

Another gene therapy product was approved by the FDA

Another gene therapy product, Luxturna from Sparks Therapeutics, was approved December 19 by the FDA, the US food and drug regulatory authority. This clearly demonstrates what potential gene therapy has.

A statement from the commissioner of the FDA, Scott Gottlieb, also shows how well positioned we, as a gene therapy company, are:

"I believe gene therapy will become a mainstay in treating, and maybe curing, many of our most devastating and intractable illnesses..." and "We're at a turning point when it comes to this novel form of therapy and at the FDA, we're focused on establishing the right policy

framework to capitalize on this scientific opening. Next year, we'll begin issuing a suite of disease-specific guidance documents on the development of specific gene therapy products to lay out modern and more efficient parameters – including new clinical measures – for the evaluation and review of gene therapy for different high-priority diseases where the platform is being targeted."

About CombiGene AB

By combining modern neuroscience with recent advances in gene delivery, CombiGene has developed a method shown to suppress epileptic seizures in preclinical studies. The current focus is on continuing to develop this method into an effective and safe therapy for epilepsy patients, but the method may also have development potential as a means of treating other neurological disorders. Founded on the basis of scientific discoveries made at Lund University and the University of Copenhagen, CombiGene has offices at Medicon Village in Lund, Sweden. The company is public and listed on the Swedish marketplace AktieTorget. www.combigene.com

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