Expanded Access Program (EAP) Patient Access Form

This form should be fully completed by the treating physician and submitted to: ExpandedAccess@taihooncology.com

Physicians Details
(PLEASE USE BLOCK CAPITAL LETTERS)

First Name: _____

Last Name: _____

Work Email Address: _____

Work Telephone Number: _____

Institution:_____

Street/Number:_____

City: _____

State: _____

Zip Code: _____

Medical License Number: _____

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Delivery Details
Pharmacist's Details
(PLEASE USE BLOCK CAPITAL LETTERS)
First Name: _____

Last Name: _____

Work Email Address: _____

Work Telephone Number: _____

Pharmacist's Registration/License Number: _____

Delivery Address:

Name Hospital/Pharmacy: _____

Street/Number: _____

City:_____

State: _____

Zip Code: _____

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Section 1 : Information & Medical History of the Patient (the "Patient")			
Patient Initials		**Year of birth** (YYYY)	
Sex		**Weight** (☐ **kg or** ☐ **lbs.)**	**Height** (☐ **cm or** ☐ **in)**
Indications for EAP and drug Requested	*Please indicate the intended treatment - Cancer Diagnosis:*		
Reason(s) for applying for EAP	*Please describe shortly the main reason(s) for applying for EAP:*		
DOSE TO BE ADMINISTERED TO PATIENT _____			
Prior therapies			
Was the patient intolerant or have they clinically/radiologically progressed on prior therapy/therapies? Please provide a description.			

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Physician Declaration

1. I have requested the supply of [_____] for the Patient on an unlicensed basis.
   (Insert name of Taiho Drug or Company Drug Code)
2. NOTE: For the purposes of this document "unlicensed" means the product is not commercially available in the country of destination and is an investigational compound.
3. Processing of Physician Personal Data.
   I acknowledge and agree that:
   - Taiho Oncology, Inc. 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 / license number.

   - Taiho shall be entitled to contact me by post, email and / or telephone to obtain my views on its product and seek information on patient's outcome to carry out studies and research. I may opt out at any time by using the **signature section below**

   I opt out from providing Taiho information related to my views regarding [_____] or information on patient's outcomes.
   (Insert name of Taiho Drug or Company Drug Code)

   Signature:_____

   - Taiho 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.
   - Under applicable data protection laws, 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. To do this, I will contact Taiho Oncology, Inc. at PrivacyOfficer@taihooncology.com.

4. **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
   [ ] may be:
   (Insert name of Taiho Drug or Company Drug Code)
   - provided to and processed by Taiho Oncology, Inc.,
   - disclosed to governmental, tax or regulatory authorities and other persons as required or permitted by law; and
   - used to enable Taiho Oncology, Inc. to track medical outcomes and the progress of the Patient, to perform statistical analysis, including to analyze participation levels in relation to the program and produce related reports, and that his / her personal data may potentially be anonymized into aggregate form to facilitate this.

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Acknowledgment and Consent

I have acknowledged and understood the "**Terms and Conditions**" attached hereto, and, by signing below, agree to comply with them once Taiho Oncology, Inc. has decided to supply [_____] to me on an unlicensed basis.

(Insert name of Taiho Drug or Company Drug Code)

1. I hereby consent to the use and processing of my personal data as further specified above under **Physician Declaration Section**.
2. 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 **Processing of Patient Personal Data Section**.

Physician's Name
(PLEASE USE BLOCK CAPITAL LETTERS)

_____

Physician's signature

_____

Date _____ (DD-MMM-YYYY)

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"Terms and Conditions"

These Terms and Conditions are between you (the Physician) and Taiho Oncology, Inc.

1) Prescription of [_____] and Treatment of the Patient
(Insert name of Taiho Drug or Company Drug Code)

a) The prescription of [_____] 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.
(Insert name of Taiho Drug or Company Drug Code)

b) The Physician will receive from Taiho Oncology, Inc. the Investigator Brochure ("IB") for [_____]
(Insert name of Taiho Drug or Company Drug Code)

c) The Physician shall comply with all legislations, rules, regulations and guidelines on unlicensed use that are applied in the United States of America where the Physician conducts the treatment of the Patient (the "Applicable Laws"), including but not limited to submitting a patient specific IND to the FDA.

2) Investigational Drug Supply

a) The Physician requests that Taiho will supply [_____] to the Physician in the quantities necessary for the treatment according to the patients' needs month by month unless otherwise provided by the Applicable Laws. However, the Physician agrees that Taiho Oncology, Inc. may decide, at its sole discretion, to terminate the further supply of [_____] for this unlicensed use.
(Insert name of Taiho Drug or Company Drug Code)
(Insert name of Taiho Drug or Company Drug Code)

b) The Physician agrees that Taiho Oncology, Inc. supplies [_____] "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 [_____], and commits to comply with the storage requirements.
(Insert name of Taiho Drug or Company Drug Code)
(Insert name of Taiho Drug or Company Drug Code)

c) The Physician shall not use [_____] supplied by Taiho Oncology, Inc. for any other purposes than the treatment of the specific Patient that the drug was requested and distributed for. In case the treatment of the Patient with [_____] is no longer needed, or these "Terms and Conditions" are terminated, or upon the completion of the treatment of the Patient, the Physician shall destroy as appropriate the drug remaining, pursuant to applicable laws, regulations and guidelines.
(Insert name of Taiho Drug or Company Drug Code)
(Insert name of Taiho Drug or Company Drug Code)

3) Local Authority's Approval

a) In line with Applicable Laws, the Physician shall obtain the approval of the local competent authority - FDA - for the treatment of the Patient with [_____]. The Physician shall include all required information for Expanded Use in the Individual Patient Expanded Access Investigational New Drug Application (IND) submitted to FDA.
(Insert name of Taiho Drug or Company Drug Code)

b) The Physician shall obtain the approval of the Institutional Review Board for the treatment of the Patient with [_____]. The Physician shall include all required information for Expanded Use in the application for IRB Approval.
(Insert name of Taiho Drug or Company Drug Code)

c) The Physician shall notify Taiho Oncology, Inc. without undue delay when the IND for Expanded Access is in effect or when FDA notified the physicians that treatment may begin, in order to initiate drug shipment.

4) Informed consent

a) The Physician shall obtain the written informed consent of the Patient or their legal representative for the treatment with [_____], which in this case means the informed consent of the Patient.
(Insert name of Taiho Drug or Company Drug Code)

5) Pharmacovigilance

a) The Physician shall monitor the Patient for adverse events and fulfil all the reporting requirements to FDA in accordance with Applicable Laws. The Physician shall also inform Taiho Oncology of serious adverse events:

- *Unexpected Fatal or Life Threatening Suspected Adverse Reactions*- Report to FDA within 7 calendar days of awareness and send a copy to Taiho Oncology within 24 hours.
- *Serious & Unexpected Suspected Adverse Reactions*- Report to FDA within 15 calendar days of awareness and send a copy to Taiho Oncology within 24 hours.
- *All other Serious cases (Expected and Related; Expected and Not related; Unexpected and Not related)* - send a copy to Taiho Oncology within 2 weeks of awareness.

b) All serious adverse events must be sent on a completed MedWatch Form to Taiho Oncology via fax: 609-750-7371 or e-mail: Safety@taihooncology.com

- All MedWatch Forms must clearly specify SAE term(s) and corresponding investigator causality assessment.

6) Confidentiality

a) The Physician shall treat all information supplied by Taiho Oncology, Inc. in relation to [_____] whether before or after the effective date, including but without limitation the Investigator's Brochure as confidential information of Taiho Oncology, Inc., and shall not disclose [_____] information to any third party unless required by Applicable Laws.
(Insert name of Taiho Drug or Company Drug Code)
(Insert name of Taiho Drug or Company Drug Code)

b) After the end of the treatment of the Patient, the Physician shall confirm destruction of all [_____] Information to Taiho, or, to the extent [_____] Information have been supplied by Taiho in electronic format, delete them permanently.
(Insert name of Taiho Drug or Company Drug Code)
(Insert name of Taiho Drug or Company Drug Code)

7) 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 Taiho Oncology, Inc. a written copy of such proposed publication or presentation, along with its manuscripts, abstracts or slides. In order to ensure that Taiho will be able to make comments and suggestions where pertinent, material for public dissemination will be submitted to Taiho Oncology, Inc., 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 Taiho on the proposed publication or presentation have been incorporated into the publication and any information has been removed that is determined by Taiho to be Confidential Information or that Taiho desires to maintain in secrecy to preserve the value of its rights relating to [_____].
(Insert name of Taiho Drug or Company Drug Code)

8) Governing Law and Jurisdiction

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

9) Miscellaneous

a) Sections 6, 7, 8 and 9 shall survive the termination or the completion of the treatment of the Patient.

10) Communications

a) All communications to Taiho Oncology, Inc. shall be addressed via email to ExpandedAccess@taihooncology.com