



## Press Release

MEDINET Japan signs Option License Agreement with Stempeutics India for Stempeucel® product for Chronic Limb Threatening Ischemia (CLTI) indication for Japan Territory

- ✓ MEDINET Co., Ltd. (2370.T)., is a listed Regenerative Medicine/CDMO company in Tokyo, Japan
- ✓ First Made in India Cell Therapy product to be licensed by a Japanese Firm. Stempeucel® product has been patented in Japan
- ✓ Stempeucel® Cell Therapy product has been granted marketing approval by the Indian FDA (CDSCO) for treating Critical Limb Ischemia due to Buerger's Disease and due to Atherosclerotic Peripheral Arterial Disease (CLI).
- ✓ As per the agreement, **MEDINET** will develop and commercialize Stempeucel® in Japan as per Pharmaceuticals and Medical Devices Agency, Japan (PMDA) regulations. **MEDINET** and Stempeutics had pre-consultation meetings with PMDA in this regard.

Japan/India, October 27<sup>th</sup>, 2025: MEDINET Japan and Stempeutics India (a group Company of Manipal Education & Medical Group) jointly announced today that they have signed an option license agreement with rights to enter into an exclusive license agreement for Stempeucel® product for the Japanese market for CLTI indication. If exercised, the option would allow MEDINET to license exclusive rights to develop and commercialize Stempeucel® product in Japan territory. Stempeutics received an upfront payment upon signing of the option license agreement and will receive license granted fees and additional milestones and royalty payments if MEDINET exercises the option to license Stempeucel®. Stempeucel® product will be manufactured in the cGMP facility located at Bangalore and shipped to Japan for conduct of clinical trials and for commercial use if exercised, based on the transfer price agreed between the parties.

CLTI is a progressive form of peripheral arterial disease that is caused by severe blockage in the arteries thereby reducing blood flow. This may result in the development of sores and wounds in legs and feet with a high risk of limb amputation. With the current contemporary vascular techniques, it is estimated only 25% of patients can be managed with satisfactory clinical outcomes. Stempeucel® is a breakthrough treatment which is designed to enhance the body's limited capability to restore blood flow in ischemic tissue.

Stempeucel® is produced by pooling bone marrow-derived MSC's (Mesenchymal Stromal Cells) of healthy individuals through a proprietary, patented process. Research conducted at Stempeutics has shown that pooling balances out variations observed with individual donor cells, resulting in a product with strong immune-modulatory properties, broader cytokine / growth factors array, longer lifespan





and consistent clinical outcomes. Pooling underpins the clinical success demonstrated by Stempeucel®. Stempeucel® works thru' anti-inflammatory & immuno-modulatory properties and by inducing angiogenesis in ischemic muscle — ultimately leading to improvement in the clinically relevant endpoints for CLI. Real World Evidence published by the practicing doctors reflects these improvements.

Commenting on this collaboration, Mr. Kanenao Kubushiro-san, President and Representative Director of the Board, MEDINET said, "Our focus on innovation is guided by our strong sense of responsibility to address unmet patient needs in Japan and alleviate suffering We are happy to partner with Stempeutics since its product Stempeucel® has already been approved in India and treated more than 600 CLTI patients. Also, the product has been patented in Japan. Data from Indian clinical trials will be useful for getting pivotal study approval in Japan. CLTI is a serious and painful condition that impacts patients in Japan, and we are happy that we will be able to introduce this therapy in the country in the near future."

Mr Kunihiko Suzuki-san, Executive Fellow, MEDINET and ISCT Regional Vice President Elect in Asia said, "Today is not only a great day for MEDINET & Stempeutics, but for everyone involved in the responsible development of stem cell therapies for urgent needs. Through MEDINET & Stempeutics collaboration, we will be bringing next generation of biologics to address unmet medical needs. Physicians will have off-the-shelf stem cell therapy in their hands to fight Chronic Limb Threatening Ischemia Disease. We believe that Stem Cells will become a major branch of medical treatment and will become a standard of care for challenging diseases."

Mr BN Manohar, CEO of Stempeutics said, ""Signing a licensing agreement with a Japanese Regenerative Medicine Company is an important and historic milestone for Stempeutics. It is a strong recognition for Stempeutics for its sustained excellence of scientific and clinical work and underscores our global leadership in allogeneic, pooled MSC technology. We believe that the Stempeucel® product is a game-changer, offering an advanced therapeutic treatment for millions of patients suffering from this dreadful disease".

It is a significant milestone for Stempeutics and a satisfying journey for Stempeutics, commented **Dr. Pawan Kumar Gupta, President, Medical & Regulatory Affairs and ISCT Asia Regional Vice President.** Patients with CLTI are at an immediate risk for limb amputation and death. Now Stempeucel® provides hope for a new, effective treatment and a better quality of life for such CLTI patients".

## **About Stempeutics:**

Stempeutics is the leading Regenerative Medicine company in India with CDSCO (Indian FDA-equivalent) approved and marketed: cell-based therapeutic products (Stempeucel®) for three clinical indications; and acellular cell-derived bio-cosmetic products (Stempeucare®) for three indications.





Published data from Phase 1, Phase 2, Phase 3 and Phase 4 trials demonstrate Stempeucel® products are disease-modifying, wherein a single administration leads to clinically meaningful efficacy and durable outcomes. Beyond the approved products, product pipeline comprises of three additional Stempeucel products in late/early stage human clinical trials and four additional Stempeucare® products in development. Stempeutics was founded in 2006 based out of innovative stem cell research originating from Manipal Education and Medical Group (MEMG). This research has culminated into proprietary platform (Stempeutics Pooling Technology™) supported by nearly 100 issued patents and filed patent applications world-wide. Stempeutics Pooling Technology™ permits robust, scalable, costeffective, industrialized manufacture of Stempeucel® and Stempeucare® products with consistent biological activity and product potency, unencumbered by individual donor variabilities across bone marrow or cord blood collections and leads to pharmaceutical margins for cell-based therapeutic drugs. Stempeutics has marketing partnerships with Cipla and Alkem Labs for product sales and distribution in India. Stempeutics has also licensed its technology and products for commercial development and marketing in multiple countries outside India. Stempeutics continues to innovate and build upon its unique technology platform to in future customize biological activity of its therapeutics products for bespoke clinical indications by further engineering of pooled donor derived Mesenchymal Stromal Cells.

For more information, please visit www.stempeutics.com

## About MEDINET:

MEDINET Co., Ltd. is a Japanese company focused on regenerative medicine and cell therapy, acting as a Contract Development and Manufacturing Organization (CDMO). MEDINET has a cumulative experience of approximately 200,000 cases of cell processing in Japan over the past 30 years. They provide comprehensive solutions for the entire value chain, from research and development to manufacturing and commercial launch. MEDINET offers services like personnel training, facility and equipment design, quality management, and logistics, supporting medical institutions, research institutions, and biopharmaceutical companies in Japan.

For more information pl ease visit <a href="https://www.medinet-inc.co.jp/english/">https://www.medinet-inc.co.jp/english/</a>

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