Delamanid Compassionate Use Patient Access Form (242-302-00014)

This form should be fully completed by the treating physician and submitted to Medical@otsuka-onpg.com

Physicians Details

First Name:

Last Name:

Work Email Address:

Work Telephone Number:

Institution:

Street/number:

City:

Post code/ Zip Code:

County/State/Province:

Country:

Delivery Details
Pharmacist's Details
(PLEASE USE BLOCK CAPITALS: TITLE, FULL FIRST NAME, FULL FAMILY NAME)

First Name:

Last Name:

Work Email Address:

Work Telephone Number:

Pharmacist's Registration/License Number:

Delivery Address:

Name hospital/pharmacy:

Street/number:

City:

Post Code/Zip Code:

County/State/Province:

Country:

Section 1 : Indications for CU, bacteriological examinations, DST results					
Patient Initials		**Patient age at the time of application/request**			
Sex		**Weight (in kg)**		**BMI**	
ECG (please attach recent ECG result)	Date of ECG:	**QTcF (ms):**			

Indications for CU	*Please describe shortly the main reason(s) for applying for CU*		
TB history	*Please provide details on previous TB episodes (dates, diagnosis, bacteriological status, DST results, Tx regimen, Tx outcome)*		
Current TB diagnosis	*Site, cavities, bacteriological status (SS+/-; SC+/-); DST results* *Example: Bilateral pulmonary TB with cavities in right upper lobe, SS+, SC+, resistant to H, R, E, S, Pto.*		
Type	☐ pulmonary ☐ extrapulmonary if extrapulmonary, please specify _____		
Resistance status	☐ MDR-TB ☐ pre-XDR-TB ☐ XDR-TB		
Cavitary status	☐ none ☐ unilateral ☐ bilateral		
Comorbidities	☐ none ☐ diabetes ☐ hepatitis ☐ other, please specify _____		
HIV status	*Date (dd/mm/yyyy), result*	**CD4+ count**	*Date (dd/mm/yyyy), result*
ART (if HIV +)	*Date of initiation (dd/mm/yyyy), regimen*		

Bacteriological examinations (in this TB episode)							
Sputum/other collection date (dd/mm/yyyy)	**Smear result**	**Culture result**	**Date of culture result (dd/mm/yyyy)**	**Sputum/other collection date (dd/mm/yyyy)**	**Smear result**	**Culture result**	**Date of culture result (dd/mm/yyyy)**

	DST results *(Resistant (R) or Susceptible (S) or Unknown (U))*																		
Sputum/other collection date (dd/mm/yyyy)	**Method**	**H**	**R**	**E**	**S**	**Z**	**Am**	**Km**	**Cm**	**Ofx**	**Lfx**	**Mfx**	**Pto**	**Cs**	**PAS**	**Lzd**	**Cfz**	**Dlm**	**Others (please specify)**	**Result date (dd/mm /yyyy)**

Section 2: Treatment regimen in current TB episode and the proposed treatment regimen

Treatment regimen in current TB episode *(please write the date of start and end for each drug and specify their dosage. If drug stopped, specify the reason)*																									
Year/ Month / **Drug, dosage**																									

Comments:

Proposed treatment regimen		
Nr.	**Drug**	**Dosage and administration**
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.		
12.		

Section 3. Patient eligibility assessment (please tick yes or no for each criterion)

Inclusion criteria for DLM CU	YES	NO
Patient with MDR-TB with limited therapeutic options		
Male or female patient ≥ 3 years old		
Patient unable to participate in an ongoing delamanid clinical trial		
Patient receiving TB treatment and care at a health care institution which is in line with site selection minimum requirements		
Current treatment regimen for this patient has been designed by the physician in accordance with the national and WHO recommendations for the management of MDR-TB		

Non Eligibility Criteria

Exclusion criteria for DLM CU	YES	NO
Patient with any previous (during the last 6 months) or concomitant use of the following drugs for the treatment of MDR-TB: PNU-100480/sutezolid, SQ-109, Pa-824, AZD-5847, TBA-354, CPZEN-45, DC-159a, SQ-609, SQ-641, BTZ 043, Q201, SPR-10199, perchlozone		
Hypersensitivity to the active substance or to any of the excipients stated in the European Summary of Product Characteristics		
Serum albumin < 2.8 g/dL		

Taking medicinal products that are strong inducers of CYP3A (e.g. carbamazepine)		
QTcF at baseline > 500 msec or > 450 msec in case of bedaquiline co-administration		
Serum potassium (K+), magnesium (Mg++), or calcium (Ca++) outside normal range at baseline		
<2 active or likely to be active drugs (not counting delamanid) to be included in the proposed optimized background regimen based on recent DST and/or treatment history		

Section 4: Physician Declaration

1. I have requested the supply of Delamanid for the Patient on an unlicensed basis for the treatment of multi-drug resistant tuberculosis. NOTE: For the purposes of this document "unlicensed" means that Marketing Authorization has not yet been granted in a given country or access is otherwise restricted and CU program is possible according to local regulations.
2. Processing of Physician Personal Data.
   - I acknowledge and agree that:
     - Otsuka Novel Products GmbH (Otsuka) and affiliated companies shall be entitled to collect my personal data in this form including my name, address and place(s) of work, work telephone number and email address and physician registration / licence number.
     - Otsuka shall be entitled to process my personal data to obtain an overview on participation, activity and safety reporting in the program, in respect of the safety reporting obligations of Otsuka, to provide Delamanid to the Patient and to manage the program, as otherwise required by law and/or for internal business processes such as accounting and records requirements which are required to carrying out the program, and for other good governance.
     - Otsuka shall be entitled to process my personal data to track medical outcomes and the progress of the Patient, to perform statistical analysis, including analysing participation levels in relation to the program and producing related reports, and my personal data may potentially be anonymised into aggregate form to facilitate this.
     - Otsuka shall be entitled to contact me by post, email and / or telephone to obtain my views on its product and to carry out studies and research, including market research. I may opt out at any time by using the **signature section below** or by contacting Medical@otsuka-onpg.com
     - Otsuka shall be entitled to archive my records as long as required by statutory law.
     - Otsuka shall be entitled to disclose my personal data to:
       - its affiliated companies (as relevant for the purposes set out above; business partners, service providers, subcontractors and agencies which are involved in the program who may contact me in relation to the program (as relevant); and
       - governmental, tax or regulatory authorities and other persons as required or permitted by law.
     - It is possible that your health information is send to such external parties, and these external parties may be located in countries or territories which may have a lower data protection level. In those cases steps may be taken to protect personal data if needed.
     - Under applicable data protection laws, at any time I have a right to access or obtain copies of my personal data and to request the correction, blocking or deletion of my personal data that Otsuka or affiliated companies hold in relation to me. To do this, I will contact the "data controller", which within the meaning of applicable data protection laws is Ostuka at privacy@otsuka-onpg.com . The contact details of Otsuka's data protection officer will be provided upon request, where applicable. I may also ask for data portability and I am entitled to object to the processing of personal data in certain instances. I may lodge a complaint with the competent Data Protection Authority, which may be the supervisory authority in the country of residence, place of work or of an alleged infringement of data protection laws.

- The legal basis for the processing of personal data is (i) my consent with respect to the processing activities described in this Section 4, and/or (ii) the performance of this PAF in relation to the data processing activities described in it, and/or (iii) compliance with a legal obligation to which Otsuka is subject.

3. **Processing of Patient Personal Data (including Sensitive Personal Data)**:

- I have informed the Patient that:
  - his / her personal data, including sensitive personal data such as health data, as is collected in this form in relation to the supply of Delamanid, may be:
    - provided to and processed by Otsuka, and disclosed to its affiliated companies (as relevant), Global TB Consilium experts or other previously agreed advisory group for seeking their clinical advice, business partners, service providers, subcontractors and agencies, in each case to provide Delamanid to the Patient and to manage the program, to obtain an overview of participation, activity and safety reporting in the program and, in respect of certain limited personal data, for Otsuka to comply with its own safety reporting obligations;
    - disclosed to governmental, tax or regulatory authorities and other persons as required or permitted by law; and
    - used to enable Otsuka to track medical outcomes and the progress of the Patient, to perform statistical analysis, including to analyse participation levels in relation to the program and produce related reports, and that his / her personal data may potentially be anonymised into aggregate form to facilitate this.
  - All of the recipients mentioned above may be located in countries or territories outside the EEA which may not have adequate data protection laws and that in those cases steps will be taken to protect personal data, as required by applicable data protection laws.
  - Otsuka shall be entitled to archive the Patient's records as long as required by stautory law.
  - under applicable data protection laws, at any time the Patient has a right to access or obtain copies of its personal data and to request the correction, blocking or deletion of its personal data that Otsuka or affiliated companies hold in relation to the Patient. To do this, the Patient will contact the "data controller", which within the meaning of applicable data protection laws is Ostuka at privacy@otsuka-onpg.com The contact details of Otsuka's data protection officer may be provided upon request, where applicable. The Patient may also ask for data portability and is entitled to object to the processing of personal data in certain instances. The Patient may lodge a complaint with the competent Data Protection Authority, which may be the supervisory authority in the country of residence, place of work or of an alleged infringement of data protection laws.
  - the legal basis for the processing of personal data is (i) the Patient's consent with respect to the processing activities described in this Section 4, and/or (ii) the performance of this PAF in relation to the data processing activities described in it, and/or (iii) compliance with a legal obligation to which Otsuka is subject.

Acknowledgment and Consent

1. I have acknowledged and understood the "**Terms and Conditions**" attached hereto, and, by signing below, agree to comply with them once Otsuka has decided to supply Delamanid to me on an unlicensed basis.
2. I hereby consent to the use and processing of my personal data as further specified above under Section 4, paragraph 2. I hereby confirm that any given consent is freely given, not mandatory, and may be revoked at any time and without justification by sending a written notice to that effect to Otsuka.
3. I confirm that I have shown a copy of this Patient Access Form and explained its content to the Patient and that the Patient (or his / her parent / guardian or legal representative where required) has explicitly consented in writing to his / her personal data, including sensitive personal data, being used and disclosed as described in Section 4, paragraph 3 and any given consent is freely given, not mandatory, and the Patient is informed that it may revoke any given consent at any time and without justification by sending a written notice to that effect to me the local physician.
4. I hereby acknowledge that I am obliged to forward any data related requests, and/or complaints by the Patient directly to Otsuka without any delay in order to enable Otsuka to deal with any such request and/or complaint in due time.

Physician's Name (PLEASE USE BLOCK CAPITALS: TITLE, FULL FIRST NAME, FULL FAMILY NAME)

_____

Physician registration / License Number

_____

Physician's signature

_____

Date ☐☐ ☐☐ ☐☐☐☐ (DD/MM/YYYY)

If you DO NOT wish to receive information and surveys by post, email and / or telephone from Otsuka about products, services and future projects, programs and events which may interest you, each as described in paragraph 2 of "Section 4 Physician Declaration", please tick here ☐

"Terms and Conditions"

These Terms and Conditions are between you (the Physician) and Otsuka

1) Prescription of Delamanid and Treatment of the Patient

a) The prescription of Delamanid for the Patient is at the sole discretion and responsibility of the Physician within the therapeutic freedom granted to doctors with respect to determining the best treatment for their patients. The Physician is solely responsible for the treatment of the Patient.

b) The Physician will receive from Otsuka the Investigator Brochure for Delamanid ("IB") and the protocol entitled "242-302-00014: Compassionate use of delamanid in patients with multidrug-resistant tuberculosis with limited therapeutic options." (the "CU Protocol").

c) Reviewing the IB and the CU Protocol, the Physician shall ensure that the Patient meets the inclusion and exclusion criteria set out in the CU Protocol, and that, from a clinical perspective, Delamanid is appropriate for use in the Patient.

d) In the treatment of the Patient, the Physician shall adhere to the CU Protocol.

e) The Physician shall comply with all legislations, rules, regulations and guidelines on unlicensed use that are applied in the country where the Physician conducts the treatment of the Patient (the "Applicable Laws").

f) The Physician shall immediately inform Otsuka, in advance, if the Patient is transferred to a different hospital or doctor.

2) Supply and Use of Delamanid

a) The Physician requests that Otsuka will supply Delamanid to the Physician in the quantities necessary for the treatment according to the CU Protocol unless otherwise provided by the Applicable Laws. However, the Physician agrees that Otsuka may decide, at its sole discretion, to terminate the further supply of Delamanid for this unlicensed use.

b) The Physician agrees that Otsuka supplies Delamanid "as is", without any warranties to the suitability for the treatment of the Patient. The Physician will receive and understand the specific storage and administration requirements for Delamanid.

c) The Physician shall not use Delamanid supplied by Otsuka for any other purposes than the treatment of the Patient. In case the treatment of the Patient with Delamanid is no longer needed, or these "Terms and Conditions" are terminated, or upon the completion of the treatment of the Patient, the Physician shall notify Otsuka of the quantity of Delamanid in the possession of the Physician. Thereafter, the Physician shall immediately i) return all such Delamanid to Otsuka's designated place at the Physician's cost, or ii) dispose of all such Delamanid, pursuant to applicable laws, regulations and guidelines, and provide Otsuka with the certificate of disposal.

3) Importation

The Physician shall be responsible for custom clearance and approval of the importation of Delamanid supplied by Otsuka in accordance with Applicable Laws.

4) Local Authority's Approval

a) In line with Applicable Laws, the Physician shall obtain the approval of the local competent authority for the treatment of the Patient with Delamanid on an unlicensed basis (the "Approval"). The Physician shall include all required information for the unlicensed use in the application for Approval.

b) If applicable, the Physician shall obtain the approval of the competent ethic committee for the treatment of the Patient with Delamanid on an unlicensed basis (the "EC Approval"). The Physician shall include all required information for the unlicensed use in the application for EC Approval.

c) The Physician shall provide without undue delay a copy of the Approval (and the "EC Approval" when applicable) to Otsuka or its authorized distributor.

5) Informed consent

The Physician shall obtain the written informed consent of the Patient or its legal representative for the treatment with Delamanid, which in this case means the informed consent of the Patient.

6) Pharmacovigilance

a) The Physician shall monitor the Patient for adverse events and fulfil all the requirements of pharmacovigilance reporting to local competent authority (ies) in accordance with Applicable Laws.

b) Notwithstanding the provisions of CU Protocol related to pharmacovigilance reporting, the Physician shall report adverse events according to the pharmacovigilance training which will be provided by Otsuka.

7) Confidentiality

a) The Physician shall treat all information supplied by Otsuka in relation to Delamanid, whether before or after the Effective Date, including but without limitation the IB as well as the CU Protocol (collectively the "Delamanid Information") as confidential information of Otsuka, and shall not disclose Delamanid Information to any third party unless required by Applicable Laws.

b) After the end of the treatment of the Patient, the Physician shall return all Delamanid Information to Otsuka, or, to the extent the Delamanid Information have been supplied by Otsuka in electronic format, delete them permanently.

8) Publicity

a) In the event that the Physician intends to make any academic, scientific or medical publication or public presentation relating to the result of the treatment of the Patient under these "Terms and Conditions", the Physician shall submit to Otsuka a written copy of such proposed publication or presentation, along with its manuscripts, abstracts or slides. In order to ensure that Otsuka will be able to make comments and suggestions where pertinent, material for public dissemination will be submitted to Otsuka for review no later than forty five (45) days prior to the planned submission for the proposed publication or presentation.

b) No publication or presentation shall be made unless and until all the reasonable comments made by Otsuka on the proposed publication or presentation have been incorporated into the publication and any information has been removed that is determined by Otsuka to be Confidential Information or that Otsuka desires to maintain in secrecy to preserve the value of its rights relating to Delamanid.

9) Governing Law and Jurisdiction

a) These "Terms and Conditions" shall be construed and interpreted in accordance with the laws of Germany, with the exclusion of its conflict of law rules.

b) The courts of Munich (Landgericht München I) shall have exclusive jurisdiction on any claims or disputes in relation to the validity, interpretation or performance of these "Terms and Conditions".

10) Miscellaneous

a) Sections 2 c), 7, 8 and 9 shall survive the termination or the completion of the treatment of the Patient.

11) Communications

All communications to Otsuka shall be addressed as follows:

Office Address: Otsuka Novel Products GmbH, Erika-Mann-Str. 21, 80636 Munich, Germany

Tel No.: + 49 89 2060205-00

E-mail address: Medical@otsuka-onpg.com