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"Stem cell-based therapeutics poised to become mainstream optionÃ¢â?¬Â•

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In conversation with Dr Koji Tanabe, Founder and CEO, I Peace, Inc., The United States/Japan



To make the trial investments more meaningful and to avoid ambivalence in animal models, medical science is adopting novel in vitro models of specialised human pluripotent cell lines. Pluripotent stem cells (PSCs) have the agility to expand indefinitely and differentiate into almost any organ-specific cell type. iPSC-derived organs and organoids are currently being evaluated in multiple medical research arena like drug development, toxicity testing, drug screening, drug repurposing, regenerative therapies, transgenic studies, disease modeling and more across clinical developments. Innovative pharmacovigilance methodologies are preferring induced pluripotent stem cells (iPSCs) for pre-clinical and clinical investigational studies. Global Induced Pluripotent Stem Cell (iPSC) market is expected to reach $2.3 B by 2026. The iPSC market in Asia-Pacific is estimated to witness fast growth due to increasing R&D projects across countries like Australia, Japan and Singapore.

I Peace, Inc. a Palo Alto-based global biotech company with its manufacturing base in Japan, has succeeded in developing and mass-producing clinical grade iPS cells through its proprietary iPS cell manufacturing services. The human iPSC (hiPSC) lines at I Peace leverage differentiated cells across clinical research and medical applications. Biopsectrum Asia discovered more about Japan's stem cell manufacturing ecosystem with **Dr Koji Tanabe, Founder and CEO, I Peace, Inc., (The United States/Japan)**. Tanabe earned his doctorate under Dr Shinya Yamanaka, a Kyoto University researcher who received the

2012 Nobel Prize in Physiology or Medicine for discovery of reprogramming adult somatic cells to pluripotent cells. I Peace is focusing on this Nobel Prize-winning iPSCs technology where Tanabe had played a key role in generating the world's first successful human iPSCs as one of the team members and is currently industrialising it in the US and Japan.

- **How do you define Japan's Stem cell manufacturing dynamics aligning with regional and APAC market potential?**

We believe that human cells play a pivotal role in next-generation drug therapy. Clinical trials of iPSC applications are in full swing not only in Japan, but worldwide as well. In the US, the momentum of clinical trial research is astounding. Yet, mass production of GMP compliant cell products remains a challenge. Entry into this venture is no easy task. As a contract development and manufacturing organisation (CDMO), I Peace is geared to tackle that challenge and become the pioneer of mass production technology of clinical grade cell products.

- **Can you elaborate I Peace's cost-effective proprietary stem cell synthesis solution and its manufacturing scale?**

The key advantage of iPSCs is the ability to create pluripotent cells from an individual's own cells. Furthermore, iPSCs can multiply indefinitely and evolve into any type of cell, making iPSCs an ideal tool for transplant and regenerative medicine and drug research. However, clinical applications of iPSCs to date, utilise heterogenic transplantation. It is because manufacturing of just one line of iPSCs requires a cost intensive clean room to be occupied for several months. Manufacturing process complexities also pose a barrier to cost reduction and mass production.

In contrast, I Peace has developed a proprietary, fully automated closed system for iPS manufacturing, enabling cost-effective production of multiple lines of iPSCs from multiple donors in a single room. Within a few years, we expect to manufacture several thousand lines of iPSCs simultaneously in a single room. With this technology, I Peace can efficiently generate an ample supply of various iPSCs for heterogenic transplant, while also fostering a society where everyone can bank their own iPSCs for potential medical use.

- **How does I-Peace better position its businesses objectives and go-to-market strategies?**

I Peace's manufacturing facility and its processes have undergone rigorous audits and are certified to be in compliance with GMP guidelines of the US, Japan, and Europe. We have the capacity to manufacture clinical-grade iPSCs and iPSC-derived cells for clinical use in the global market. Our manufacturing staff have unparalleled expertise in the manufacturing of iPSCs, and their knowledge and experience make it possible to mass produce high quality clinical-grade iPSCs in the shortest possible time. Additionally, we streamlined the iPSC use licensing scheme to expedite collaborative ventures with downstream partners. We believe these strategies position I Peace as a global leader in iPSC technology.

- **How do you outline the concept of 'democratising access to iPSC manufacturing'?**

At I Peace, we envision a world in which everyone would possess their own iPSCs and if needed, receive autologous transplant medication using their own iPSC. We believe in the importance of raising awareness of Nobel Prize winning iPSC technology and we think much more needs to be done. We need to enlighten the public about iPSCs - what they are, how they are created, and how they play a role in next-generation medical therapies. We also need to underscore the benefits of early banking one's own iPSCs, such as autologous transplant and the fact that cells taken in the early stages of life are preferable over cells collected later in life.

To democratise iPSC access, it is also important to expedite application research. We work closely with downstream partners, and support their iPSC-derived drug therapy development efforts by providing iPSCs to meet their needs. We also collaborate with downstream partners in the development of promising therapies including the use of T-cells for cancer therapy, cardiomyocytes for the treatment of heart disease, and neurocytes for neurological disease.

- **What is your outlook around boosting public-private stakeholder’s initiatives to encourage awareness on stem-cell-based therapeutics?**

iPSC research has advanced tremendously over the past 16 years, and even more so since Dr Shinya Yamanaka’s Nobel Prize award in 2012. The acceleration of applied research is paving the way for stem cell-based therapeutics to become a common treatment modality in the near future. As human cell manufacturing requires specialised professional skills and knowledge, it is important to promote functional specialisation. These specialisations include donor recruiting, cell manufacturing (where I Peace is the key player), and implementing cell transplant as a medical practice. We believe that creating a systematic industry structure will build awareness and further drive the growth of stem cell-based therapy.

- **Can you brief Japan’s licensing key notes to manufacture and process clinical-grade cells in the region?**

Japan enacted three laws to promote the use of regenerative medicine as a national policy:

  - The Regenerative Medicine Promotion Act -- representing the country's determination to promote regenerative medicine;
  - The Pharmaceuticals, Medical Devices, and Other Therapeutic Products Act (PMD Act); and
  - The Act on the Safety of Regenerative Medicine (RM Act). The U.S. also has various tracks such as the Regenerative Medicine Advanced Therapy (RMAT) Designation, Breakthrough Therapy designation, and Fast Track designation.

Of significance, the PMD Act enables a fast-track for regulatory approval of regenerative medical products in Japan. In compliance with the RM Act, I Peace was audited by the PMDA and licensed by the Ministry of Health, Labour, and Welfare to manufacture specific cell products.

Because cell product manufacturing regulations are not standardised globally, cell therapy developers are forced to source GMP iPSCs for each market. I Peace however, has overcome this hurdle. We have built in compliance with global GMP regulations, including FDA's cGMP regulations per 21 CFR 210/211 in our operation. As a result, we can provide cells for global use in multiple markets, accelerating both product development and regulatory approval.

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