

SPARC licenses ELEPSIA XRTM(Levetiracetam ER Tablets) to Sun Pharma

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Sun Pharma Advanced Research Company Ltd. and Sun Pharma announced a licensing arrangement for SPARC's ELEPSIA XRTM (Levetiracetam Extended Release tablets).

As per the agreement, SPARC will license ELEPSIA XRTM (Levetiracetam Extended Release tablets) to a wholly-owned subsidiary of Sun Pharma for the US market. SPARC will receive an up-front payment of US\$10 million from Sun Pharma. It is also eligible for certain additional milestone payments and defined royalties linked to any future sales of ELEPSIA XRTM.

ELEPSIA XRTM was approved by the USFDA in March 2015. However, in September 2015, SPARC received a complete response letter (CRL) from the USFDA rescinding its earlier approval, citing that the compliance status of the manufacturing facility viz., Halol site of Sun Pharma was not acceptable on the date of approval. Sun Pharma has undertaken a detailed remediation at Halol for restoring cGMP compliance status for the site.

Anil Raghavan, CEO, SPARC said, "The licensing of ELEPSIA XRTM is a step ahead in our desire to make it available for thousands of epilepsy patients taking multiple pills of Levetiracetam every day. ELEPSIA XRTM is designed as a novel once-a-day formulation of Levetiracetam using SPARC's proprietary Wrap Matrix technology. It is designed to reduce pill burden and help improve convenience and compliance in these patients. If and when the USFDA reapproves the ELEPSIA XRTM application, Sun Pharma's significant US presence will help SPARC in commercializing this important product for patients in the US market."

Commenting on the in-licensing, Kirti Ganorkar, Senior Vice President, Business Development, Sun Pharma said, "The in-licensing of ELEPSIA XRTM will facilitate Sun Pharma's anticipated entry into the proprietary CNS segment in the US. This is a part of Sun Pharma's strategy, to strengthen its presence in the US specialty segment through its newly created Sun Neurosciences business unit. We believe that SPARC's Wrap Matrix™ technology will help in differentiating ELEPSIA XRTM amongst other competing products."