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## VNS Therapy Update: A Look into the Future

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The Vagus Nerve Stimulation (VNS) Therapy System received FDA approval for adjunctive treatment of medically refractory epilepsy in 1997. Since that time, over 60,000 implants have been performed worldwide. VNS Therapy has a well-established efficacy and safety profile and is the only implantable neurostimulation device of its kind approved for use in this patient population in the US. Observational data suggest that responder rates increase over time from approximately 25% to 45% (Morris, et al. *Neurology* 1999), with some individual sites reporting greater response rates (e.g., Vonck, et al. *J Clin Neurophysiol* 2004; Elliott et. al. *Epilepsy & Behavior* 2011). In addition, long-term observational data suggest that the incidence of typical VNS adverse events (e.g., hoarseness, cough, etc) may decrease over time (Morris, et al. *Neurology* 1999).

Patient reports from the original clinical trials supporting regulatory approval (Morris. *Epilepsy Behav* 2003) and other investigations (e.g., Schachter, et al. *Epilepsia* 1998, Boon, et al. *J Clin Neurophysiol* 2001) suggest that manual magnet induced VNS stimulation at the onset of seizures, may diminish both seizure duration and intensity. Based on this rationale, Cyberonics is developing a new generation of VNS devices that can initiate additional stimulation in response to significant increases in heart rate associated with seizures (i.e., ictal tachycardia). This responsive stimulation will supplement the normal mode stimulation of standard VNS Therapy.

Currently, Cyberonics is initiating the first clinical trial of this new generation device in Europe. This study will evaluate both the performance and tolerability of automatic stimulation in the medically refractory epilepsy population, among patients demonstrating ictal tachycardia. In addition, planning is underway to submit a US protocol under the FDA IDE review process. With this first effort to build on the VNS Therapy platform, Cyberonics intends to create a succession of future products to address unmet medical needs for patients with drug-resistant epilepsy.