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Press Release

**Stempeutics India signs an agreement with Novumcella Japan for development co-operation of Stempeucel® product for the Japanese market to treat Critical Limb Ischemia due to Buerger's Disease**

- ✓ Novumcella Inc., is a Regenerative Medicine/CRO company based in Tokyo, Japan
- ✓ Stempeucel® product is approved by Drugs Controller General India (DCGI) for Phase 4/PMS study for treating Critical Limb Ischemia due to Buerger's Disease. Stempeucel® product has been tested successfully in 122 Buerger's patients in India
- ✓ As per the agreement, Novumcella will initially provide regulatory support services to Stempeutics for getting approval from Pharmaceuticals and Medical Devices Agency, Japan (PMDA) for conduct of bridge study in Japan for commercializing Stempeucel® product for Buerger's Disease
- ✓ Upon PMDA approval for conduct of bridging study, Novumcella will take care of the cost required for conduct of the bridge study in Japan based on commercial agreement
- ✓ Stempeucel® product has been patented in Japan. Stempeutics had preliminary consultation meeting with PMDA in 2019 towards commercializing Stempeucel® product for Buerger's disease.

**Japan/India, May 28<sup>th</sup>, 2020:** Stempeutics Research India and Novumcella Inc. Japan, jointly announced today that they have signed an agreement for development co-operation of Stempeucel® product for the Japanese market for Buerger's Disease. Buerger's Disease is an orphan indication in Japan. In 2017, Drugs Controller General (India) granted conditional approval for manufacturing & marketing of Stempeucel® product for the treatment of Critical Limb Ischemia due to Buerger's Disease. Now Stempeutics plans to commercialize Stempeucel® product for the same indication in Japan in partnership with Novumcella.

Buerger's Disease is a rare and severe disease affecting the blood vessels of the legs. It is characterized by inflammation and occlusion of the vessels of extremities resulting in reduced blood flow to these areas, thus leading to severe pain and ulcers or necrosis, which finally may require amputation. Stempeucel® treatment is designed to enhance the body's limited capability to restore blood flow in ischemic tissue by reducing inflammation and improving neovascularization.

Commenting on this initiative, **Mr Yasuyuki Kusuhara, Founder & CEO of Novumcella** said, "We are happy to partner with Stempeutics since its product Stempeucel® is already validated in multiple clinical trials

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in India for Buerger's Disease and also the product has been patented in Japan. Data from Indian clinical trials will be useful for getting bridge study approval in Japan. Moreover Stempeutics has successfully completed PreIND meeting with US FDA and Scientific Advisory meeting with European Medicinal Agency for the Buerger' Disease. The feedback received from these regulatory agencies will support our Japan strategy".

**Mr BN Manohar, CEO of Stempeutics said,** "Japan is showing a great leadership in innovating regulatory frame work for regenerative medicine there by addressing major unmet medical needs faster. The new regenerative medicine law implemented in Japan allows conditional approval of stem cell products thereby enabling more rapid entry into the Japanese market. We would like to leverage this new framework for rapid development of Stempeucel® product for the benefits of the patients in Japan in collaboration with Novumcella. Novumcella will support us in finding a suitable Japanese Pharma partner for marketing Stempeucel® product in Japan"

**Dr Pawan Kumar Gupta, Senior VP, Medical and Regulatory Affairs of Stempeutics added** "Stempeucel® is an alternative method of treating CLI due to Buerger's disease patients especially those unsuitable for revascularization and are suffering from a very poor quality of life. We completed preliminary consultation meeting with PMDA in 2019. Now along with Novumcella, we will be having formal discussion with PMDA in 2020 on Quality/CMC/Safety/Clinical aspects of Stempeucel® product for getting necessary approval for conduct of pivotal bridge study for commercializing Stempeucel® in Japan. Also Buerger's being an Orphan indication, we are actively evaluating accelerated development of Stempeucel® product in Japan with support from Novumcella".

#### **About Stempeutics:**

Stempeutics is an advanced clinical stage Biotech Company based out of Bangalore. It was founded by Manipal Education and Medical Group (MEMG) in 2006 and later entered into an alliance with Cipla in 2009 and Kemwell Biopharma in 2019. Stempeutics strength lies in developing innovative stem cell products by nurturing cutting edge research and clinical applications through dedicated efforts of its highly qualified team. Its goal is to develop novel stem cell drugs addressing major unmet medical needs with an India first global next approach.

For more information please visit [www.stempeutics.com](http://www.stempeutics.com)

#### **About Novumcella:**

Novumcella Inc. is a regenerative medicine venture. The company was established in Tokyo Japan in August 2016. While developing products such as regenerative medicine products, Novumcella Inc. can support analysis using medical big data, regulatory consultations and full services of CRO for domestic and overseas ventures.

For more information please visit <https://novumcella.com/en/>