2021/8/26

Company:	CYBERDYNE Inc.
Name of Representative:	Yoshiyuki Sankai, President and CEO
Code:	7779 (Mothers Section of the Tokyo Stock Exchange)
Contact:	Shinji Uga, Director and CFO (Tel. +81-29-869-9981)

【News】Notice of application for the additional indication of Medical HAL for Spastic Paraplegia including HTLV-1 Associated Myelopathy (HAM)

CYBERDYNE Inc. (Tsukuba, Ibaraki, Japan; President and CEO: Yoshiyuki Sankai; from now on referred to as "the Company") announced today that it had applied for an additional indication of spastic paraplegia such as HTLV-1 Associated Myelopathy (HAM) for its Medical HAL Lower Limb Type ("Medical HAL") in Japan.

The Company used the result of an investigator-initiated clinical trial led by Dr. Takashi Nakajima (Director, National Hospital Organization Niigata Hospital) supported by the Japan Agency for Medical Research and Development (AMED). The clinical trial was titled “Investigator-Initiated Clinical Study of Wearable Assistive Robot for Lower Limbs Controlled Voluntarily by Bioelectric Signals etc., (Hybrid Assistive Limb [HAL]-HN01) as a New Medical Device to Delay Progression of Intractable Rare Neuromuscular Diseases -A Multicenter Randomized Controlled Parallel-Group Study to Evaluate the Short-Term Gait Improvement Effect on Ambulation Disability Caused by Spastic Paraplegia such as HTLV-1-Associated Myelopathy (HAM), etc.-(STUDY NCY-2001R).”

HAM, the main target for this application for approval, is a designated intractable disease with approximately 3,000 patients in Japan. The condition gradually damages the spinal cord, causing progressive symptoms such as difficulty in walking, urination, defecation, numbness, and pain in the legs. The damage caused will eventually force the patient to use a wheelchair or make them bedridden, causing a severe decline in quality of life. Currently, there is no effective preventive or therapeutic drug for the onset of the disease. Therefore, there is high anticipation for developing a new treatment that is highly effective in improving functional prognosis such as gait disorders.

This application for approval may establish Medical HAL as a standard treatment for HAM and other spastic paraplegia.

＜About the NCY2001 Study

The study hypothesized that "the progression of diseases such as gait instability could slow down when Medical HAL Lower Limb Type (from now on referred to as “HAL-HN01”) is worn therapeutically on a regular and intermittent basis for appropriate muscle contraction." Therefore, this investigator-led clinical trial aimed to evaluate the efficacy and safety of HAL-HN01, including its effect on improving gait in the patients concerned.

- Primary efficacy endpoint: 2-minute walk test (distance)
- Secondary endpoints: 10-meter walk test (speed), the patient-reported outcome measure (PRO), gait assessment by health care providers, barn motor disability severity (OMDS), spasticity (Modified Ashworth scale (MAS) assessment, SCATS Clonus scale, manual muscle testing (MMT), ADL assessment (Barthel index), operator's assessment of HAL-HN01 use.

(Reference link) Japan Medical Association Clinical Trial Promotion Center's Clinical Trial Registration System
https://dbcentre3.jmacct.med.or.jp/JMACTR/App/JMACTRE02_04/JMACTRE02_04.aspx?kbn=3&seqno=5969

Dr. Nakajima conducted the trial under the research and development agreement that the National Hospital Organization Niigata Hospital concluded with AMED on April 1, 2017, concerning the Research for Practical Application of Intractable Diseases Project promoted by the agency. The National Hospital Organization Niigata Hospital subcontracted the Company to conduct part of the contract research and development.