Sedor Pharmaceuticals NDA for CE-Fosphenytoin for Status Epilepticus Receives PDUFA Date

Potential significant advance for life threatening condition

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PAOLI, Pa., --(BUSINESS WIRE)— **Sedor Pharmaceuticals, LLC (Sedor)** announced that the US FDA accepted its 505(b)2 NDA (210864) for Sedor's lead program, IM/IV Captisol-Enabled™ (CE) Fosphenytoin,(fosphenytoin sodium and sulfobutylether beta-cyclodextrin sodium for injection**)** with a PDUFA date of March 22, 2019. IM/IV Captisol-Enabled™ (CE) Fosphenytoin has been filed for (1) treatment of generalized tonic-clonic status epilepticus, (2) prevention and treatment of seizures occurring during neurosurgery, (3) substitution short-term use for oral phenytoin, when oral phenytoin administration is not possible, and (4) pediatric use.

Status epilepticus is a single epileptic seizure lasting more than five minutes or two or more seizures within a five-minute period. Importantly, it is critical that status epilepticus seizures be treated in a short time window. The Neurocritical Care Society Guidelines estimates that if cessation of seizure is not achieved within 60 minutes of onset, irreversible brain damage or death may result.

Cerebyx (fosphenytoin sodium) is currently indicated for status epilepticus, but requires refrigerated storage in the pharmacy, raising the risk of delayed treatment. CE-Fosphenytoin does not require refrigeration and if approved, holds potential for optimal onsite storage and rapid dispensing in emergency rooms, intensive care units, first responder vehicles, and long-term care facilities for serial seizures.

Barry Frankel, Chief Business Officer and co-founder of Sedor, commented, "We are delighted to report the achievement of this major milestone. It is clear from both US and EU guidelines that time to treat and cessation of a status epilepticus seizure is critical to avoiding the potential for irreversible morbidity and associated hospital costs, and mortality. CE-Fosphenytoin, if approved by the FDA, will offer health care providers the only room temperature readily available fosphenytoin and, as such, an important alternative when treating this critical condition."

CE-Fosphenytoin is available for licensing in North America, Europe, and other territories except for the Peoples Republic of China, where it has already been successfully licensed. Sedor is also in the process of seeking additional financing for pipeline development. Geller Biopharm, Inc exclusively represents Sedor Pharmaceuticals for all business development activities.

About Sedor Pharmaceuticals, LLC

Sedor Pharmaceuticals, LLC identifies and acquires acute care hospital pharmaceutical assets and applies its team's deep development, operational, manufacturing and commercialization expertise to create global clinical and economic value. The company is led by John Sedor as Chairman and an experienced team of pharmaceutical professionals with a proven track record building pharmaceutical companies and shareholder value. The company's lead program, CE-Fosphenytoin, has been filed with the FDA for the treatment of status epilepticus offering, if approved, the potential to shorten seizure duration and improve outcomes. The company's second program, CE-Meloxicam, is preparing for Phase I development for the treatment of acute post-surgical pain and, if approved, offers the potential to replace or delay the use of IM/IV opioids. Both products were licensed from Ligand Pharmaceuticals.

Forward-Looking Statements

This news release contains forward-looking statements that involve risks and uncertainties and reflect the parties' judgment as of the date of this release. Words such as "plans," "believes," "expects," "anticipates," and "will," and similar expressions, are intended to identify forward-looking statements. These forward-looking statements include, without limitation, statements regarding: growth in the number of products in Sedor's portfolio, the research and development expenditures of Sedor's partners, and the timing and results of Sedor's clinical trials and clinical trials. Actual events or results may differ from Sedor's expectations. For example, Sedor and its partners may not be able to timely or successfully advance any product(s) in its internal or partnered pipeline. In addition, there can be no assurance that results of any clinical study will be timely, favorable or confirmed by later studies, that products under development by Sedor or its partners will receive regulatory approval, that there will be a market for the product(s) if successfully developed and approved, or that Sedor's partners will not terminate any of its agreements or development or commercialization of any of its products. Also, Sedor and its partners may experience delays in the commencement, enrollment, completion or analysis of clinical testing for its product candidates, or significant issues regarding the adequacy of its clinical trial designs or the execution of its clinical trials, which could result in increased costs and delays, or limit the ability to obtain regulatory approval. Further, unexpected adverse side effects or inadequate therapeutic efficacy of Sedor's or its partners' product(s) could delay or prevent regulatory approval or commercialization. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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