

REGiMMUNE and Kiji Therapeutics Announce Intention to Merge

The intended merger will create a pan-global Treg specialist to use multiple modalities to target Tregs for a number of indications.

Taipei, Taiwan, and Paris, France, October 18, 2024 – [REGiMMUNE](#), the regulatory T cell targeting drugs for immunotherapy and [Kiji Therapeutics](#), the specialist in Induced Pluripotent Stem Cells-Mesenchymal Stem Cells (iPSC-MSC) engineered cell therapies for inflammatory diseases, today announce an intention to merge both companies. This merger will create the Treg specialist REGiMMUNE. The merger will be subject to customary conditions and full final due diligence by both parties.

The creation of the merged new company will combine the complimentary portfolio of platforms and therapies to create an international Treg biotech, and the leading company globally in modulating Treg function. Both companies have been focused on addressing unmet medical needs by the modulation of the Treg function. REGiMMUNE has been able to regulate the role of the Treg by using a molecule enhancer to increase Treg function, and monoclonal antibodies (depleter; inhibitor) to reduce the function of, or eliminate Tregs. Kiji can add an advanced, next generation multigene engineered stem cell therapy IL10 enhancer to increase Treg anti-autoimmune function.

The combination of these technologies will create an international specialist in Treg modulation and will focus on immune-oncology and autoimmunity. It will combine three diverse platforms, based on small molecules, monoclonal antibodies and cell and gene therapy. This will give REGiMMUNE/Kiji TX the ability to augment or reduce Treg function in vivo by downregulating Tregs in immune-oncology and upregulating Tregs in autoimmunity.

Commercially, REGiMMUNE/Kiji TX will prepare for an IPO with a listing in the Emerging Stock Market in Taiwan. Therapeutically, REGiMMUNE/Kiji TX will now initially focus its multiple target pipeline on 4 therapies. It will establish proof of concept with gene engineered mesenchymal stem cells (KJ01) in graft-versus-host disease (GvHD), and prepare for clinical entry in the second half of 2025, develop its iPSC platform (KJ02) for Inflammatory Bowel Disease (IBD), Psoriasis and CNS disorders, define clinical readiness with a Treg depleting/inhibiting monoclonal antibody (RGI6004) and advance clinical development with the launch of a phase III clinical trial with a clinical stage small molecule Treg enhancer targeting GvHD (RG2001). This will be developed for potential partnering activities.

The companies were brought together in discussions by the main REGiMMUNE shareholder, DCI Partner Co., Ltd. With high level executives based in Taiwan, Japan, Europe and the US, REGiMMUNE/Kiji TX will provide a global bridge for cell and gene therapy (CGT) development, and take advantage of the strong and growing interest in Southeast Asia, and specifically Taiwan for CGT.

The companies will be led by a highly experienced senior management team, with Miguel Forte as CEO and Kenzo Kosuda as co-CEO. Miguel Forte will contribute his extensive experience and network as the current President of leading global CGT association, the International Society for Cell & Gene Therapy (ISCT) and Alliance for Regenerative Medicine (ARM) board and executive committee member. Kenzo Kosuda brings extensive financial and management expertise together with East Asia experience. Tony Ting will be chief scientific officer, Ping Chung will be chief technology officer, TsungYen Wu will be chief business officer and Steve Yang will be chief operating officer.

“Tregs have proved themselves to be a leading promising modality in the cell and gene therapy field, both therapeutically and commercially. As a result of this potential, we have collectively created a global Treg specialist super-company to realize this potential,” said Miguel Forte, CEO, Kiji TX. “We will also be able to combine several fields, including small molecule, CGT and monoclonal antibodies to use Tregs to their full potential. These approaches are off-the-shelf and allogeneic, with a competitive advantage over autologous or patient matched Treg approaches currently in development in the sector. The new company now has a variety of options, including an IPO by mid-2025 in the Taiwan Stock Exchange. This will enable REGiMMUNE/Kiji TX to develop our multiple therapeutic pipeline in-house, as well as partnering for co-development or out-licensing.”

“Modulating Treg function in both directions has significant potential in a variety of conditions with major commercial benefits. Creating the new Treg specialist REGiMMUNE/Kiji TX will result in a company that will have the resources to achieve this potential. With a planned IPO in 2025, we will be able to combine leading modalities to develop therapies for conditions involving significant numbers of patients globally,” said Kenzo Kosuda, CEO, REGiMMUNE. “The global reach of the company and experience of the senior management also enables us to explore development across the globe to match the therapeutic potential and size of the market that is open to us.”

About REGiMMUNE Limited

REGiMMUNE is a clinical-stage biopharmaceutical company focused on creating innovative immunotherapies by harnessing the power of regulatory T cells (Tregs). REGiMMUNE is creating a pipeline of novel product candidates that either enhance Treg activities for immune diseases or suppress Treg activities for cancer. REGiMMUNE is based on Taiwan.

About Kiji Therapeutics

Kiji Therapeutics is a company founded by EU Biotech VC AdBio Partners specializing in next generation iPSC-MSC engineered cell therapy for the treatment of a broad range of inflammatory diseases. Kiji TX is developing superior potency multi-gene engineered stem cell therapies (GePS). Kiji TX has the first-in-industry multi-gene engineered iMSC. Initial pre-clinical data demonstrates an over 70 percent improvement in selected targeting and augmented efficacy. It is achieving this

through the induction of Tregs and Regulatory B cell (Bregs), with an innate immune system control. It is also developing allogeneic, off-the-shelf 3D manufactured, iPSC derived stem cells, gene engineered for targeted and potent therapeutic delivery. The initial targets are significant unmet medical needs with significant market potential in autoimmune diseases, including aGvHD, IBD and Psoriasis. Kiji TX's lead product KJ01 is currently at IND-enabling stage for aGvHD. Kiji TX is based in France and Spain.

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