

## NEWS RELEASE

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**TMS submits Clinical Trial Plan Notification for TMS-008 Phase I clinical trial in Japan**

TMS Co., Ltd. (the "Company") announces today that the Company has submitted a Clinical Trial Plan Notification to the Pharmaceuticals and Medical Devices Agency ("PMDA") to start Phase I clinical trial (the "Trial") for TMS-008, which is under development for acute kidney injury and other indications.

This is the First-In-Human study of TMS-008, in which TMS-008 will be administered incrementally to healthy adult male subjects to evaluate the pharmacokinetics, pharmacodynamics, and safety of TMS-008. The Trial is scheduled to begin after a 30-day investigation period by the PMDA.

TMS-008 is a small molecule compound belonging to the SMTP (*stachybotrys microspora* triprenyl phenol) compound family derived from black mold, as TMS-007/JX10, expected to have potential as a therapeutic agent for acute kidney injury (AKI) with its anti-inflammatory activity based on soluble epoxide hydrolase (sEH) inhibition as well as antioxidant activity. AKI is an indication in which renal function rapidly declines over a period of hours to days, and no drug has been approved for treatment of AKI to date. AKI can be caused by a variety of reasons, including cardiac surgery and drug side effects. In a study of patients who underwent coronary artery bypass surgery or heart valve surgery, 43% of patients developed acute kidney injury after surgery, and the mortality rate within 30 days was reported to be as high as 20%.<sup>1</sup> Due to these, it is expected there is a significant unmet medical need for effective therapeutic agents for AKI.

This matter will have no impact on the Company's financial results.

<sup>1</sup> Machado MN, et al. Rev Bras Cir Cardiovasc. 29: 299-307 (2014)

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