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Taiwanâ??s Regenerative Medicine Rise Is Redefining the Rules of Cell Therapy

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Speaking with BioSpectrum Asia during BIO Asiaâ??Taiwan 2026, Steminentâ??s Ling-Mei Wang and Ching-Huai Ko explain why dedicated regulation, standardised manufacturing and intelligent automation will be critical to taking regenerative medicines from scientific promise to patients at scale.

Cell therapy is approaching a defining transition: from highly specialised science to a reproducible, scalable pharmaceutical industry. Making that leap will require more than clinical breakthroughs. It demands regulatory frameworks designed for living medicines, pharmaceutical-grade manufacturing and an ecosystem capable of delivering consistent products to patients at sustainable cost.

In an exclusive conversation with **BioSpectrum Asia during BIO Asia–Taiwan 2026, Dr. Ling-Mei Wang, Chairperson and Chief Strategy Officer, and Dr. Ching-Huai Ko, President and CEO of Steminent,** discuss Taiwan's emergence as a regenerative medicine hub and the journey behind Stemchymal®, the company's mesenchymal stem cell-based therapy being developed for spinocerebellar ataxia. They also outline why the industry's next frontier will depend on automation, standardisation and global partnerships—and why, as they put it, **"you cannot find a new land with an old map."**

Steminent has achieved several milestones for Taiwan's regenerative medicine industry, including advancing one of the country's first allogeneic stem cell therapies into international clinical development. How do you assess the evolution of Taiwan's cell therapy ecosystem over the past decade, and what factors have contributed most to its progress?

Over the past decade, Taiwan's cell therapy landscape has evolved from a largely academic, research-driven field into a genuine translational industry. Ten years ago, most of the activity sat inside universities and hospitals; today we have companies taking products through international clinical development, dedicated manufacturing capability, and a steadily growing pool of specialised talent and capital.

The single most important driver of that progress has been the maturing of the regulatory environment. As international frameworks for cell and gene therapy advanced, and as scientific and clinical evidence accumulated, our regulators were able to build a rational, evidence-based oversight system rather than legislating in a vacuum. Taiwan's 2018 Special Regulations for cell therapy (ç?¹ç®¡è¾¦æ³?), and more recently the Regenerative Medicine dual acts, gave developers a clearer pathway from bench to patient and gave patients a legitimate route to access.

That regulatory clarity, reinforced by scientific and clinical validation, has been the foundation on which everything else — talent, capital and manufacturing capability — could accumulate. Taiwan also brings real structural strengths: a strong healthcare system, a deep clinical research infrastructure, and a manufacturing culture that prizes precision and quality. Steminent's own experience — advancing one of the country's first allogeneic stem cell therapies into international clinical development — was only possible because this broader ecosystem grew up around us over the same period.

Stemchymal® is recognised as the world's first mesenchymal stem cell-based therapy developed specifically for Spinocerebellar Ataxia. What have been the most significant clinical and scientific learnings from the programme's development journey thus far?

The Stemchymal programme has taught us as much about the disease as about the therapy itself. Spinocerebellar ataxia is a rare, progressive neurodegenerative disorder for which patients have historically had essentially no disease-modifying options — care has been largely supportive.

Running a dedicated clinical programme in this indication has, in itself, accelerated the scientific understanding of the disease. We have learned a great deal about its natural history, about which clinical endpoints genuinely reflect meaningful change for patients, and about the mechanisms through which an allogeneic mesenchymal stem cell therapy may act. Working in a rare indication also imposes its own discipline: every patient matters, every data point is precious, and the trial design has to be exceptionally rigorous.

The most significant learning is that a cell therapy can point toward a credible direction for slowing — or exerting some measure of control over — disease progression, together with a plausible and defensible mechanism of action. In a field where so little has previously been possible, that is a meaningful scientific result. Our aspiration throughout the journey has been straightforward, and it has never changed: to give patients a genuine, meaningful option to manage and control a disease that, until now, has offered them very little. Everything we learn scientifically is ultimately in service of that goal.

With conditional approval pathways emerging across several Asian markets, how do you view the regulatory environment in Taiwan and Japan for advanced therapies, and what opportunities do these frameworks create for patients with rare neurodegenerative diseases?

Japan planned for cell and regenerative therapies relatively early, and in doing so built important foundations — particularly around reimbursement and the treatment of rare diseases. Its conditional, time-limited approval pathway is comparatively well defined, which gives both developers and patients a clear frame of reference and a predictable route to market.

Taiwan is progressively building its own regulatory system, and it is doing so in the spirit of both the US and Japanese experiences. Because Japan's framework is relatively explicit, it offers a useful and practical model to follow. As Taiwan's own oversight system continues to take shape — through the special regulations and now the Regenerative Medicine dual acts — I expect the two environments to become mutually reinforcing, with complementary guidance and support mechanisms emerging quickly.

For patients with rare neurodegenerative diseases, these conditional pathways matter enormously. Rare-disease populations are, by definition, small, and conventional development timelines can be prohibitively long. A well-designed conditional approval framework — one that pairs early access with a rigorous obligation to keep generating evidence — can meaningfully shorten the distance between a validated therapy and the patients who urgently need it, without compromising the scientific standards that protect them.

Bringing cell therapies from development to commercialisation presents unique manufacturing, regulatory, and reimbursement challenges. What do you see as the critical success factors for ensuring broader patient access to innovative cell therapies?

Cell therapies are fundamentally different from small-molecule or biologic drugs, and so I believe they need a regulatory regime of their own, rather than being forced into frameworks designed for other modalities. The critical success factors follow directly from that conviction.

First, we must integrate cell therapy product development with an evolving discipline of industrial pharmacy — bringing pharmaceutical-grade rigour to how these products are manufactured, characterised and specified. A cell therapy has to become a well-defined product, not a bespoke procedure. Second, we need dedicated talent development: the required skills span cell biology, process engineering, quality and regulatory science, and they remain specialised and scarce, so cultivating that talent deliberately is essential. Third, we need to build out a genuine cell therapy industry chain and ecosystem — from raw materials and reagents, through manufacturing, to logistics and delivery at the point of care.

When science and clinical evidence have validated a product, the ultimate goal must be a clearly specified, standardised and reproducible cell product. Reimbursement then becomes far more tractable, because payers can evaluate something consistent and well-characterised. In my view, it is precisely this combination — a purpose-built regulatory system, specialised talent, a mature supply chain and standardised specifications — that will ultimately broaden patient access to innovative cell therapies, and turn scientific promise into routine clinical reality.

Steminent has successfully engaged in international licensing and partnership activities. How do global pharmaceutical and biotechnology companies currently perceive opportunities emerging from Taiwan's regenerative medicine sector?

Establishing a credible foothold in cell therapy is critically important, and Steminent made a deliberate choice to start from the field of rare neurodegenerative disease, developing Stemchymal to pharmaceutical-grade specifications. That decision shapes how we are perceived internationally.

Increasingly, global pharmaceutical and biotech companies are looking at Taiwan's regenerative medicine sector as a source of differentiated, well-characterised opportunities — programmes built to a genuine drug-product standard, with proper specifications and clinical discipline, rather than as isolated academic exercises. That is a meaningful shift in perception, and it plays directly to Taiwan's strengths.

Our own experience in international licensing and partnership shows that this approach travels well. The discipline we have built around a single rare-disease programme — in specification, manufacturing and regulatory strategy — can be extended to a broader global commercial footprint and to further indications. We very much look forward to collaborating and connecting with partners in related fields around the world. That collaboration can take many forms: commercial licensing, manufacturing, the harmonisation of regulatory specifications, and even cooperation on building the regulatory systems themselves. We see partnership not as a one-off transaction, but as the mechanism through which Taiwan's regenerative medicine capability becomes globally relevant.

Looking ahead, what are Steminent's strategic priorities over the next two to three years, and what role do you envision the company playing in shaping the future of cell therapy development in Asia and globally?

Over the next two to three years, our strategic priority is to strengthen international linkages and to continue moving beyond Taiwan — building a truly international value chain rather than operating as a purely domestic company.

We want to use our own experience, together with our partners, to form an ecosystem, and to move decisively toward cell preparations that can be produced intelligently: with automation, standardisation, reproducibility and genuine scalability. Manufacturing that is intelligent and automated is, I believe, what will finally allow high-quality cell products to reach patients at scale and at sustainable cost. Throughout, we will keep validating the science and the clinical evidence — from bench to bedside — because credibility in this field is earned through data, not claims.

As for the role I envision for Steminent: I hope we can serve as a bridge — connecting Taiwan's scientific and manufacturing strengths with global partners, and helping to demonstrate that a rare-disease cell therapy developed here can meet international standards. We often say that you cannot find a new land with an old map. We firmly believe that by combining our own strength with that of our partners, we can create the greatest value — and, in doing so, help shape the future of cell therapy development across Asia and globally.