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NEWS RELEASE

Name of Representative Takuro Wakabayashi, President and
Representative Director
(Code No. 4891 TSE Growth Market)

TMS submits CTN for Phase II/III ORION Study Japan Cohort of JX10 to PMDA

TMS Co., Ltd. (TSE: 4891) (the "Company"), a clinical-stage biopharmaceutical company focused on discovering and accelerating the development of transformative medicines in areas of high unmet medical need, is pleased to announce that the Company has submitted a Clinical Trial Plan Notification (CTN) to the Pharmaceuticals and Medical Devices Agency ("PMDA") for ORION (*Optimizing Reperfusion to Improve Outcomes and Neurologic Function*), the global registrational study conducted by Corxel Pharmaceuticals Limited (CORXEL) including Japan cohort, that will investigate the effects of JX10 (also known as TMS-007) on functional recovery in acute ischemic stroke (AIS) patients, who present within 4.5 to 24 hours from "last known well".

The impact of this matter on the Company's financial results of this fiscal year is minor.

About TMS-007 (JX10)

TMS-007 (JX10) is an investigational drug candidate for the treatment of acute cerebral infarction (AIS), and its mechanism of action is both thrombolytic and anti-inflammatory. The important thing in the treatment strategy for acute cerebral infarction is to restore blood flow as soon as possible after the onset of symptoms. TMS-007 (JX10) extends the short treatment period of administration within 4.5 hours after the onset of symptoms, which is the current standard of treatment, and may provide treatment opportunities to many patients. In a Phase II clinical trial conducted by the Company in Japan, subjects administered TMS-007 (JX10) showed significantly improved clinical outcomes (no symptoms at all or symptoms but able to work without obvious impairment) after 90 days compared to placebo. This result was also confirmed by angiographic findings. TMS-007 (JX10) is currently undergoing a global study to further evaluate its efficacy and safety for the treatment of acute cerebral infarction by CORXEL.

About TMS Co., Ltd.

TMS Co., Ltd. is a clinical-stage biopharmaceutical company focused on the discovery and development of transformative medicines for the treatment of serious diseases in areas of high unmet medical need. The Company's pipeline consists of a family of small molecule compounds called SMTPs (*Stachybotrys microspora* triprenyl phenols) derived from a fungus. TMS' lead program, TMS-007 (JX10), has demonstrated efficacy and safety in its Phase 2a study for the treatment of acute ischemic stroke. The Company's robust pipeline also includes programs in resistant or uncontrolled hypertension, acute kidney injury, and spinal cord injury. TMS continues to explore new pipeline products by leveraging its established partnerships with leading academic institutions in Japan, with the intention to build a bridge between academic discoveries and the global pharmaceutical market. For more information about TMS, please visit <https://www.tms-japan.co.jp/>.

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