Biogen Announces Exercise of Option to Acquire the Investigational Drug TMS-007 for Acute Ischemic Stroke Based on Positive Phase 2a Data

May 12, 2021

- *TMS-007 has the potential to be a next generation thrombolytic with an improved benefit-risk profile*
- *Acute ischemic stroke is caused by a blockage of blood supply to the brain, and current thrombolytics are limited in use due in part to increased risks of bleeding*
- *Phase 2a study demonstrated positive impacts on blood vessel reopening and patient functional recovery with no incidence of symptomatic intracranial hemorrhage*
- *Biogen to make a one-time payment of $18 million and may pay potential milestone payments and royalties to TMS Co., Ltd.*

CAMBRIDGE, Mass. and FUCHU-SHI, Tokyo, May 12, 2021 (GLOBE NEWSWIRE) -- Biogen Inc (Nasdaq: BIIB) and TMS Co., Ltd. announced today that Biogen exercised its option to acquire TMS-007, an investigational drug for acute ischemic stroke, from TMS. Biogen's decision to acquire TMS-007 was based on positive data from a Phase 2a study. The study met its primary safety objective with no incidence of symptomatic intracranial hemorrhage (sICH) and demonstrated positive impacts on both blood vessel reopening in the brain as well as patient functional recovery. Patients were dosed up to 12 hours after the onset of stroke symptoms; average time to treatment was 9.5 hours for patients who received TMS-007 and 9.3 hours for those who received placebo. All patients who received TMS-007 were dosed beyond the time window of approved thrombolytic agents.

"We are encouraged by these results and made the decision to acquire TMS-007 based on the totality of the safety, imaging and clinical outcome data from the Phase 2a study," said Alfred Sandrock, Jr., M.D., Ph.D., head of research and development at Biogen. "It has been almost 25 years since the last thrombolytic agent was approved for acute ischemic stroke and we believe this novel investigational drug may expand the number of eligible patients who could potentially receive thrombolytic therapy and thus have a higher chance of functional independence after stroke."

Approved thrombolytic agents are limited in their use due to their benefit-risk profile in later time windows. According to the American Heart Association[1], sICH is the most feared complication of the current thrombolytic therapy, tissue Plasminogen Activator (tPA), which works by dissolving blood clots that block blood flow to the brain. In time windows up to 9 hours after stroke onset, sICH has occurred in patients receiving tPA at rates as high as six percent in controlled studies.

The randomized, placebo-controlled, ascending dose Phase 2a study included 90 participants in Japan (n=52 TMS-007, n=38 placebo). The primary endpoint of the study evaluated safety as assessed by the incidence of sICH with worsening of National Institute of Health Stroke Scale of four points or more. There were no events reported in the patients who received TMS-007 compared to an incidence of three percent in the patients who received placebo.

In addition, TMS-007 demonstrated a significant improvement on the secondary endpoint of functional independence at 90 days, with 40 percent of patients who received TMS-007 achieving scores of 0 or 1 on the modified Rankin Scale, a measure of independence in daily living, indicating either no residual symptoms or no significant disability, compared to 18 percent of patients who received placebo (P=< 0.05). This was supported by objective angiographic evidence of recanalization in the subset of patients with a visible occlusion receiving TMS-007. The recanalization rate, as measured by magnetic resonance angiography, was 58.3 percent (14 out of 24) for patients who received TMS-007 compared to 26.7 percent (4 out of 15) for patients who received placebo (odds-ratio 4.23; 95 percent confidence interval (0.99, 18.07)).

Biogen will make a one-time $18 million payment as part of the acquisition of TMS-007. TMS is eligible to receive up to an additional $335 million in potential post-acquisition development and commercial payments should TMS-007 achieve certain developmental milestones and sales thresholds. TMS is also eligible to receive tiered royalties in the high single digits to sub-teen percentages on annual worldwide net sales. Biogen will be solely responsible for the costs and expenses related to the development, manufacturing and commercialization of TMS-007 following the acquisition.

Biogen is currently evaluating the next steps for the clinical development of TMS-007, including plans for global studies. Final data results from the Phase 2a study are expected to be communicated at a future scientific forum.

About Acute Ischemic Stroke
Stroke is a potentially debilitating or even deadly cerebrovascular event. It is the second leading cause of death worldwide, with about 13 million cases and 5.5 million deaths each year, and with lasting functional deficits in stroke survivors caused by irreversible damage to the brain. Caused by blockages of blood supply to the brain, acute ischemic stroke accounts for about 85 percent of all strokes, with no approved medical therapies for treatment beyond the 3 to 4.5-hour time window. There is a substantial unmet medical need for new therapies that can both improve clinical outcomes with improved efficacy and safety as well as extend the time after stroke onset that a patient can receive a thrombolytic treatment.

About TMS-007
TMS-007 is a small molecule plasminogen activator with a proposed novel mechanism of action associated with breaking down blood clots and potentially inhibiting local inflammation at the site of thrombosis. This unique combination could position TMS-007 as a potential next generation thrombolytic for individuals with acute ischemic stroke with the aim to provide an extended treatment window as compared to currently approved thrombolytic agents.

About the Phase 2a Study
TMS-007 was evaluated in a multi-center, single-administration, double-blinded, randomized, placebo-controlled, ascending dose trial with three TMS-007 groups (1, 3 and 6 mg/kg) and a placebo group (52 patients who received TMS-007 and 38 patients who received placebo). The study run by TMS Co, Ltd., which took place in Japan, included patients with acute ischemic stroke within 12 hours after onset and ineligible for tissue Plasminogen Activator (tPA) or thrombectomy. The primary endpoint was evaluation of safety with secondary endpoints evaluating vessel recanalization as well as clinical outcomes at 90 days after stroke onset.

About Biogen

At Biogen, our mission is clear: we are pioneers in neuroscience. Biogen discovers, develops and delivers worldwide innovative therapies for people living with serious neurological and neurodegenerative diseases as well as related therapeutic adjacencies. One of the world's first global biotechnology companies, Biogen was founded in 1978 by Charles Weissmann, Heinz Schaller, Kenneth Murray and Nobel Prize winners Walter Gilbert and Phillip Sharp. Today Biogen has the leading portfolio of medicines to treat multiple sclerosis, has introduced the first approved treatment for spinal muscular atrophy, commercializes biosimilars of advanced biologics and is focused on advancing research programs in multiple sclerosis and neuroimmunology, Alzheimer's disease and dementia, neuromuscular disorders, movement disorders, ophthalmology, neuropsychiatry, immunology, acute neurology and neuropathic pain.

We routinely post information that may be important to investors on our website at www.biogen.com. To learn more, please visit www.biogen.com and follow us on social media – Twitter, LinkedIn, Facebook, YouTube.

About TMS Co., Ltd.
TMS Co., Ltd. is a privately held, clinical stage biotechnology company based in Fuchu-shi, Tokyo. The company was founded in 2005 to develop therapeutics based on novel discoveries to modulate the 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.

Biogen Safe Harbor Statement
This news release contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including statements about results from the Phase 2a study of TMS-007; the potential clinical effects of TMS-007; the potential benefits, safety and efficacy of TMS-007; clinical development programs, clinical trials, data readouts and presentations related to TMS-007; the potential of Biogen's commercial business and pipeline programs, including TMS-007; Biogen's strategy and plans; the identification and treatment of acute ischemic stroke; and risks and uncertainties associated with drug development and commercialization. These forward-looking statements may be accompanied by words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "potential," "possible," "will," "would" and other words and terms of similar meaning. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early-stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements or the scientific data presented.

These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including, without limitation, uncertainty of success in the development and potential commercialization of TMS-007; unexpected concerns may arise from additional data, analysis or results obtained during clinical studies; actual timing and enrollment of future studies of TMS-007; regulatory authorities may require additional information or further studies, or may fail or refuse to approve or may delay approval of Biogen's drug candidates, including TMS-007; the occurrence of adverse safety events; the risks of other unexpected hurdles, costs or delays; failure to protect and enforce Biogen's data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; product liability claims; third party collaboration risks; and the direct and indirect impacts of the ongoing COVID-19 pandemic on Biogen's business, results of operations and financial condition. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from Biogen's expectations in any forward-looking statement. Investors should consider this cautionary statement as well as the risk factors identified in Biogen's most recent annual or quarterly report and in other reports Biogen has filed with the U.S. Securities and Exchange Commission. These statements are based on Biogen's current beliefs and expectations and speak only as of the date of this news release. Biogen does not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

Reference:

1. https://www.ahajournals.org/doi/pdf/10.1161/STR.0000000000000152

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