October 13 2017

Spark Therapeutics surge premarket after getting FDA committee endorses its blindness treatment

Spark Therapeutics Inc. (NASDAQ:ONCE) shares surged in premarket trade after a U.S. Food and Drugs Administration advisory committee recommended approval of its gene therapy treatment for a rare eye disease that causes blindness.

Its shares rose 6.03% at US$91.40 in premarket trade.

The committee voted unanimously to approve Luxturna (voretigene neparvovec) in the treatment of patients with biallelic RPE65-mediated inherited retinal disease.

No current treatment available
There is currently no treatment for the disease, which causes childhood blindness.

Luxturna has received orphan drug, breakthrough therapy and rare pediatric disease designations from the agency, the company said in a statement.

Although the committee’s ruling is non-binding, it is taken into consideration by the FDA when reviewing drug applications.

The drug has also orphan product designation from the European Medicines Agency. Its marketing authorisation application for Luxturna was validated by the EMA, the company added.

Spark Therapeutics is engaged in developing products in the field of gene therapy. Spark's product candidate, SPK-RPE65, which is in Phase III clinical trial stage, targets a group of rare blinding conditions known as inherited retinal dystrophies, caused by non-sex linked or autosomal recessive mutations in the RPE65 gene.

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