

Organization	<b>Name of Organization / 会社名</b>
	Stempeutics Research Pvt. Ltd.
	<b>URL</b>
	<a href="http://www.stempeutics.com">www.stempeutics.com</a>
	<b>Brief Descriptions of Organization / 会社概要</b>
	<p>Stempeutics Research Bangalore is a late stage life science company focused on developing and commercializing novel therapeutics based on adult stem cells.</p> <p>Company's flagship product - Stempeucel® is a Phase III ready, allogeneic, cultured, pooled, off-the-shelf, bone marrow derived mesenchymal stromal cell ("MSC") product. Stempeucel® is being developed for the treatment of Critical Limb Ischemia due to Buerger's disease (amongst other indications such as osteoarthritis and diabetic foot ulcer). In 2017, DCGI (Indian FDA) granted limited marketing approval. Stempeucel® is the FIRST innovative stem cell based biological product to be approved by DCGI for limited sales for the treatment of Critical Limb Ischemia due to Buerger's disease. Currently Phase 4/PMS study is in progress in India. Stempeutics is seeking partners for further clinical development and commercialization of Stempeucel® in Japan</p>

Oral Presentation	<b>Title of Presentation / 講演タイトル</b>
	<b>Pooled Mesenchymal Stromal Cells – A potential breakthrough therapy for Critical Limb Ischemia due to Buerger's disease Management</b>
	<b>Abstract / 要旨</b>
	<p>CLI is the most serious form of Peripheral Arterial Disease and is due to Non-atherosclerotic (Buerger's disease) or atherosclerosis. Thromboangiitis Obliterans, is a non-atherosclerotic, segmental inflammatory disease that most commonly affects the small and medium-sized arteries and veins in the upper and lower extremities. Patients suffering from TAO usually have a history of smoking and presents with pain while walking and in severe cases at rest, upper and lower limb discoloration and gangrene. As the possibility of vascular bypass is usually low, due to the distal impact on vessels, the consequence of their disease in the more advanced stage may be limb amputation especially in the lower extremities.</p> <p>Stempeucel® is a first of its kind allogeneic, MSC therapy. It is <b>produced by pooling bone marrow-derived MSC's of healthy individuals through a proprietary, patented process</b>. 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. Stempeucel® works thru' anti-inflammatory &amp; immuno-modulatory properties and by inducing angiogenesis in ischemic muscle – ultimately leading to improvement in the clinically relevant endpoints for CLI.</p> <p>Stempeutics conducted the largest ever Phase II dose finding clinical trial in no-option patients with Buerger's disease (n=90) in India. Stempeucel® demonstrated statistically significant results in cell arm (2million/kg body weight) patients for all critical endpoints:</p> <ul style="list-style-type: none"> <li>• Improved rate of ulcer healing</li> <li>• Improved rest pain</li> <li>• Increased Ankle Brachial Pressure Index (indicator of blood flow due to vascularization)</li> <li>• Improvement in Quality of Life</li> </ul> <p>Also Phase 4 data is consistent with Phase 2 data.</p>
	<b>Objectives and/or Motives / 目的</b>
<p>Stempeutics is currently seeking in-licensing partners for co-development and commercialization of Stempeucel® to treat CLI due to Buerger's disease in Japan (an Orphan indication). The opportunity is significantly de-risked due to:</p> <ul style="list-style-type: none"> <li>• Positive results from a large Phase 2 trial &amp; Phase IV PMS study that demonstrated efficacy &amp; safety</li> <li>• Patent-protected pooling technology provides unique differentiation by reducing the inter-donor and inter-batch variations compared to other allogeneic stem cell products</li> </ul>	

in the pipeline, whilst providing defensibility against the competition

- Stempeucel® offers significant benefits for vascular as well as other regenerative diseases
- With no other allogeneic pooled MSC therapy in development, Stempeucel® is expected to re-define the treatment landscape for CLI due to Buerger's disease and other Peripheral Arterial Diseases
- Currently the pooled cells is also undergoing phase 3 trials in India for CLI due to atherosclerotic PAD, Osteoarthritis and Diabetic foot ulcer