



February 20, 2025

NEWS RELEASE

Company name: TMS Co., Ltd.
Name of representative: Takuro Wakabayashi, Chief Executive Officer
(Securities code: 4891; Growth Market)

Notice on the Status of JX10 (TMS-007) Clinical Trial Application in China

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 Corxel Pharmaceuticals ("CORXEL") today announced that the Center for Drug Evaluation (CDE) of the National Medical Products Administration of the PRC (NMPA) has approved the Clinical Trial Application (CTA) for ORION (*Optimizing Reperfusion to Improve Outcomes and Neurologic Function*), the global registrational study including China cohort, that will investigate the effects of JX10 (TMS-007) on functional recovery in acute ischemic stroke (AIS) patients, who present within 4.5 to 24 hours from "last known well". The Company plans to participate in the global study as partner in Japan.

CORXEL press release :

[CORXEL Announces China National Medical Products Administration Approval of the Clinical Trial Application for ORION, the Global Registrational Study of JX10 in Patients with Acute Ischemic Stroke](#)

Please note that, because applications for the ORION clinical trial are expected to be submitted and approved in multiple countries, we do not plan to actively publicize the status of applications in every country.

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 our 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/>.

Investor and Media Contact:
ir@tms-japan.co.jp

End