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Update to the Duchenne Community

As many of you are aware, in late January the Committee for Medicinal Products for Human Use (CHMP) issued a negative opinion regarding the annual renewal of the conditional marketing authorization for Translarna™ (ataluren). Today we announced that the European Commission (EC) has decided against the adoption of the negative opinion and has returned the opinion to the CHMP for re-evaluation. **This action allows Translarna to remain on the market and available for patients in Europe consistent with its current marketing authorization.**

The EC has directed the CHMP to further consider the totality of evidence, including data from patient registries and real-world evidence in a revised opinion. This is a positive step to help maintain access to Translarna for boys and young men living with nonsense mutation Duchenne muscular dystrophy in Europe and reinforces the importance of the totality of evidence gathered from clinical trials and the STRIDE real-world patient registry.

We look forward to providing additional updates when available, but, for now Translarna remains authorized and available in Europe.

We are grateful for the support of the entire Duchenne community as we work towards making Translarna available to all that may benefit from it.