Sedor Pharmaceuticals Files NDA for CE-Fosphenytoin for Status Epilepticus

Potential significant advance in treatment of life threatening condition

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PAOLI, Pa.,--(BUSINESS WIRE)— **Sedor Pharmaceuticals, LLC (Sedor)** announced that it has filed with the US FDA an NDA for the approval of Sedor's lead program, IM/IV Captisol-Enabled™ (CE) Fosphenytoin for the treatment of patients that are at risk for status epilepticus seizures or to prevent/control status epilepticus seizures that occur during or following neurosurgery or neurologic trauma.

Status epilepticus are single epileptic seizures lasting more than five minutes or two or more seizures within a five-minute period. Importantly, status epilepticus seizures can create irreversible neurologic damage or death if not treated in a short time window, estimated by the Neurocritical Care Society Guidelines as treatment and cessation of seizure within 60 minutes of onset, if not sooner. Cerebyx (fosphenytoin) is currently indicated in these conditions but requires refrigerated storage in the pharmacy, raising the risk of delaying treatment. CE-Fosphenytoin does not require refrigeration and if approved holds potential for onsite storage and rapid dispensing in emergency rooms, intensive care units, first responder vehicles, and serial seizures in long-term care facilities.

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 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.

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 the seizure 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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