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Notice on investigator-initiated multicenter parallel-group clinical trial on HAL—HN-01 for rare-intractable spinal cord diseases to expand target diseases

-CYBERDYNE entered into a re-consigned research agreement with Niigata Hospital-

Following the previous year, CYBERDYNE,INC. (the "Company") again entered into a re-consigned research agreement with National Hospital Organization Niigata National Hospital ("Niigata Hospital") to conduct an investigator initiated multicenter parallel-group clinical trial on a new treatment with Wearable Assistive Robot Controlled Voluntarily by Bioelectric Signals ("HAL-HN01") of ambulation disability caused by rare-intractable spinal cord diseases. Outcome of the clinical trial could expand the target diseases of Medical HAL (also known as "HAL for Medical Use Lower Limb Type"), which is currently used for patients with slowly progressive neuromuscular diseases\*.

The Company and Niigata Hospital enter into this contract so that Niigata Hospital re-consigns the Company to take part in the relevant research and development program pursuant to the consigned research and development contract signed between Niigata Hospital and Japan Agency for Medical Research and Development ("AMED") on April 1, 2017 concerning practical application of researches on intractable diseases,.

## 1. Name of the research project

"Investigator-initiated multicenter parallel-group clinical trial with HAL-HN01 on patients with ambulation disability caused by rare-intractable brain and spinal cord diseases" led by Takashi Nakajima Deputy Director of Niigata Hospital, Director of Department of Neurology.

## 2. Assigned roles in the research project

In order to assist the investigator- initiated clinical trial and to promote social application of the relevant technology, the Company conducts HAL-HN01 operator training and safety assessment based on information gathered from investigator-initiated clinical trial. To be more specific, the Company provides the training for safe use of HAL-HN01 and gives support on appropriate use of the device to operators in each site alongside research on safe usage of it. Further, if any unfavorable information regarding HAL-HN01 is found or if there are adverse events that may have been caused by HAL-HN01, the Company will gather and analyze the information, and provide appropriate measures to investigators as well as assisting doctors.

- 3. Period of re-consignment From April 1, 2017 to March 31, 2018
- 4. Re-consigned research and development expenses (as planned) 10 millions of yen

## 5. Future prospects

Re-consigned research and development expenses are planned to be posted as non-operating income for the fiscal year ending March 31, 2018. However, the amount to be reimbursed will only be determined after the examination of Niigata Hospital by AMED, which will take place after the conclusion of the re-consigned period.

\*The following are the current target diseases of Medical HAL in Japan

- · Spinal Muscular Atrophy (SMA)
- · Spinobulbar Muscular Atrophy (SBMA)
- · Amyotrophic Lateral Sclerosis (ALS)
- · Charcot-Marie-Tooth disease (CMT)
- · Distal Myopathy
- · Inclusion Body Myositis (IBM)
- · Congenital Myopathy
- · Muscular Dystrophy

## Links

Clinical trial registry by The Japan Medical Association Center for Clinical Trials <a href="https://dbcentre3.jmacct.med.or.jp/JMACTR/App/JMACTRE02\_04/JMACTRE02\_04/JMACTRE02\_04.aspx?kbn=3&seqno=596">https://dbcentre3.jmacct.med.or.jp/JMACTR/App/JMACTRE02\_04/JMACTRE02\_04.aspx?kbn=3&seqno=596</a>