



Press Release // November 18, 2021

## **SCG Cell Therapy Sets Singapore as International Hub for Cell Therapy Research, Manufacturing and Clinical Development**

### **Collaborates with the Cell Therapy Facility at Health Sciences Authority to Validate Processing Methods for T Cell Therapy Manufacturing**

- The Cell Therapy Facility of Singapore Health Sciences Authority (HSA-CTF) under HSA's Blood Services Group complies with current Good Manufacturing Practice (cGMP) requirements.
- Validation result to support global Investigational New Drug (IND) Application

SINGAPORE – November 18, 2021 – Singapore-based SCG Cell Therapy Pte Ltd (“SCG”), a leading biotechnology company, plans to establish Singapore as its international hub for cell therapy research, manufacturing and clinical development to deliver high-quality products across Asia Pacific, the United States, Europe and across the world.

In line with this, the company has signed an agreement with the Cell Therapy Facility of Singapore Health Sciences Authority (HSA-CTF) for the evaluation and validation of SCG's proprietary cell therapy manufacturing process to develop a new treatment option for patients with Hepatitis B virus (HBV) related hepatocellular carcinoma (HCC). The process validation will be performed in the Good Manufacturing Practice (GMP)-certified facility at HSA-CTF and the procedures will be fully compliant to current GMP (cGMP) requirements. SCG Cell Therapy will utilise the validation result to support global Investigational New Drug (IND) Application of SCG101 – autologous T-cell receptor (TCR) T cell therapy.

“HSA-CTF has a proven track record of cell therapy product manufacture, and their staff are well-versed in the stringent cell manufacturing processes under cGMP requirements. This will allow us to ensure a high quality standard of our T cell therapy product”, said Frank Wang, Chief Executive Officer of SCG Cell Therapy. SCG's proprietary cell therapy manufacturing process employs sophisticated closed and automated technologies which eliminates the expansive clean room and the labor-intensive manual manufacturing steps. The process has been validated in SCG's cell therapy manufacturing site in Shanghai, China and is currently being supplied for clinical trials. “Singapore is an attractive location to set up an international hub with its world-class research and manufacturing infrastructures, GMP-certified manufacturing talent and openness to embrace new technologies. With the technology transferred and validated in Singapore, we look forward to establishing SCG's international hub of cell therapy research, manufacturing and clinical development in the country to deliver high-quality products of our broad cell therapy pipeline worldwide,” Frank added.

HCC, especially associated with HBV, remains a major cause of cancer-linked mortality worldwide. In 2018, the estimated annual incidence and mortality increased to 841,000 cases

and 782,000 deaths respectively<sup>1</sup>, with the highest HCC incidence rates found in East and Southeast Asia<sup>2</sup>. Treatment options are limited and overall prognosis for survival is poor, with a five-year relative survival rate of 12%.

Cell therapy is one of the most promising and rapidly advancing treatment for chronic and life-threatening diseases such as cancers. As cell-based therapy involves growing and expansion of living cells, a reproducible and high-quality manufacturing process is essential. “We are excited to partner SCG in their pioneering work on novel cell therapies. With our expertise in GMP compliant cell products manufacturing, we are confident that we can accelerate the access of these treatments to patients in Singapore and around the world. We look forward to providing this new field of treatment to help patients”, said Dr Marieta Chan, Facility Director of HSA-CTF.

“Primary hepatocellular or liver cancer represents one of the most common types of cancer in Asia where hepatitis B is endemic. There still remains significant treatment challenges for this type of cancer and this continues to be a significant unmet need. I am therefore excited by this collaboration between HSA and SCG, and the prospect of developing a novel treatment for patient use in targeting this cancer. This partnership underscores the importance Singapore has placed on the future and promise of cell-based medicine and provides a great opportunity for HSA to validate a highly specialised cell-based manufacturing process that conforms to international regulatory requirements,” said Dr Mickey Koh, Medical Director of HSA-CTF.

### **About SCG Cell Therapy**

SCG is a leading biotechnology company focusing on the development of novel immunotherapies in infections and its associated cancers. The company targets the most common cancer-causing infections: helicobacter pylori, human papillomavirus, and hepatitis B, and develops a broad and unique pipeline of T cell therapies, antibodies, and therapeutic vaccines against infections and to prevent and cure its associated cancers. Established and headquartered in Singapore, SCG combines regional advantages in Singapore, China and Germany, covering the entire value chain from innovative drug research and discovery, manufacturing, clinical development and commercialization. SCG collaborates with leading scientists and researchers to bring first-in-class and best-in-class medical products/technologies to enhance innovation in medical product development. For more information about SCG, please visit us at [www.scgcell.com](http://www.scgcell.com).

### **About SCG101**

SCG101, an autologous T-cell receptor (TCR) T cell therapy targeting specific hepatitis B virus (HBV) epitopes, is a potential novel treatment for HBV-related hepatocellular carcinoma (HCC). HCC is the most common type of liver cancer. In Asia, HBV accounts for at least 80% of virus-associated HCC cases. HCC is typically diagnosed late in its course and is associated with the poor prognosis. Preliminary data indicates that SCG101 is a novel TCR-T therapy against HBV-related HCC. SCG101 currently being investigated in clinical trials.

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<sup>1</sup> <https://hrjournal.net/article/view/3851#B1>

<sup>2</sup> <https://hrjournal.net/article/view/3851#B2>

## **About Health Sciences Authority's Cell Therapy Facility**

The Cell Therapy Facility (CTF) of HSA's Blood Services Group houses a fully accredited Good Manufacturing Practice (GMP) facility with a highly trained and skilled specialist team and has been in existence since 2006. It is committed to the development of novel translational cell therapies for treatment of diseases, such as cancer, autoimmune and degenerative diseases. The Facility manufactures cellular products which fulfil international regulatory Good Tissue Practices (GTP) and GMP requirements. A stringent overarching quality programme fully compliant with international regulatory standards ensures a level of consistency and stringency of these manufactured cellular products for safe application to patients. It has successfully partnered both academic and commercial cell therapy companies to deliver innovative cell-based therapy that have demonstrate efficacy and safety.

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