



**FOR IMMEDIATE RELEASE**

## **SPARC Provides Update on Pivotal Phase III Studies of Baclofen GRS for Treatment of Spasticity in Patients with Multiple Sclerosis**

*Baclofen GRS did not meet the primary end point in placebo controlled studies.*

**SPARC to Host Analyst Conference Call on October 9, 2017 at 4:30 PM IST**

**Mumbai (India), Oct 6, 2017** - Sun Pharma Advanced Research Company Ltd. (SPARC) (Reuters: SPRC.BO, Bloomberg: SPADV IN, NSE: SPARC, BSE: 532872) announced the top-line results of the Phase III efficacy study and duration of action study for Baclofen GRS.

**The Phase III efficacy study (CLR\_09\_21)** was a placebo controlled randomized discontinuation study that investigated the efficacy and safety of Baclofen GRS in patients with spasticity due to multiple sclerosis.

The primary efficacy outcome was the proportion of subjects who experienced loss of efficacy following discontinuation of Baclofen GRS. Loss of efficacy was defined as becoming "minimally worse", "much worse" or "very much worse", and experiencing a  $\geq 1$  unit increase in the modified Ashworth score, following discontinuation of drug. The study consisted of a total of 293 subjects in the intent to treat population.

Although there was a trend towards a difference in treatment failure rates between placebo and Baclofen GRS following drug discontinuation, the results did not reach statistical significance ( $p \sim 0.20$ ).

The subject global impression of severity score (SGIS) was assessed as a secondary endpoint. Results for this endpoint were statistically significant, and favored Baclofen GRS ( $p < 0.05$ ). Several other endpoints, such as spasm frequency and nighttime awakenings, also favored Baclofen GRS (both  $p < 0.001$ ).

**The Phase III duration of action study (CLR\_11\_03)** was a double-blind, randomized, placebo-controlled, parallel group trial to evaluate the duration of action of baclofen GRS 30 mg and 60 mg compared to placebo in subjects with spasticity due to multiple sclerosis.



Duration of effect was assessed using the total modified Ashworth score over time following administration of Baclofen GRS or placebo.

The intent to treat population consisted of 135 subjects. Baclofen GRS did not show a statistically significant improvement in total modified Ashworth score over 24 hours compared to placebo in this study.

**An Open Label Extension study (CLR\_11\_04)**, consisting of subjects from the efficacy and duration of action studies is ongoing.

"We are disappointed with the outcomes of these studies and will evaluate the data in greater detail to decide on our next steps. We thank all the patients, investigators and caregivers whose hard work has contributed important information to the Baclofen GRS program", stated Anil Raghavan, CEO, SPARC.

#### **About Baclofen GRS**

Baclofen GRS is a novel, once-a-day formulation developed by SPARC's proprietary Gastro-Retentive System (GRS) Technology. The GRS technology uses a combination of size expansion, adhesion and flotation techniques to permit once-a-day administration.

#### **Forward looking statement of SPARC**

Statements in this document describing the Company's objectives, projections, estimates, expectations, plans or predictions or industry conditions or events may be "forward looking statements" within the meaning of applicable securities laws and regulations. Actual results, performance or achievements could differ materially from those expressed or implied.

#### **Analyst Conference Call (04.30 pm IST, October 9, 2017)**

The Company will host an analyst call at 04.30 pm IST on October 9, 2017, where senior management will answer questions from participants. This call will be accessible through an audio dial-in.

*Audio conference*      *Participants can dial-in on the numbers below*  
**Primary number:** +91 22 3960 0899  
**Playback of call:** +91 22 3065 2322, *Playback code: 58599*

To participate in the audio call, please dial the primary number provided above five to ten minutes ahead of the scheduled start time. The operator will provide instructions on asking questions before the call. The playback will be available for a few days.



**About SPARC (CIN: L73100GJ2006PLC047837)**

Sun Pharma Advanced Research Company Ltd. (SPARC) is an international pharmaceutical company engaged in research and development of drugs and delivery systems. More information about the company can be found at [www.sparc.life](http://www.sparc.life)

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