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## **Nebulized Propofol Hemisuccinate for Epilepsy and Migraine**

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We are developing an inhaler system for the acute treatment of intractable epilepsy and migraine, and also for the treatment of status epilepticus. Patients experiencing a seizure aura will use the inhaler to prevent a full-blown (motor) seizure. The inhaler can also be used in conjunction with seizure advisory systems currently under development. This is the first medication system to give patients control over their epilepsy. A related inhaler system will be used by a caregiver or by a bystander to treat a patient with epilepsy who is experiencing status epilepticus or seizure clusters in an out-of-hospital setting. The inhaler will also be used to treat migraine; a patient experiencing a migraine aura or early migraine attack will use the system to abort the migraine symptoms and prevent the development of a full-blown headache. The system administers propofol hemisuccinate (PHS), a proprietary water-soluble prodrug form of propofol, by nebulization into the deep lung. Extensive proof-of-principle studies demonstrate that intrapulmonary PHS rapidly and effectively protects against seizures in animal models. There is a wide margin between the doses that confer seizure protection and those that cause untoward effects, such as sedation or respiratory or cardiovascular depression. Safety studies have demonstrated that intrapulmonary PHS does not cause pulmonary damage or inflammation. We plan to conduct human safety and efficacy studies of nebulized PHS in normal volunteers and in persons with epilepsy who experience seizure auras prior to a full-blown motor seizure.