



NEWS RELEASE

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TMS Co., Ltd.

### **TMS signs Option Agreement with Biogen**

Fuchu-shi, Tokyo, June 7, 2018

TMS Co., Ltd. (Fuchu-shi, Tokyo, JAPAN / CEO Takuro Wakabayashi, “TMS”) today announced that the company enters into an exclusive option agreement to assign TMS-007 and related assets to Biogen (Nasdaq: BIIB, Cambridge, Massachusetts, US / CEO Michel Vounatsos, “Biogen”). TMS-007 is currently under Phase IIa clinical trial for acute ischemic stroke patients.

TMS receives an upfront payment of \$4 million and an additional \$18 million payment if Biogen exercises its option, with up to \$335 million in potential development and commercialization milestones as well as tiered royalties.

Ischemic stroke causes approximately 66,000 deaths per year and is also a leading cause of nursing care in Japan. Stroke, 75% of which are ischemic stroke patients, costs 1.7 trillion JPY of medical expenditures per year, a heavy burden for social security system for the country. There are 15 million annual cases of stroke worldwide, leading to 5.8 million deaths.

TMS-007 belongs to a group of novel small molecule compounds named SMTP, produced by *Stachybotrys Microspora*. The compound has dual mode of action, one is to enhance endogenous clot dissolution activities and the other is to suppress inflammation at clot lesion. This unique combination could position TMS-007 as a best in class thrombolytic for individuals with acute ischemic stroke (AIS) with potential for extended treatment window as compared to current thrombolytic agents (4.5 hours after onset) that could lead to treatment of larger patient population.

Thrombolytic action of TMS-007 is based on a conformation change of plasminogen which in turn promotes plasminogen-fibrin binding and plasmin activation. It is thought that this mechanism locally promotes thrombolysis and leads to less hemorrhagic risks. Strong anti-inflammatory action due to inhibition of soluble Epoxide Hydrolase is believed to mitigate ischemic reperfusion injuries.

TMS-007 is currently being evaluated in a double-blind, randomized Phase IIa clinical study at hospitals, including Tohoku University Hospital, designed to investigate the safety and efficacy in approximately 60-90 patients with AIS up to 12 hours after stroke onset. The Phase IIa study initiated with the first patient dosed in February 2018. Previously, an acceptable safety of TMS-007 was demonstrated in a Phase I clinical study with healthy volunteers conducted at the University of Tokyo Hospital, completed in August 2015. (The University of Tokyo Hospital is one of the facilities in the Neurology and Psychiatry field of “Early/Exploratory Clinical Trial Centers” to conduct First-In-Human studies designated by the Ministry of Health, Labour, and Welfare.)

“This program originated from researches at Tokyo University of Agriculture and Technology and reached a point we could start Phase II clinical study with support from many people,” Dr. Keiji Hasumi, the Chief Scientist of TMS, stated. “Effective treatment of stroke is limited despite it is a serious disease. TMS will keep striving to help many ischemic stroke patients by TMS-007.”

Research and development of TMS-007 has been primarily conducted through collaborative relationships between TMS and Tokyo University of Agriculture and Technology, Showa University, and Tohoku University, and has been supported by Japan Science and Technology Agency (JST) and New Energy and Industrial Technology Development Organization (NEDO).

#### About TMS Co., Ltd.

TMS Co., Ltd. is a privately-held, clinical stage biotechnology company based in Fuchushi, Tokyo. The company was founded in 2005 to develop therapeutics based on novel discoveries to modulate fibrinolytic system, identified by a team of scientists at Tokyo University of Agriculture and Technology (TUAT), led by Dr. Keiji Hasumi, Professor of the university and Chief Scientist of TMS.

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