Statement from Novartis on AVXS-101 filing with Health Canada

Jun 19, 2020

June 18, 2020 – Dorval - Novartis Pharmaceuticals Canada Inc. is pleased to announce the filing of a marketing application to Health Canada for AVXS-101 (onasemnogene abeparvovec), known in the US and other countries where it is approved as Zolgensma™, for the treatment of spinal muscular atrophy (SMA). The file has been granted Priority Review status and the company anticipates a decision by the end of the year.

Health Canada may grant Priority Review status to drug submissions intended for the treatment, prevention or diagnosis of serious, life-threatening or severely debilitating diseases or conditions where there is no existing drug on the Canadian market or where the new product represents a significant improvement in the benefit/risk profile over existing products.[1]

“Today’s announcement marks an important milestone in our journey to tackle the unmet needs of children diagnosed with SMA. As Novartis prepares to bring this one-time gene therapy to Canadians, we are committed to working collaboratively with regulatory, pricing and reimbursement authorities in providing eligible patient access as quickly as possible,” said Gerrit Zijlstra, Chief Scientific Officer and Vice President Scientific Affairs (a.i.).

Novartis welcomes the ongoing interest in our commitments in SMA and will continue publicly communicating updated information on our activities and key milestones whenever possible. We share the community’s wish for the best possible outcomes for those living with and affected by SMA and look forward to Health Canada’s decision.

For more information:

Julie Schneiderman
Novartis Corporate Communications
+1 514 633 7873
E-mail: camlph.communications@novartis.com

References

1. Health Canada. Priority Review of Drug Submissions (Therapeutic Products). Available at: https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/prfs_tpfd-eng.pdf (PDF 0.1 MB). Last accessed June 10, 2020.

3. https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/prfs_tpfd-eng.pdf