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# Alnylam launches first-ever RNAi therapeutic in Germany

08 October 2018 | News

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Alnylam Pharmaceuticals, Inc., the leading RNA interference (RNAi) therapeutics company has announced that ONPATTRO (patisiran) is now available in Germany.

ONPATTRO has been developed to meet a significant unmet need for patients with hereditary ATTR amyloidosis, a devastating, chronic and often fatal disease. Hereditary transthyretin (TTR)-mediated amyloidosis (hATTR) is an inherited, progressively debilitating, and often fatal disease caused by mutations in the TTR gene.

ONPATTRO is based on Nobel Prize-winning science and is the first-ever RNAi therapeutic to be approved in the European Union. Alnylam plans to launch ONPATTRO in additional markets in Europe throughout 2018 and 2019.

“The launch of ONPATTRO in Germany, just over a month after being granted approval by the European Medicines Agency, is a demonstration of our commitment to deliver innovative medicines with the potential to transform the lives of patients suffering from hATTR amyloidosis and our recognition of the urgency of unmet medical needs in this patient community,” said Hannes Schmeil, Country General Manager, Alnylam Germany. “Up until now, patients in Germany lacked medical treatment options with the potential to halt the progression of their disease. ONPATTRO will provide physicians, patients and their families with a new treatment option that we hope will make a meaningful difference to patients’ lives, restoring their hope for the future.”

The European Commission decision was based on the evaluation of the effects of patisiran in hATTR amyloidosis patients with polyneuropathy and its safety profile as demonstrated in the APOLLO Phase 3 study, the largest-ever study in hATTR amyloidosis patients with polyneuropathy. Results from the APOLLO study were published in the July 5, 2018, issue of The New England Journal of Medicine. The Summary of Product Characteristics (SmPC) includes data from APOLLO on primary and secondary endpoints, as well as exploratory cardiac endpoints. The SmPC allows for the administration of patisiran in the home setting under the supervision of a healthcare professional provided infusions are being tolerated well by the patient. The European Medicines Agency reviewed patisiran under the accelerated assessment procedure that is granted to medicines judged to be of major interest for public health and therapeutic innovation.