



Eisai Co., Ltd. Nihon Medi-Physics Co., Ltd.

# EISAI AND NIHON MEDI-PHYSICS ENTER COLLABORATION AGREEMENT TO CONTRIBUTE TO DIAGNOSIS AND TREATMENT OF DEMENTIA WITH LEWY BODIES

Eisai Co., Ltd. (Headquarters: Tokyo, Representative Corporate Officer and CEO: Haruo Naito, "Eisai") and Nihon Medi-Physics Co., Ltd. (Headquarters: Tokyo, Representative Director, President: Dr. Yutaka Takeuchi, "Nihon Medi-Physics") announced today that they have entered into a collaboration agreement to contribute to the diagnosis and treatment of dementia with Lewy bodies (DLB) in Japan.

DLB is considered to be one of Japan's three major types of dementia, alongside Alzheimer's disease and vascular dementia. According to a number of reports, DLB affects between  $4.3\%^{*1}$  (based on epidemiology) and  $41.4\%^{*2}$  (based on autopsies) of elderly patients with dementia in Japan, with the number of patients increasing due to the aging of the population. It is pointed out that DLB is difficult to be diagnosed because the disease presents characteristic symptoms such as cognitive fluctuations, visual hallucinations and parkinsonism in addition to progressive cognitive impairment.

Nihon Medi-Physics markets the brain disorder diagnostic agent DaTSCAN<sup>®</sup> Injectable (ioflupane [<sup>123</sup>I], "DaTSCAN"), which is the only product indicated for the use of dopamine transporter scintigraphy in diagnosing DLB in Japan. DaTSCAN is a radiopharmaceutical for use in Single Photon Emission Computed Tomography (SPECT) imaging. Low dopamine transporter uptake in basal ganglia, one of the suggestive features included in the criteria for clinical diagnosis of DLB (determined at the 3rd international workshop on DLB), can be verified by an examination using DaTSCAN and contributes to improving the accuracy of DLB diagnosis and influencing decisions on treatment strategy.

On the other hand, Eisai markets Aricept<sup>®</sup> (donepezil hydrochloride), the world's only treatment approved for the suppression of progression of dementia symptoms in DLB in Japan. Eisai has a wealth of experience and knowledge gained from more than 30 years of drug discovery in the field of dementia and information provision activities for Aricept.

Based on this agreement, both companies will share with each other information on the dementia including DLB, and work to generate new evidence as well as hold study meetings in order to improve the diagnosis and treatment of DLB.

Through this collaboration, Eisai and Nihon Medi-Physics will contribute to the diagnosis and treatment of DLB in order to further contribute to addressing the diverse needs of, and providing increased benefits to patients with DLB, and their families.

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#### [Notes to editors]

### 1. About Dementia with Lewy Bodies (DLB)

DLB is a degenerative form of dementia discovered in Japan that is pathologically characterized by decreased neurons in the brain and brainstem and the appearance of vast numbers of Lewy bodies. In neurochemistry, DLB is characterized by a loss of acetylcholine-producing neurons in the brain similar to that seen in patients with Alzheimer's disease. In addition to obligatory symptoms associated with progressive cognitive impairment, the disease also presents with behavioral and neuropsychiatric symptoms, motor disturbances, and dysautonomia. Of these, cognitive fluctuations, visual hallucinations and idiopathic parkinsonism have a high rate of incidence and are considered to be core symptoms of the disease\*3. In Japan, DLB constitutes one of the three major types of dementia diagnosed, alongside Alzheimer's disease and vascular dementia, affecting between 4.3% (based on epidemiology) to 41.4% (based on autopsy) of elderly patients with dementia, according to various studies\*1,2.

# 2. About DaTscan® Injection

DaTSCAN® Injectable (ioflupane [123] injection) "DaTSCAN") is a brain imaging agent to be used in evaluating the distribution of presynaptic dopamine transporters in the striatal region of the brain for diagnosing Parkinson's Syndrome and dementia with Lewy bodies. DaTSCAN is a radiopharmaceutical used in Single Photon Emission Computed Tomography (SPECT) procedure and contains ioflupane (123) as its active ingredient. Usually, one vial (111-185 MBq) of DaTSCAN is intravenously administered to an adult patient for brain scintigram which is taken 3 to 6 hours after administration. Dopaminergic information obtained by DaTSCAN, used as an adjunct to other diagnostic evaluations, is expected to contribute to improving accurate diagnosis and influencing decisions on treatment strategy for patients with the above diseases.

DaTSCAN, which has been approved as a pharmaceutical in 34 countries and areas globally by GE Healthcare, is considered as a standard healthcare procedure in Europe and the United States. In Japan, Nihon Medi-Physics obtained the approval of DaTSCAN in September 2013, and following the listing in the National Health Insurance Drug List in November 2013, launched the agent in January 2014.

## 3. About Nihon Medi-Physics Co., Ltd.

Nihon Medi-Physics Co., Ltd. (NMP) is a joint venture of Sumitomo Chemical Company, Limited and GE Healthcare (United Kingdom) and a leading manufacturer of radiopharmaceuticals. NMP has been working on development, manufacture and supply of high-quality radiopharmaceuticals used in diagnostic nuclear medicine valuable for disease diagnosis, and is determined to continue contribution to further improvement of medical care in Japan.

For more information about NMP, please visit: <a href="http://www.nmp.co.jp/eng/index.html">http://www.nmp.co.jp/eng/index.html</a>

#### 4. About Eisai Co., Ltd.

Eisai Co., Ltd. is a research-based pharmaceutical company that discovers, develops and markets products worldwide. Guided by its corporate mission of "giving first thought to patients and their families, and to increasing the benefits that health care provides," all Eisai employees aspire to meet the various needs of global health care as representatives of a "human health care (hhc) company" that is capable of making a meaningful contribution under any healthcare system.

For more information about Eisai, please visit: <a href="http://www.eisai.com">http://www.eisai.com</a>

<sup>&</sup>lt;sup>\*1</sup> MHLW Grants System – Prevalence of dementia in urban areas and measurements for living impairment in dementia: The Report for Scientific Research, 2013

<sup>&</sup>lt;sup>\*2</sup> Wakisaka Y, Furuta A, Tanizaki Y, Kiyohara Y, Iida M, Iwaki T. Age-associated prevalence and risk factors of Lewy body pathology in a general population: the Hisayama study. *Acta Neuropathol* 2003; 106:374-382

<sup>&</sup>lt;sup>\*3</sup> McKeith IG, Dickson DW, Lowe J, et al. Diagnosis and management of dementia with Lewy bodies: Third report of the DLB consortium. *Neurology* 2005; 65:1863-72.