

EAP General Information

The Expanded Access Program (EAP) is not an Open Label Extension (OLE) or clinical research. Expanded Access Programs are also referred to as Compassionate Use programs and in Italy, Nominal Therapeutic Use programs. The EAP gives patients a treatment option that allows the use of an unauthorized/investigational medicinal product outside of clinical trials.

- Nominal Therapeutic Use approvals are issued for individual patients on a case-by-case basis as requested by their physician
- A request for evaluation must come from a licensed health care professional (HCP)
- Participation in the expanded access program is voluntary
- The drug is provided at no cost to the patient while in the EAP

For patients currently or previously enrolled in the SPIMD-301 NuPower clinical trial:

- Subjects that complete at least the Week 48 visit have the opportunity to continue (or begin if on placebo) elamipretide treatment
 - Entering the EAP at the Week 48 or Week 52 study visit ensures that the cost of travel to the visit and the visit itself will be covered by the NuPower study budget
 - Subjects that completed NuPower and choose not to enter the EAP by the Week 52 visit, may be evaluated at a later date with a new request from their HCP
- NuPower trial treatment assignments (whether the subject received drug or placebo) will remain blinded until at least the second half of 2025
 - The last enrolled subject will complete the study in the fall of 2024
- Patients that screen-failed for SPIMD-301 NuPower may be evaluated for the EAP.
- Once in EAP, all patients receive the drug. There is no placebo in EAP.
- Approval is based on individual case review and is not guaranteed

For new patients requesting EAP:

- Physician to submit a request to Stealth Biotherapeutics through the access@stealthbt.com email address or on company website
- Stealth will evaluate each request on a case-by-case basis

Overview of EAP Visits

- In order to participate in EAP, informed consent must be obtained from the patient or their legal guardian.
- Drug will be shipped to the physician's site for patient pickup. If a patient is unable to pick up supply, site can ship drug to patient's home.
- The following are required to continue to receive drug in the EAP:
 - First visit with physician in person to monitor 1st injection of EAP drug
 - Quarterly phone calls with physician and/or their team in which the patient will answer survey questions to evaluate safety and clinical benefit
 - Annual in person visit for standard of care

For questions regarding the EAP or to submit a request for evaluation, please contact access@stealthbt.com