**Enrollment in Diaphragm Pacing Systems for People with ALS Halted**

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In September, the Data Safety and Monitoring Board (DSMB), constituted to oversee the Diaphragm Pacing System in Participants with Amyotrophic Lateral Sclerosis (DPS in ALS) study, being conducted in the United States, issued a recommendation that new enrollment be halted. At the same time, the DSMB recommended that patients already randomized to the diaphragm pacing arm continue to be actively stimulated and followed according to the protocol.

These recommendations were offered after consideration of published data from a randomized pacing trial in Great Britain, as well as press reports regarding a French study utilizing much different inclusion criteria than the U.S. study.  Data from both of the studies conducted outside the U.S. suggested potential harm to patients who receive diaphragm pacing. The DSMB also reviewed data from a third open-label study in the U.S. that found much longer survival in paced patients than was observed in the British study. In addition, data from the current U.S. study were analyzed. While results from this study are still preliminary, the investigators have not seen evidence of the risk to patients that was found in the other trials.

Based on the DSMB recommendation, the principal investigators and the study sponsors (The ALS Association, the Muscular Dystrophy Association, and Synapse Biomedical) all agree that it is prudent to suspend enrollment at this time, but to continue active follow-up and pacing in subjects with the device implanted. While being cautious, the investigators continue to believe that the utility of diaphragm pacing in ALS patients remains undetermined given the mixed data from the different studies. The data from continued follow-up of study participants will be extremely important to better inform future decisions regarding diaphragm pacing.

The investigators in the ongoing U.S. DPS trial plan to ask the DSMB to conduct a safety review of ongoing data in three months, and to completely reassess all available data in six months. If the data still indicate a lack of risk and possible benefit to patients, investigators will ask the DSMB to reconsider its recommendation to suspend enrollment. In six months, the investigators should have further details on both the French trial and the open-label experience in the United States.

Together with the investigators for the ongoing U.S. DPS trial, The ALS Association and the MDA continue to believe that if there is a role for diaphragm pacing in the care of ALS patients, it is critical that this role is appropriately identified.

Roxan Olivas  
MDA Vice President  — Public Relations & Community Programs  
(520) 529-5317  
[rolivas@mdausa.org](mailto:rolivas@mdausa.org)