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ASIA EDITION

China approves world's first XellSmart's Allogeneic iPSC-derived Regenerative Cell Therapy for Spinal Cord Injury

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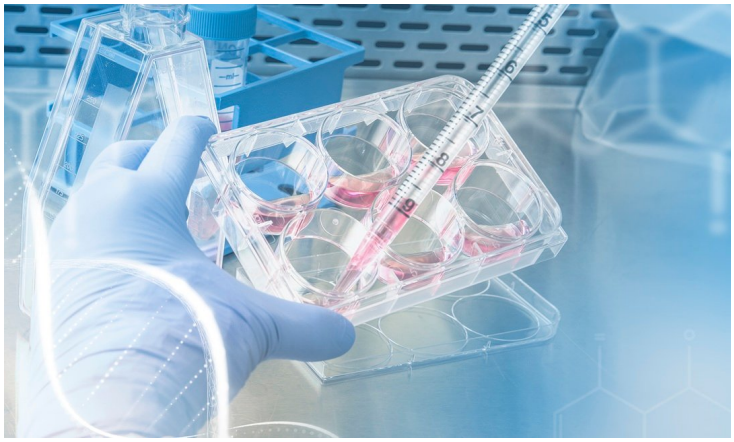
World's First -- XellSmart's Allogeneic iPSC-derived Regenerative Cell Therapy for Spinal Cord Injury Officially Approved by the U.S. FDA for a Registrational Phase I Clinical Trial



XellSmart Biopharmaceutical (Suzhou/Shanghai) Co., Ltd. announced that the National Medical Product Administration (NMPA) in China and the U.S. approved XellSmart's off-the-shelf allogeneic iPSC-derived neural regenerative cell therapy. A Phase I clinical trial application has been submitted to the Food and Drug Administration (FDA) to address spinal cord injury (SCI), an untreatable disease of the central nervous system that affects more than 15 million people worldwide.

As the first regenerative clinical trial globally employing a subtype-specific neural progenitor cell therapeutic product to treat spinal cord injury, the study will be led by the Third Affiliated Hospital of Sun Yat-sen University, a nationally recognized leader in spinal cord injury treatment.

Spinal cord injury (SCI) is a globally prevalent neurological disorder. SCI often leads to partial or complete paralysis, with the loss of motor and sensory function. Most patients experience permanent disability, severely compromising their quality of life. Due to the limited regenerative capacity of the central nervous system, nerve repair following SCI remains extremely challenging. Current treatments are largely limited to rehabilitation and supportive care, with no effective therapies available to promote neural regeneration during the injury phase.

XellSmart has partnered with leading clinical experts in spinal cord injury to initiate the world's first registrational clinical trial of an off-the-shelf, allogeneic, iPSC-derived, subtype-specific, regenerative neural cell therapy for spinal cord injury. This pioneering trial represents a landmark achievement in the global effort to develop regenerative therapies for spinal cord injury. Committed to advancing breakthrough treatments, XellSmart aims to redefine possibilities for SCI recovery — bringing a new hope to patients in China and around the world, and delivering tangible relief to families and communities affected by this devastating condition.