



**FOR IMMEDIATE RELEASE**

## **SPARC Licenses Commercialization Rights of Elepsia™ XR to Tripoint Therapeutics**

**MUMBAI – September 22, 2020**, Sun Pharma Advanced Research Company Ltd. (SPARC) (Reuters: SPRC.BO, Bloomberg: SPADV IN, NSE: SPARC, BSE: 532872) today announced the grant of an exclusive license to Tripoint Therapeutics LLC, USA (Tripoint) to commercialize Elepsia™ XR 1000 mg and Elepsia™ XR 1500 mg tablets in the USA.

Under terms of the license agreement, SPARC will be eligible to receive tiered royalties ranging from 15% to 50% on net sales. Tripoint will be responsible for all US regulatory submissions and payment of annual PDUFA fees for Elepsia™ XR 1000 mg and Elepsia™ XR 1500 mg.

The initial term of the agreement shall be 5 years and may be further extended as per mutual agreement between the parties.

“Elepsia™ XR can bring down the daily pill burden significantly and will be an alternative treatment option for patients suffering with epilepsy,” said Anil Raghavan, CEO of SPARC.

President of Tripoint, Steve Squashic said “We are very excited about the relationship with SPARC and look forward to bringing Elepsia™ XR to patients in USA.”

### **About Elepsia™ (Levetiracetam) XR 1000 mg/1500 mg tablet:**

Elepsia™ XR is a novel product designed and approved by the USFDA as an extended release formulation of Levetiracetam 1000 mg/1500 mg, indicated as adjunctive therapy for the treatment of partial onset seizures in patients 12 years of age and older, developed using SPARC’s WrapMatrix™ technology.

### **Important Safety Information**

#### **Contraindications**

Elepsia™ XR is contraindicated in patients with a hypersensitivity to levetiracetam. Reactions have included anaphylaxis and angioedema.

#### **Warnings and Precautions**

**Behavioral Abnormalities and Psychotic Symptoms:** Elepsia™ XR may cause behavioral abnormalities and psychotic symptoms. Patients treated with Elepsia™ XR should be monitored for psychiatric signs and symptoms.

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Registered Office : SPARC, Akota Road, Akota, Vadodara - 390 020, Gujarat, India.



**Suicidal Behavior and Ideation:** Antiepileptic drugs (AEDs), including Elepsia™ XR, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Patients treated with any AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior.

**Somnolence and Fatigue:** Elepsia™ XR may cause somnolence and fatigue. Patients should be monitored for these signs and symptoms and advised not to drive or operate machinery until they have gained sufficient experience on Elepsia™ XR to gauge whether it adversely affects their ability to drive or operate machinery.

**Anaphylaxis and Angioedema:** Elepsia™ XR can cause anaphylaxis or angioedema after the first dose or at any time during treatment. Signs and symptoms in cases reported in the post-marketing setting in patients treated with levetiracetam have included hypotension, hives, rash, respiratory distress, and swelling of the face, lip, mouth, eye, tongue, throat and feet. In some reported cases, reactions were life-threatening and required emergency treatment. If a patient develops signs or symptoms of anaphylaxis or angioedema, Elepsia™ XR should be discontinued and the patient should seek immediate medical attention. Elepsia™ XR should be discontinued permanently if a clear alternative etiology for the reaction cannot be established.

**Serious Dermatological Reactions:** Serious dermatological reactions, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), have been reported in patients treated with levetiracetam. The median time of onset is reported to be 14 to 17 days, but cases have been reported at least four months after initiation of treatment. Recurrence of the serious skin reactions following rechallenge with levetiracetam has also been reported. Elepsia™ XR should be discontinued at the first sign of a rash, unless the rash is clearly not drug-related. If signs or symptoms suggest SJS/TEN, use of this drug should not be resumed and alternative therapy should be considered.

**Coordination Difficulties:** Coordination difficulties were not observed in the extended-release levetiracetam controlled trials, however, the number of patients exposed to levetiracetam extended-release tablets was considerably smaller than the number of patients exposed to immediate-release levetiracetam tablets in controlled trials. However, adverse reactions observed in the immediate-release levetiracetam controlled trials may also occur in patients receiving Elepsia™ XR.

**Withdrawal Seizures:** As with most antiepileptic drugs, Elepsia™ XR should be withdrawn gradually because of the risk of increased seizure frequency and status epilepticus. But if withdrawal is needed because of an adverse event, rapid discontinuation can be considered.

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**Hematologic Abnormalities:** Elepsia™ XR can cause hematologic abnormalities. Hematologic abnormalities occurred in clinical trials of immediate-release levetiracetam and included decreases in white blood cells (WBC), neutrophil, and red blood cell (RBC) counts; decreases in hemoglobin and hematocrit; and increases in eosinophil counts. Cases of agranulocytosis, pancytopenia, and thrombocytopenia have also been reported in the post-marketing setting. A complete blood count is recommended in patients experiencing significant weakness, pyrexia, recurrent infections, or coagulation disorders.

**Seizure Control During Pregnancy:** Physiological changes may gradually decrease plasma levels of levetiracetam throughout pregnancy. This decrease is more pronounced during the third trimester. It is recommended that patients be monitored carefully during pregnancy. Close monitoring should continue through the postpartum period especially if the dose was changed during pregnancy.

**Adverse Reactions:** In the controlled clinical study in patients with partial-onset seizures, the most common adverse reactions in patients receiving levetiracetam extended-release tablets in combination with other AEDs, for events with rates greater than placebo, were irritability and somnolence. The following table lists the adverse reactions that occurred in at least 5% of epilepsy patients receiving levetiracetam extended-release tablets in the placebo-controlled study and were numerically more common than in patients treated with placebo. In this study, either levetiracetam extended-release tablets or placebo was added to concurrent AED therapy.

**Adverse Reactions in the Placebo-Controlled, Add-On Study in Patients Experiencing Partial-Onset Seizures**

Adverse Reactions	Levetiracetam Extended-Release Tablets (N=77) %	Placebo (N=79) %
Influenza	8	4
Somnolence	8	3
Irritability	7	0
Nasopharyngitis	7	5
Dizziness	5	3
Nausea	5	3

**Discontinuation or Dose Reduction in the Levetiracetam Extended-Release Tablets Controlled Clinical Study:** In the controlled clinical study, 5% of patients receiving levetiracetam

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extended-release tablets and 3% receiving placebo discontinued as a result of an adverse reaction. The adverse reactions that resulted in discontinuation and that occurred more frequently in levetiracetam extended-release tablet-treated patients than in placebo-treated patients were asthenia, epilepsy, mouth ulceration, rash, and respiratory failure. Each of these adverse reactions led to discontinuation in a levetiracetam extended-release tablet-treated patient and no placebo-treated patients.

**About SPARC (CIN: L73100GJ2006PLC047837):**

Sun Pharma Advanced Research Company Ltd. ('SPARC') is a pharmaceutical company focused on continuously improving standards of care for patients globally through innovation in therapeutics and delivery. SPARC consistently aims to lower costs and improve operational efficiencies to advance availability and affordability of cures for patients across the world. More information about the company can be found at [www.sparc.life](http://www.sparc.life).

**About Tripoint Therapeutics LLC.**

Tripoint Therapeutics LLC ('Tripoint') is a private, USA focused growth-oriented specialty pharmaceutical company based in Westfield, NJ. Tripoint is focused on developing and commercializing high-value products in CNS, pain and primary care. Tripoint partners with numerous pharmaceutical companies throughout the world for acquisitions, licensing and the development of commercial products and late stage development assets.

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