject always to, the eligibility criteria applicable to the same (which can be found [here](#)) and the remaining terms of this Diet Food Eligibility Criteria); and

2.1.4 a person who is resident in the United States of America. Also, please see paragraph 2.4 of this Diet Food Eligibility Criteria.

2.2 Subject to, amongst other things:

2.2.1 appropriate verification;

2.2.2 applicable law; and

2.2.3 the remaining terms of this Diet Food Eligibility Criteria,

caregivers of Eligible Patients (a “**Caregiver**”) will be permitted to participate in the Diet Food Program but only for and on behalf of such Eligible Patients (and this Diet Food Eligibility Criteria will be construed accordingly). Also, please see paragraph 2.5 of this Free Trial Eligibility Criteria.

2.3 For the avoidance of doubt:

2.3.1 if you are seeking to participate in the Diet Food Program and you are enrolled in any state or federally funded prescription insurance program (which includes, but is not limited to, Medicare Part D, Medicaid, Medigap, Children’s Health Insurance Program, the Department of Veterans Affairs health network, the Indian Health Service, Maternal and Child Health Services Block Grant Program, Department of Defense programs, or TriCare) (being an “**Excluded Insurance Program**”) you will not, in any way, constitute an Eligible Patient and you will not therefore be eligible to participate in the Diet Food Program. Furthermore, any person who is Medicare eligible and who is enrolled on any employer-sponsored group waiver health plan or government-subsidized prescription drug benefit program for retirees will also be considered by us to be enrolled in an Excluded Insurance Program and will not, therefore, be eligible to participate in the Diet Food Program; and

2.3.2 if you are enrolled in an Excluded Insurance Program, you will not in any way constitute an Eligible Patient and may not participate in the Diet Food Program (even if you elect to be processed as an uninsured (i.e. cash paying) person).

2.4 This offer is restricted to residents of the United States of America. If you are not resident in the United States of America, you will not be eligible to participate in the Diet Food Program or otherwise qualify in any way as an Eligible Patient.

2.5 This offer is subject to applicable federal and state law. Accordingly, and subject to the remaining terms of this Diet Food Eligibility Criteria, not all Eligible Patients will be able to qualify for this offer.

2.6 If you are an Eligible Patient under the age of 18 years of age a Caregiver must act for and on your behalf. If you are a Caregiver acting for and on behalf of an Eligible Patient, you must be 18 years of age or older.

### **3 Terms applicable to the Diet Food Program**

3.1 The Diet Food Program is subject to applicable law and, in particular (but not limited to) the provisions of clause 4 of this Diet Food Eligibility Criteria.

3.2 Eligible Patients will be entitled to:

3.2.1 when such Eligible Patient has been successfully enrolled on the Free Trial, receive only one Coupon together with information about how such Coupon can be redeemed against applicable Cambrooke Products; or

3.2.2 when such Eligible Patient has been successfully enrolled in an Eligible Program, receive information regarding monthly Contributions and how each contribution can be redeemed against applicable Cambrooke Products.

Coupons and information concerning Contributions, and the redemption of each thereof, will only be issued and provided with a valid dispense of NITYR™ (nitisinone) tablets pursuant to an Eligible Program.

3.3 Each Coupon and each Contribution:

3.3.1 may only be used and redeemed by an Eligible Patient;

3.3.2 will have a face value of \$200 and entitle only an Eligible Patient to redeem an amount equal to \$200 from the value of the Cambrooke Products at Cambrooke's published retail prices set out on Cambrooke's website (<http://www.cambrooke.com/>) from time to time;

3.3.3 may not be used on any sale or other discounted Cambrooke Products;

3.3.4 cannot be used to pay in whole or in part for any costs of shipping and delivery of any Cambrooke Products. For clarity, this includes dry and cold ship orders. Minimum rates apply;

3.3.5 will only be permitted by Cambrooke to be redeemed for a period of thirty (30) days from, in the case of a Coupon, the date of receipt of the same, or in the case of a Contribution, the date of receipt of your dispense of NITYR™ (nitisinone) tablets (as evidenced by the packing slip accompanying the same);

3.3.6 is non-transferrable;

3.3.7 is personal to an Eligible Patient; and

3.3.8 is only capable of being used and redeemed once, such use and redemption to be effected by an Eligible Patient (or that Eligible Patient's Caregiver) placing an order with Cambrooke through Cambrooke's toll-free customer order telephone number on 866-456-9776 (option 2). For clarity, neither Coupons nor Contributions will be capable of being used and redeemed in any way via Cambrooke's website.

3.4 Notwithstanding the above and in order to ensure compliance with all applicable federal and state laws, an Eligible Patient may be required by Cambrooke to provide to it, prior to Cambrooke permitting the redemption of any Coupon or Contribution (as the case may be), certain personal information about that Eligible Patient and that Eligible Patient's dispense of NITYR™. Such personal information so disclosed will be retained by Cambrooke solely:

3.4.1 for ensuring compliance with this Diet Food Eligibility Criteria;

3.4.2 for fulfilling orders of Cambrooke Products for the Eligible Patient in question; and

3.4.3 to enable Cambrooke to contact the Eligible Patient in question regarding the availability of new Cambrooke Products and/or to provide to the Eligible Patient in question information on how to use existing or new Cambrooke Product (being "**Cambrooke Communications**") (and nothing in this clause affects, or in any way limits, an Eligible Patient's rights under applicable law to require Cambrooke to discontinue, cease or termination any of all of such Cambrooke Communications).

For clarity, all rights of actions, claims, suits and otherwise in respect of any: (a) personal information disclosed to Cambrooke; and (b) Cambrooke Communications will, in each case, be dealt with solely between the Eligible Patient in question (or that Eligible Patient's Caregiver) and Cambrooke and we make no: (i) representation, warranty as to any party's

performance, rights or otherwise; or (ii) guarantee, in each case regarding the same or the discontinuation, cessation or termination thereof.

- 3.5 If an Eligible Patient orders Cambrooke Products, the costs of which exceed the amount of a Coupon or a Contribution (as the case may be), such Eligible Patient will be responsible to Cambrooke for all of the outstanding costs of, and related to, such order.
- 3.6 Eligible Patients are responsible for any and all applicable taxes payable for, or otherwise related to, Cambrooke Products and any other benefit conferred by the Diet Food Program.
- 3.7 An Eligible Patient enrolled in the Free Trial will only be entitled to receive a maximum of one Coupon with the delivery of their free NITYR™ (nitisinone) tablets medication delivery. In the event that such Eligible Patient wishes to continue to participate in the Diet Food Program from the conclusion of the Free Trial, such Eligible Patient will be required to enrol in an Eligible Program and, pending successful enrolment in the same and subject to the remainder of this Diet Food Eligibility Criteria, will thereafter be entitled to receive information about Contributions.
- 3.8 Subject to clause 4, Eligible Patients will be entitled to participate in this Diet Food Program for a maximum aggregate period of 24 months. Accordingly, for clarity and subject to the remaining terms of this Diet Food Eligibility Criteria, each Eligible Patient will not be able to receive or otherwise redeem: (a) in aggregate, an amount exceeding \$2,400 per year from the face value of applicable Cambrooke Products under this Diet Food Program; and (b) a maximum lifetime aggregate amount exceeding \$4,800 from the face value of applicable Cambrooke Products under this Diet Food Program. Neither Coupons nor Contributions are cumulative. Other restrictions may apply.

#### **4 Other terms**

- 4.1 We reserve the right to rescind, revoke, or amend this Diet Food Program, this Diet Food Eligibility Criteria or any other terms applicable to it at our sole discretion and at any time without notice. Following any such rescission, revocation or amendment, you agree to be bound by the same. It is your responsibility to check this Diet Food Eligibility Criteria from time to time.
- 4.2 Eligible Patients, Caregivers and any prescribers of Eligible Patients may not seek reimbursement from any health insurance (including commercial insurance and/or any Excluded Insurance Program) or any third party for all or any part of any Coupon or all or part of any Contribution or all or part of any other benefit received through the Diet Food Program.
- 4.3 If you have any questions regarding the Diet Food Program or the Free Trial please contact the PSP on: 1-800-847-8714 (Monday to Friday 9 am to 5 pm EST), or If you have any questions regarding the Diet Food Program please contact Cambrooke on 866-456-9776 (option 2) or by e-mail to [info@cambrooke.com](mailto:info@cambrooke.com).

#### **5 Intellectual property rights**

- 5.1 **The term “intellectual property rights”** means rights such as: copyright, trademarks, domain names, design rights, database rights, patents and all other intellectual property rights of any kind whether or not they are registered or unregistered (anywhere in the world). We and Cambrooke each retain and reserve all of our respective rights in any intellectual property in connection with the Diet Food Program and this Diet Food Eligibility Criteria.
- 5.2 You agree not to adjust to try to circumvent or delete any provisions of this Diet Food Eligibility Criteria.
- 5.3 The trademarks: “NITYR™” and “Cycle®” are our trademarks. Other trademarks and trade names may also be used our website and in this Diet Food Eligibility Criteria. The use of

any of our trade marks is strictly prohibited unless you have our prior written permission and the use of any of third-party trademarks is strictly prohibited unless you the written permission of the relevant third party.

**6 Accuracy of information**

None of the information set out in this Diet Food Eligibility Criteria constitutes technical, financial, medical or legal advice or any other type of advice and should not be relied on for any purpose(s).

**7 Limitation on our liability**

Except for any legal responsibility that we cannot exclude in law, we are not legally responsible, or otherwise liable, for any direct, indirect, incidental, consequential or special damages or injuries resulting from the reliance on this Diet Food Eligibility Criteria or the Diet Food Program.

For full prescribing information please visit: [www.nityr.us/PI](http://www.nityr.us/PI)