Expanded Access and Compassionate Use Policy (US)

Sumitomo Dainippon Pharma Oncology, Inc. is committed to the development of therapies to benefit patients who have not had success with existing, available therapies. Our aim is to provide these therapies to the broadest number of patients possible, through performance of clinical research with the goal of obtaining regulatory approval. Approval by regulatory authorities is the only way to make medicines broadly available to patients by prescription from a qualified healthcare provider. The performance of clinical research allows SDP Oncology to properly evaluate our investigational therapies to generate requisite safety and efficacy data to secure such an approval. Please see clinicaltrials.gov for a full listing of ongoing SDP Oncology clinical trials.

We believe investigational products are best studied within the conduct of a clinical trial and encourage patients to enroll in a clinical trial wherever possible. We do recognize, however, that some patients with serious or immediately life-threatening diseases may not be eligible for any clinical trials and may not have other options. Therefore, SDP Oncology may consider expanded access to investigational products for patients residing in the United States and who may benefit from our investigational therapies currently in development. SDP Oncology's Expanded Access and Compassionate Use Policy, as summarized below, describes the principles and general procedures that SDP Oncology will follow when considering a request for such use.

Criteria for Evaluating Access to Investigational Agents Outside of SDP Oncology Sponsored Clinical Trials

As stated above, SDP Oncology does not currently provide access to these therapies in an expanded access setting. In the event that SDP Oncology may, in the future, consider such a request, each request for expanded access shall be evaluated in accordance with the SDP Oncology Expanded Access and Compassionate Use Policy, the principles and criteria of which are summarized as follows:

- **The patient must have a serious or immediately life-threatening cancer.**
- **The investigational therapy must be in active clinical development.** SDP Oncology must currently be studying the investigational therapy in human subjects. Once a medicine has been approved by the Food and Drug Administration, expanded access is no longer available.
- **There must be no other viable therapy options, including participation in ongoing and relevant clinical trials.** In order for SDP Oncology to grant expanded access to an investigational therapy, there must be no comparable or satisfactory alternative

therapy for the disease or condition, or the patient must have exhausted all available therapies typically used to treat the disease, and no longer be responsive to, or able to tolerate, these treatments. In addition, the patient must not be able to qualify for participation in, or have access to, any ongoing or soon opening SDP Oncology sponsored clinical trials. Geographic limitations to participation in clinical trials are not sufficient to meet this criterion.

- **There must be adequate supply of the investigational therapy as needed to accommodate the duration of the requested treatment.**
- **Access on an expanded basis cannot delay, interfere with, or compromise ongoing clinical trials or the potential approval for the product.** Granting access to an investigational therapy cannot interfere with completion of ongoing clinical trials that could support regulatory approval of the investigational therapy.
- **There must be a positive benefit-risk ratio for the patient.** The potential benefit to the patient must always be considered to outweigh the collective potential risks to the patient of offering the therapy. Data from phase 2 or phase 3 studies is typically necessary to support a robust risk-benefit analysis. Consideration will also be given as to whether or not the relevant patient's underlying medical condition may pose a safety risk that has not been sufficiently studied.
- **There is sufficient clinical data to support an appropriate dose (amount and frequency) for the investigational therapy.** It is also required that the therapy can be administered outside of the clinical trial setting.
- **The request must be made by a physician who is qualified and licensed in the United States, who agrees to directly supervise treatment, and who has the expertise and facilities appropriate to administer the investigational therapy.** The requesting physician must also obtain relevant health authority and Institutional Review Board approval/clearance, comply with relevant local and/or country regulations, and agree to follow any conditions or restrictions set by SDP Oncology for the investigational therapy and patient.

Procedure for Requesting Single Patient Expanded Access and Response Times

Requests for access to investigational therapies must be made by a qualified and licensed physician by contacting SDP Oncology Medical Information at: info@bostonbiomedical.com. A link to the Expanded Access clinical program on ClinicalTrials.gov will be provided when the Expanded Access program for the investigational product is initiated.

The physician requesting access must provide specific case information, including pertinent patient history, as well as the following:

- A scientifically sound rationale to evaluate the investigational therapy in this particular case
- A statement that approved therapies typically used to treat the disease have been exhausted and the patient is no longer responsive to, or able to tolerate, these therapies
- A statement that there are no other viable therapy options, including participation in ongoing relevant clinical trials

No Personally Identifiable Information or Personal Health Information should be provided in any request. SDP Oncology will make every effort to acknowledge individual requests that have been submitted **in accordance with the above requirements within five (5) business days of receipt.**

How Decisions Are Made

SDP Oncology is committed to a fair and unbiased evaluation of each request made for access to investigational therapies. All decisions are based solely on the clinical circumstances surrounding each request, in accordance with the principles detailed above. Whenever possible, patients will be referred to ongoing clinical trials as the primary route to access investigational medicines. While the above criteria are those that will be considered by SDP Oncology in its evaluation of whether or not to offer expanded access, SDP Oncology cannot make any guarantee that an investigational therapy will be made available.

Contact for Further Information

Persons with questions about SDP Oncology's policy and procedures for expanded access to SDP Oncology investigational drugs may send an email to the following address: info@bostonbiomedical.com. A link to an Expanded Access clinical program on ClinicalTrials.gov will be provided when the Expanded Access clinical program for the investigational product is initiated.

To learn more about the FDA's regulatory framework for expanded access, including expanded access for individual use please see: www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse