

4<sup>th</sup> May, 2018

Dear Board Members of SMA Europe,

In response to your request for information, we would like to provide you with an update on the Expanded Access Program (EAP) in Belgium.

In 2016, based on the high unmet need in SMA, Biogen sponsored a global Expanded Access Program (EAP) for eligible individuals with infantile-onset SMA (consistent with Type 1). It was initiated at existing nusinersen clinical trial sites and then expanded to multiple countries where EAPs are permitted according to local laws and regulations, where they can be operationalized and where there is a path to long-term availability and reimbursement of SPINRAZA (nusinersen). This program enables wide access to nusinersen subject to applicable inclusion criteria.

In Belgium, all eligible infantile-onset SMA (consistent with Type 1) patients have been identified and treated under the EAP programme. The programme has now closed for all new patients as of 24<sup>th</sup> April 2018 and all centers have been notified. All patients currently enrolled in this EAP may remain in the program until nusinersen is reimbursed locally in Belgium.

A number of the patients participating in the EAP in Belgium are non-Belgian citizens. The decision to treat these patients was at the discretion of the physician and the specific center's institutional policies. It is important to emphasise that Biogen, by law, has not been proactively involved in the patient selection process for the EAP. Unfortunately, these non-Belgian citizens participating in the EAP will most likely be ineligible for reimbursed access to nusinersen once the drug is commercially available in Belgium. For further information, patients should refer to the competent Belgian authorities.

Where possible, patients may be repatriated to their home country for ongoing treatment and care. Repatriation of these patients must be managed by their treating EAP physician. Biogen is unable to be proactively involved in this process. For more information, patients and their families should contact their treating physician. If requested, Biogen will work with relevant stakeholders including clinicians, the patient community and health authorities to help find potential avenues for all current SMA patients who are included in the Belgium EAP to have ongoing access to nusinersen without unnecessary delays.

Finally, Biogen is unable to provide guidance on individual patient care. For more information patients and their families should contact their treating physician.

Please be assured we continue to be deeply focused on collaborating with government agencies across Europe and globally to accelerate reimbursement and broad access. We are thankful to the entire SMA community for their continued support. We remain committed to transparent and timely communications and will continue to be available to provide requested updates.

Sincerely,  
The Biogen SMA Team