# EMD Serono Position Statement on Post-Study Access to Experimental Medicine

## Why It Matters?

Patients facing life-threatening, chronic or seriously disabling illnesses or diseases livewith the hope that tomorrow will bring a new medicine to extend and improve their lives. EMD Serono is committed to developing new medicines for patients with such illnesses and diseases. EMD Serono believes the best way to fulfill this commitment isto conduct clinical studies to assess the safety and effectiveness of experimental medicines which, if proven, will allow us to obtain marketing authorization from Health Canada and provide patients with broad access to these new medicines. EMD Serono believes that patients who desire access to experimental medicines should be encouraged to participate in clinical studies, the goal of which is to secure approval of new, safe and effective medicines for the broadest number of patients.

EMD Serono also understands that in the conduct of clinical studies, access to experimental medicines following clinical studies is often necessary for the continuedhealth and well-being of patients participating in the studies. EMD Serono also recognizes that continued access to experimental medicine post-studies may be a legal, regulatory and/or ethical obligation under some circumstances. EMD Serono believes patients participating in a company-sponsored or collaborative interventional clinical study (clinical trial) should be given the opportunity to continue treatment with the experimental medicine after the regular end or early termination of a study if the patients still require treatment and are deriving benefit.

EMD Serono encourages patients to consult their physicians to determine the best course of action depending on their individual needs.

## EMD Serono Position Statement

### 1. Principles Governing Post-Study Access to Experimental Medicines

EMD Serono is committed to high quality clinical research, following all legal, ethical and scientific standards. As part of this commitment and in accordance with the Declaration of Helsinki, the ICH Good Clinical Practices and other international guidelines, EMD Serono offers patients who participate in EMD Serono-sponsored study or a collaborative study continued access to the experimental medicine that they received during the study after completing the study, when appropriate, as described below.

EMD Serono will use the following principles to govern when a patient who participates ina EMD Serono-sponsored clinical study or a collaborative study of an experimental medicine shall have continued access to that medicine after completion of the clinical study, free of charge:

a) The patient should have a life-threatening, chronic or seriously disabling illness or disease, as defined by federal or provincial laws and regulations, and the benefits outweigh the risks for this patient to continue to receivethe investigational medicine;

b) There are no appropriate alternative treatments or clinical studies available to the patient; and

c) The patient and his/her own treating physician comply with and satisfy any legal or regulatory requirements applicable to them.

## 2. Exceptions

EMD Serono will not provide post-study access to experimental medicine if:

a) The experimental medicine is commercially marketed in Canada and is reasonably accessible to the patient (e.g., is covered by the patient's insurance or would not otherwise create a financial hardship for the patient);

b) EMD Serono has discontinued development of the experimental medicine or data suggest that the experimental medicine is not effective for the relevant indication;

c) EMD Serono has reasonable safety concerns regarding the experimental medicine for the relevant indication; or

d) Provision of the experimental medicine would not be permitted under the laws and regulations of the patient's province.

## 3. Mechanisms for Providing Post-Study Access

Post-study access plans (i.e., whether drug will be provided post-study and if not, the reason why not) should be included in all EMD Serono-sponsored protocols and informed consent forms so patients are fully aware prior to agreeing to participate in a study.

Post-Study Access is typically implemented in the framework of open-label studies (including open-label extension studies and rollover studies). If no such studies are offered, then access may be considered under one of the following options: Access via EMD Serono's Early Access procedure in the form of a Special Access Programme request (if the drug has not been approved for any indication in Canada), EMD Serono's process for access to an approved medication for an unapproved use (if the drug has been approved for at least one indication in Canada and the patient's treating physician proposes to use it for an unapproved indication), or an EMD Serono patient support or patient access program.