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CYBERONICS RESPONDS TO SENATE FINANCE COMMITTEE STAFF REPORT

HOUSTON, Texas, February 16, 2006 -- Cyberonics, Inc. (NASDAQ:CYBX) today provided the following response to the Senate Finance Committee staff report on the FDA's approval process for the Vagus Nerve Stimulation Therapy System for treatment-resistant depression.

"VNS Therapy is the only safe and effective treatment option ever specifically developed, studied, FDA-approved and fully-informatively labeled for the treatment of chronic or recurrent treatment-resistant depression (TRD), the most unrelenting, disabling, life-threatening and expensive form of depression," commented Robert P. ("Skip") Cummins, Cyberonics' Chairman of the Board and Chief Executive Officer. "Unfortunately for the large number of Americans and their families who are trying to live with TRD and their psychiatrists who are trying to help them, the Senate Finance Committee today issued a report without having interviewed world renowned experts on TRD, widely published biostatisticians, patients and families living with TRD, patient advocacy organizations like NAMI, VNS Therapy TRD study investigators and all the FDA statisticians and clinicians involved in the review of the submissions, that ultimately led to the approval of the only FDA-approved treatment option for TRD.

"One of the many challenges that Cyberonics has continuously faced during its eight-year research program to develop the first safe and effective treatment option for Americans with chronic or recurrent treatment-resistant depression is that very few Americans understand TRD and can distinguish it from depression," continued Mr. Cummins. "Psychiatrists who specialize in TRD and the treatments commonly used to treat patients with TRD, such as ECT, know it and the patients whose lives have been ruined by TRD and their families know it. Most others, including many FDA drug and device regulators, politicians, third-party payers and the general public, know little about TRD and cannot distinguish TRD as an illness from depression.

"TRD is an unrelenting, lifelong and life-threatening illness that causes 15% of previously hospitalized patients with TRD to commit suicide," continued Mr. Cummins. "The patients in the VNS Therapy studies suffered from the most chronic and resistant depressions ever studied; average duration of lifetime depressive illness was 25 years; average number of failed treatments approached 20, including over half of patients who had been previously treated with ECT. All available literature and the patients' medical histories confirm that treatments-as-usual in these patients are neither safe nor effective. And considering that no treatment other than VNS Therapy is approved for TRD, there is no safety and effectiveness

information available to consumers or their psychiatrists to facilitate informed treatment decisions for these treatments.

“Cyberonics’ goal eight years ago when we began our TRD studies was to determine whether or not VNS Therapy satisfied the very specific needs of people with TRD,” continued Mr. Cummins. “People with TRD clearly did not and do not need more of the same treatments with the same mechanisms of action, studied in up-to-10-week studies of non-resistant patients, approved based on two positive studies regardless of the number of failed studies, with largely uninformative labeling including only a limited subset of data from the positive studies. People with TRD and their psychiatrists need treatment options like VNS Therapy that have been studied in patients with equally extreme TRD, over one and two years, compared to multiple controls, including a well-matched control group of patients with the same chronicity and resistance, treated not with an eight-week placebo but with any and/or all currently available treatments. People with TRD and their psychiatrists also need fully-informative labeling with all of the relevant medical histories of the patients in the studies and ALL of the data from ALL of the studies.

“That is exactly what FDA’s Center for Devices and Radiological Health, world-renowned TRD and ECT experts like Drs. John Rush and Harold Sackeim, the VNS study investigators and some 460 courageous Americans with TRD involved in the studies, gave Americans with TRD and their psychiatrists in July 2005 when VNS became the only FDA-approved treatment for TRD,” continued Mr. Cummins. “After two-years of adjunctive VNS Therapy, over half of the patients who had not responded to an average of 20 different treatments over 25 years of illness realized a meaningful clinical benefit, more than a third experienced at least a 50% improvement in their symptoms and some 20% were free from depressive symptoms. Most impressively to ECT experts, who know ECT and the high relapse rates of less chronic and resistant patients in ECT studies, 60% to 70% of the VNS responders sustained their response out to two years. Last but not least, although the VNS study patients suffered from the most resistant depressions ever studied and had failed almost every available treatment, the outcomes of the patients treated with adjunctive VNS Therapy were consistently and highly statistically and clinically significantly better at a widening margin compared to a well-matched, non-randomized control group of patients treated for a full year with significantly more intensive treatments-as-usual.

“Unfortunately, no treatment, including VNS Therapy, works for everyone, especially for patients whose TRD has failed everything,” continued Mr. Cummins. “Cyberonics has an eight-year commercial track record in 35,000 epilepsy patients with over 100,000 years of experience and a nine-month track record since approval in TRD that confirms we are very sensitive to this issue. Not only do the epilepsy and TRD VNS Physician’s and Patient’s Manuals contain ALL the data from ALL the studies, but the VNS manuals are by far the most complete and informative of all the FDA-approved anticonvulsant and antidepressant treatments manuals. We believe that all the data from all the studies is considerably more important than the details of FDA’s internal debate about the data. In addition to complete, fully-informative manuals with all the data, Cyberonics’ track record confirms that we are fully committed to rigorous post-market study programs and registries to update the VNS Therapy manuals and to facilitate fully informed decisions going

forward. That's exactly what we did in epilepsy and exactly what we are doing in TRD. Consistent with our mission to improve the lives of people touched by refractory epilepsy and TRD, we believe that fully-informed treatment decisions should be made by qualified physicians who specialize in, and patients and families who are living with refractory epilepsy and TRD, as opposed to politicians and their staffs, ill-informed payers, etc.

"It's equally unfortunate for payers, including Medicare and the various Medicaid programs, that the Senate Finance Committee issued its report without carefully examining payers' eight-year history with VNS Therapy in epilepsy and the costs of TRD," continued Mr. Cummins. "Eight years of commercial use in over 35,000 epilepsy patients with over 100,000 patient years of experience confirm that VNS is as safe, and more effective and cost-effective post approval in epilepsy than the epilepsy studies predicted. For the past six years, Americans with refractory epilepsy have had universal access to VNS Therapy with increasing reimbursement rates for VNS Therapy service providers based largely on documented long-term sustained and improving patient outcomes and savings for payers. The TRD studies and approval-to-date experience suggest that a similar phenomenon will emerge in TRD, if patients and their psychiatrists are given parity in access to VNS Therapy. There is considerably more incentive for payers to cover VNS Therapy in TRD than in epilepsy. Studies show that patients with TRD are costing payers more than \$42,000 per patient per year, almost three times the annual cost of refractory epilepsy patients. In Medicare's case, there are 250,000 under-age-65 Medicare beneficiaries who are disabled because of their TRD and who are costing Medicare \$2.7 billion per year before Part D medications expenses. That is \$2.7 billion in healthcare costs, including treatments that have no safety and effectiveness data and that all the evidence says are ineffective. Last but not least, in epilepsy, VNS Therapy is one of many treatments studied in the same population of patients with the same FDA-approved indication for use. In TRD, VNS Therapy is the ONLY treatment ever specifically developed, studied, approved and labeled for TRD.

"As to the internal FDA review process, Cyberonics, over 80 psychiatric thought leaders, hundreds of patients, and several patient advocacy organization and members of Congress were obviously surprised, when without the dignity of any post-Panel dialogue, VNS Therapy for TRD became the first Expedited Review PMA-Supplement with a favorable Panel vote in history to be deemed not approvable," continued Mr. Cummins. "We were especially surprised at the unprecedented not-approvable decision, considering that the favorable Panel vote came from a specially deputized panel of experts. Lastly, we remain puzzled as to why material inaccuracies identified in writing twice by Cyberonics (see TRD Coverage and Reimbursement section on www.vnstherapy.com) in FDA's statistical and clinical reports to the Panel and FDA's panel slides were never corrected, and those same material inaccuracies appear in the Panel Minutes that were posted on FDA's website some seven months after the panel meeting and in the June 2005 pre-approval BCBS TEC assessment, which extensively references those minutes.

"Ignorance, discrimination and stigma has for too long plagued those with chronic treatment-resistant illnesses, including refractory epilepsy and chronic or recurrent treatment-resistant depression," concluded Mr. Cummins. "Cyberonics' mission is to improve the lives of people touched by these illnesses, including

patients, families, healthcare professionals and payers, through the development of new FDA-approved, informatively labeled and accessible treatment options with more favorable risks and benefits than existing treatments. That is exactly what we've done in the past in epilepsy and exactly what we will continue to do going forward in TRD with the help of numerous psychiatric thought leaders and psychiatrists, patient advocacy organizations, patients and families and over 115 individual payers and third party appeal boards."

ABOUT VNS THERAPY AND CYBERONICS

Information on Cyberonics, Inc. and VNS Therapy™ is available at www.cyberonics.com and www.vnstherapy.com.

SAFE HARBOR STATEMENT

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. These statements can be identified by the use of forward-looking terminology, including "may," "believe," "will," "expect," "anticipate," "estimate," "plan," "intend," and "forecast," or other similar words. Statements contained in this press release are based upon information presently available to us and assumptions that we believe to be reasonable. We are not assuming any duty to update this information should those facts change or should we no longer believe the assumptions to be reasonable. Investors are cautioned that all such statements involve risks and uncertainties, including without limitation, statements concerning documentation of long-term sustained and improving patient outcomes and savings for payers who reimburse VNS Therapy for TRD. Our actual results may differ materially. Important factors that may cause actual results to differ include, but are not limited to: continued market acceptance of VNS Therapy and sales of our product; the development and satisfactory completion of clinical trials and/or market test and/or regulatory approval of VNS Therapy for the treatment of Alzheimer's disease, anxiety, or other indications; adverse changes in coverage or reimbursement amounts by third-parties; intellectual property protection and potential infringement claims; maintaining compliance with government regulations and obtaining necessary government approvals for new applications; product liability claims and potential litigation; reliance on single suppliers and manufacturers for certain components; the accuracy of management's estimates of future expenses and sales; and other risks detailed from time to time in the Company's filings with the Securities and Exchange Commission (SEC). For a detailed discussion of these and other cautionary statements, please refer to Cyberonics' most recent filings with the SEC, including its Form 10-K for the fiscal year ended April 29, 2005.

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