FOR IMMEDIATE RELEASE

HEALTH SCIENCES AUTHORITY
PRESS RELEASE
27 JULY 2009

HSA Builds Cell Therapy Facility to Expand Pioneering Work on Novel Cell-based Therapies to Treat Cancers and Other Diseases

When fully completed, it will be a leading academic facility for one-stop research and translational service for cell therapy arena in Southeast Asia

The Health Sciences Authority's Blood Services Group is expanding its scientific capacity in the field of clinical cell therapy. Cell therapy is one of the most promising and rapidly advancing areas that exploit cells such as immune and stem cells to treat cancers and immune disorders.

2 HSA's pilot Cell Processing Laboratory was set up in 2006 as a prototype facility. Clinical trials were successfully initiated and are still ongoing in collaboration with clinical investigators. With increasing demand for laboratory space, the laboratories are now being expanded into a state-of-the-art Cell Therapy Facility.

3 When fully completed in November 2009, the expansion will more than double the laboratory's current floor space to include an additional four cGMP* compliant cell processing rooms equipped with a cascading pressure system of highly filtered, directed air flow at 99.997% purity. The new Cell Therapy Facility will provide a cutting-edge translational platform for clinicians and scientists to scale up promising research protocols in the transition from bench to bedside.

**current Good Manufacturing Practice*

4 Current cell therapy projects include ongoing Phase I/II clinical studies, in collaboration with clinical collaborators from the Singapore General Hospital, that involve culturing cytokine induced killer (CIK) cells, a special type of immune cell. To date, more than 90 infusions have been administered to 30 patients with various haematological malignancies such as leukemia. The clinical trials have demonstrated the feasibility and safety of CIK cell applications to patients in autologous (from patients' own cells) and allogenic (cells from other donors) settings. The trial is ongoing, and preliminary results are encouraging with some patients continuing to remain disease free.

5 Another research focus by the team at the HSA Cell Therapy Facility is on natural killer (NK) immune cells. NK cells are fast in action and are potentially powerful weapons against a broad range of malignancies. HSA researchers are studying promising GMP-compliant culture conditions to generate large numbers of highly potent clinical grade NK cells for future applications in cancer patients. Molecular mechanisms of enhanced NK cytotoxicity (potency) are being investigated to allow future targeted NK design for the generation of an even more powerful and robust NK cell therapy product.

6 "*As cell therapy involves the growing and expansion of living cells, HSA is ideally positioned to manage this, given our long history of blood processing and testing in relation to the national blood programme. Our staff are experienced in this specialized area and have been trained in international centres of excellence. Our work culture and systems are firmly grounded in a tradition of quality management. With our well-established clinical connections, HSA's Cell Therapy Facility is poised to fully embrace this fast expanding field that is now increasingly recognised as one of the most exciting new modalities in the treatment of cancers. I see this as a one-stop research and translational facility, and new clinical trials are already being planned."* says Dr Mickey Koh, Division Director of the Patient Services Division in HSA's Blood Services Group.

7 With the high demand and current space constraints, expansion of the current laboratory capacity is supported by funding from the Ministry of Health. Future research programmes will include developing novel cell therapy products arising from promising findings in genomics, immunology and proteonomics (the study of proteins which are the main components of physiological metabolic pathways of cells). These new capacities and capabilities will continue to strengthen HSA's valued partnerships with hospitals and biomedical research institutions in clinical translational trials. This work will also give promote the facility as a regional reference centre for new advances in cellular therapy.

8 Professor Edison Liu, Chairman of HSA, officiates at today's ceremonial opening of the Cell Therapy Facility in conjunction with the opening ceremony of the 3rd Singapore-World Health Organisation (WHO) Workshop on the Management of National Blood Programmes. About 23 participants from 15 countries in the region are attending the 5-day workshop jointly organised by HSA's Blood Services Group and WHO, with the support of the Ministry of Health and sponsorship from the Ministry of Foreign Affairs through the Singapore Cooperation Programme.

Health Sciences Authority
27 July 2009

- **About the Health Sciences Authority (HSA)**

The Health Sciences Authority (HSA) applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services, Applied Sciences, to protect and advance national health and safety. HSA is a multidisciplinary authority. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. It operates the national blood bank, Bloodbank@HSA, securing the nation's blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit www.hsa.gov.sg

- **About HSA's Blood Services Group**

The Blood Services Group (BSG) of HSA, as the national blood service, secures the nation's blood supply by ensuring a safe and adequate blood supply and providing specialist transfusion medicine services.

BSG operates the Bloodbank@HSA, and it is responsible for collecting, processing, testing and distributing blood and blood products to all hospitals in Singapore, both public and private.

As the national blood service, it provides specialised services in transfusion sciences such as immunohaematology and tissue typing. Its transfusion medicine specialists also provide professional advice and consultations to clinicians in Singapore and the region, so as to promote the best practices in clinical transfusion medicine and to ensure that every blood donation is optimally and safely used.

Bloodbank@HSA is located at the HSA Building at 11 Outram Road, Singapore 169078 (directly opposite the Outram Park MRT Station). Blood donors are welcome to call the Bloodbank@HSA at Tel: 6213 0626.

Annex A

MEDIA INFORMATION SHEET
27July 2009

3rd Singapore-World Health Organisation on the Management of National Blood Programmes 27 to 31 July 2009

Blood transfusion is an essential part of healthcare. Every country shares the need to ensure the quality, safety and accessibility of blood transfusion. This is best achieved through the presence of an effective and coordinated national blood programme that is responsible for the provision and rational use of adequate supplies of safe and high quality of blood and blood components. One of the key factors towards a successful national blood programme is an efficient and well-organised national blood service.

2 It is important that directors and programme managers of national blood services are equipped with the appropriate management knowledge and skills to enable them to implement and operationalise the national blood programme. This includes the necessary skills in human resources, finance, administration and planning within the blood service that will allow them to manage their available resources and implement the national blood plans effectively.

3 To address these needs, a series of three training workshops to strengthen the organisation and management of national blood programmes in order to improve safety and availability of blood supply in the region.

4 The 3rd Singapore-World Health Organisation(WHO) on the Management of National Blood Programmes is the final of a series of three workshops held annually over three years. In its role as WHO Collaborating Centre for Transfusion Medicine, the Health Sciences Authority's Blood Services Group organises the series of workshops jointly with the WHO, with the support of the Ministry of Health and the sponsorship from Ministry of Foreign Affairs through the Singapore Cooperation Programme.

5 The first and second workshops were also held in Singapore in 2007 and 2008. Previous two workshops covered strategic and project planning, finance, communications, human resources, education and training, standards, supply management, logistics and IT systems. The first workshop saw the participation of 26 delegates from 17 countries while 25 delegates from 15 countries attended the second one.

6 About 23 participants from 15 countries from Southeast Asia and Western Pacific region are attending this third and final workshop which will emphasize on external quality schemes, risk management, project management, change management and effective leadership. About 14 local and overseas speakers will be conducting the 5-day workshop.

HEALTH SCIENCES AUTHORITY
27 July 2009

Annex B

PROCESSING OF CELL PRODUCTS IN CELL THERAPY FACILITY@HSA

HSA Health Sciences Authority

CELL EXPANSION

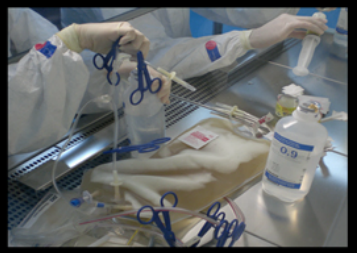
Culturing/Stimulation

Cells are grown in specific culture media and sometimes stimulated with growth factors (cytokines) to render cells more potent and generate greater numbers.

Cell culture bag

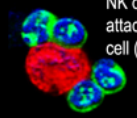
CELL HARVEST

At the end of culture (e.g. 3-4 weeks as for cytokine induced killer (CIK) cells) cells are washed and harvested using a special centrifuge. All cell cultures are done in closed systems with no exposure to the open environment.



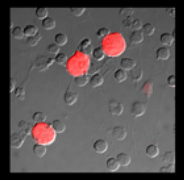
SPECIFIC CELL SELECTION

Isolation/purification of specific effector cells (e.g. Natural Killer (NK) cells).



NK cells (in green) attacking tumour target cell (in red)

NK cells (in grey) attacking tumour target cells (in red)



CRYOPRESERVATION

Cells in freezing bags, specifically designed for preserving cells at low temperatures, are then placed into a programmable controlled rate freezer and slowly cooled to -196 °C. Bags are then transferred into liquid nitrogen for long-term storage.

Controlled rate freezer for cryopreservation of cell products

Liquid nitrogen tanks for long-term storage of cell therapy product

1. Cells are harvested from patient or donor (apheresis or bone marrow) at hospital site.

2. Cells are then transported to the Cell Therapy Facility@HSA, where cell processing takes place in a current Good Manufacturing Practices (cGMP) environment. The facility has specially controlled air filtration and pressure systems.

3. After appropriate quality checks are performed (specified release criteria), the product is released and transported back to the hospital.

4. Cells are re-infused back into patient and regular follow-ups are conducted to assess disease status.