Biogen

September 28, 2016

Dear members of the SMA community,

In response to your requests for information, we want to provide an update on the important progress made in moving the development program forward. Recently, we have achieved a crucial step in the pathway to approval of nusinersen. We have completed the submission of our New Drug Application (NDA) to the Food and Drug Administration (FDA) and our application to the European Medicines Agency (EMA). Biogen will initiate regulatory filings in other countries, including Canada, in the coming months.

We are incredibly thankful to the entire SMA community for your continued support. We still have additional milestones to complete before a potential approval and the final approved label, but we are getting closer. A product label will instruct physicians on the use of an approved treatment and the final product label is ultimately decided by each regulatory authority representing a country or region where approval is being sought. For each regulatory submission we are providing all of the data we have to date, and we are seeking a broad label for the treatment of SMA. Again, if approved, the final label is decided by the regulatory agencies and is based on their assessment of the data we provide to them. We know there will continue to be many questions such as the timelines of the approval process, the potential label if nusinersen is approved, and about our ongoing plans for expanded access. We remain committed to transparent and timely communications and will continue to be available to provide any requested updates as the program moves forward.

For further questions, please contact Biogen Canada Inc

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