Supplemental Narrative
0034-EX-ML-2007

7/27/2007

This Supplemental Narrative is submitted to address what additional experimental objective will be achieved by the addition of three treatment sites in two states to EnteroMedics' clinical trial, and in particular why those additional sites qualify for expedited treatment.

As shown here, they qualify for expedited treatment on the same basis that the original sites did: the study promises to save lives.

Enteromedics does **not** propose to increase the total number of units authorized, but rather to spread the same number over more sites.

Details

EnteroMedics will shortly be initiating a clinical trial of its Maestro system for the treatment of obesity. The Maestro system entails an implantable device that delivers therapy to the patient's body in the form of electrical pulses to the vagus nerve. The operation of the device hinges on its being able to communicate with, and receive power from, an external patient-worn "Controller." The communication and power transfer is effected by an RF carrier wave at a frequency of 6.78 MHz.

FCC has granted approval to EnteroMedics to conduct its clinical trial at medical centers in 10 states in the United States. EnteroMedics is requesting FCC for permission to implant and treat patients in two additional states (Arizona: Mayo Clinic, Phoenix, and Scottsdale Bariatric Center, Scottsdale and Ohio: Cleveland Clinic, Cleveland). Reasons for requesting these additional sites are as follows:

1. Obesity in humans is a complex phenomenon with many contributing factors. Not all of these factors are fully understood, but EnteroMedics has discovered from trials of the Maestro system in other countries that genetic makeup and cultural background have a significant role to play. Accordingly, EnteroMedics desires to recruit patients from a wide geographic, genetic, and cultural mix of obese people in the United States.

2. EnteroMedics has also discovered from trials of the Maestro system abroad that successful treatment is critically dependent on the particular combination of clinical skills available at different medical centers. These skills include the surgical skills of the implanting physician, the patient follow-up skills of the clinic nurses, the skills of the nutritional counselors, and the skills of the psychological evaluators. Accordingly, EnteroMedics wishes to utilize multiple treatment centers in order to obtain a truly representative range of skill levels in the treating clinicians.

3. In order to obtain statistical certainty of the safety and efficacy of the Maestro system, the US FDA has required EnteroMedics to treat at least 220 patients in its clinical trial. The addition of 3 centers will reduce the total patient recruitment time in the clinical trial by about 3 months, thus enabling EnteroMedics to bring the benefits of Maestro therapy to the US market sooner. Obesity is an extremely serious health problem, and three months may literally make a life-or-death difference to thousands of potential patients who could benefit from Maestro therapy once FDA approval is obtained..

4. When the original request for an Experimental License was filed with FCC, EnteroMedics had not yet been granted FDA approval, and the total number of patients to be recruited in the clinical trial remained uncertain. In addition, EnteroMedics had not yet received positive responses from the three medical centers mentioned above. FDA has now granted approval for the clinical trial and all three centers have expressed enthusiasm for participating in the clinical trial. EnteroMedics would now like to move ahead rapidly with recruiting patients from a broad cross-section of the United States in order to expeditiously generate the safety and efficacy data needed for approval of the Maestro system in the United States.