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NEWS RELEASE

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Name of representative: Takuro Wakabayashi,
Chief Executive Officer
(Securities code: 4891; Growth Market)

Notice of Submission of a Clinical Trial Plan Notification for a Phase IIa Clinical Trial of TMS-008 for Acute Kidney Injury

TMS Co., Ltd. (the “Company”) announces that today it submitted a Clinical Trial Plan Notification to the Pharmaceuticals and Medical Devices Agency (“PMDA”) in preparation for initiating a Phase IIa clinical trial of TMS-008 in Japan (the “Trial”).

The Trial is a double-blind, randomized, placebo-controlled, dose-escalation, multicenter study designed to evaluate the safety and efficacy of TMS-008 in patients at risk of developing acute kidney injury following cardiovascular surgery.

Acute Kidney Injury Following Cardiac Surgery

Acute kidney injury (“AKI”) following cardiac surgery is a condition in which kidney function declines rapidly within hours to days after surgery and is an important risk factor affecting patient prognosis. One study of patients who underwent coronary artery bypass grafting or heart valve surgery reported that AKI developed in 43% of patients after surgery, and that the 30-day mortality rate among those patients was reported to be as high as 20% *. Although effective therapeutic agents are urgently needed, no drug is currently available for the treatment of AKI. Ischemia-reperfusion injury and subsequent inflammation are thought to be involved in the development of postoperative AKI. TMS-008 has been shown to be beneficial in improving these pathological conditions in animal models.

* Machado MN, *et al. Rev Bras Cir Cardiovasc.* 29: 299–307 (2014)

About TMS-008

TMS-008 is a small-molecule compound belonging to the SMTP (Stachybotrys microspora triprenyl phenol) compound family derived from black mold, as is TMS-007 (JX10). TMS-008 is expected to have potential as a therapeutic agent for acute kidney injury and other conditions through its anti-inflammatory activity based on soluble epoxide hydrolase (“sEH”) inhibition, as well as its antioxidant activity. In a Phase I clinical trial in healthy adults, TMS-008 demonstrated results suggesting favorable tolerability and safety.

Impact on Financial Result

The Company does not disclose financial forecasts. However, the costs required for the Trial during the current fiscal year are included within the range of research and development expenses presented at the beginning of the fiscal year and are not expected to affect the ranges of operating expenses previously presented for the fiscal year ending December 31, 2026.

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 Japanese Phase 2a study for the treatment of acute ischemic stroke. The Company's robust pipeline also includes programs in 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/en/index.html>.

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