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MEDIA RELEASE

NCIS/NUH stem cell transplant programme receives international accreditation

First Asian programme to be recognised by the Foundation for the Accreditation of Cellular Therapy

SINGAPORE – The hematopoietic stem cell transplantation (HSCT) programme at the National University Cancer Institute and National University Hospital has received internationally-recognised accreditation by the Foundation for the Accreditation of Cellular Therapy (FACT) at the University of Nebraska Medical Center. The programme at NCIS and NUH – both members of the National University Health System – is the first and only one in Asia to be recognised so far.

The internationally-recognised accreditation is the gold standard for hospitals and medical institutions offering stem cell transplant, and indicates the accredited institution has met the most rigorous standards in every aspect of stem cell therapy. This covers the entire spectrum of stem cell therapy, from clinical care to donor management, cell collection, cell processing, cell storage and banking, cell transportation, cell administration, cell selection, and cell release.

Accreditation is attained through rigorous evaluation of submitted documentation and on-site inspections to determine if a facility is in compliance with current FACT standards and the United States Food and Drug Administration’s current rules for Good Tissue Practice. FACT standards are defined by leading experts based on the latest knowledge of the field of cellular therapy product transplantation.

The stem cell programme offered by the National University Cancer Institute, Singapore (NCIS) and the Department of Paediatrics, Division of Haematology and Oncology at the National University Hospital (NUH) addresses adult as well as childhood illnesses, with the support of the Department of Laboratory Medicine at NUH.
All types of transplants – autologous, allogeneic, unrelated donor, cord blood and haplo-identical – are offered as a one-stop service at the NUHS, with clinical, collection and processing facilities on a single site. The programme is the only one in Singapore to serve both adult and paediatric patients, performing up to 65 of the 180 transplants that are done each year in Singapore. It treats malignant diseases such as leukaemia, lymphoma and myeloma as well as non-malignant diseases such as thalassaemia, Fanconi’s anaemia and aplastic anaemia. Patients under the programme come from Singapore as well as Southeast Asian countries and as far away as Russia, China, Mongolia, India and the Middle East. This year to date, a total of 48 transplants were performed at the NUHS.

Dr Tan Lip Kun, Programme Director of the NUHS/NCIS HSCT Programme and Senior Consultant, Department of Haematology-Oncology, NCIS, led the team that worked to gain accreditation. She said, “The decision to acquire FACT accreditation was made because the transplant team saw the need to establish a self-regulatory process and to meet international accreditation for a quality health care management system in stem cell transplant care and practices.”

The preparation process began in late 2009, when a tripartite team was appointed comprising the adult and paediatric teams as well as the laboratory workgroup. These multi-disciplinary working groups included clinicians, nurses, stem cell technologists, onco-pharmacists, physiotherapists, medical social workers, dietitians and other healthcare professionals. The preparatory phase took three years to complete: it required 1,300 FACT standards to be met and almost 200 standard operating procedures had to be drawn up and maintained.

The group reviewed processes and procedures in stem cell transplants at NCIS and the NUH Department of Paediatrics and worked together to meet the standards for FACT accreditation. Changes addressing patient safety, improvements and standardization in patient care were made to clinical processes as well as laboratory practices such as collection processes, laboratory processing, handling, labeling and storage of stem cell products. Systematic training and improved education of physicians, nurses and healthcare workers was established. A quality management health care plan for the stem cell transplant programme was put in place to ensure patient quality care and safety standards.
After almost three years of preparation, on-site inspection by FACT assessors was carried out at NCIS and NUH on 17 and 18 May 2012. Following corrective actions, the NUHS HSCT programme was granted FACT accreditation on 23 September 2012. The accreditation is reviewed by FACT every three years.

Professor John Wong, director of NCIS and deputy chief executive of the NUHS, said gaining the recognition was significant. “FACT accreditation is the capstone of our bone marrow transplant programme, signifying our commitment to high quality of care in the delivery of transplants, continuous research into novel therapies and holistic support for our patients through support groups and awareness programmes. We are pleased to be recognised as a leading stem cell transplant facility. With FACT, patients and their families can be assured that NCIS and NUH’s stem cell transplant programme maintains the highest standards in patient care and laboratory practices.”

Added Associate Professor Quah Thuan Chong, Head, Division of Paediatric Haematology-Oncology in the NUH Department of Paediatrics, “The stem cell transplant process in most cases is very complex and needs meticulous care, planning and excellent resources with very close teamwork. Top volume centres in the world standardise their practices because every step can lead to a significant difference in outcome for the patient. Being FACT-accredited not only endorses the quality of our cellular therapy treatment, it allows us to benchmark against the best and highest global standards of care for our young patients. We are also thankful to our key sponsor Viva Foundation for Children with Cancer and St Jude Children’s Research Hospital for supporting our paediatric team in the accreditation process through their generous sharing of knowledge. In particular, Dr Wing Leung, Chair of Bone Marrow Transplantation and Cellular Therapy from St Jude Children’s Research Hospital worked with the team on adapting policies for local application.”

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About FACT  
In December 1994, the International Society for Cellular Therapy (ISCT) and the American Society for Blood and Marrow Transplantation (ASBMT) merged their Standards into a single document covering all aspects of hematopoietic cell therapy (collection, processing, and transplantation). The two societies established FACT in order to develop a voluntary Inspection and Accreditation Program based on the joint Standards. FACT promotes quality medical and laboratory practice of cellular therapy through its peer-developed standards and voluntary inspection and accreditation program.

In 2006, FACT, in collaboration with the Joint Accreditation Committee–ISCT & EBMT (JACIE), developed international standards in the field of cellular therapy. JACIE was founded by the European Group for Blood and Marrow Transplantation (EBMT) and the International Society for Cellular Therapy (ISCT), the two leading scientific organizations involved with cellular transplantation in Europe.

The FACT Inspection and Accreditation Program was developed by Dr. Phyllis Warkentin, FACT Medical Director, the FACT Directors and Officers, as well as the ISCT and ASBMT Regulatory and Standards Committees. The first edition of the FACT Standards was published in September 1996, and the first inspections began in September 1997 with the first programs awarded accreditation in 1998.

About the National University Health System (NUHS)  
The National University Health System (NUHS) groups the National University Hospital (NUH), the NUS Yong Loo Lin School of Medicine, the NUS Faculty of Dentistry and the Saw Swee Hock School of Public Health under a common governance structure to create synergies to advance health by integrating clinical care, research and education.

The enhanced capabilities and capacity will enable the NUHS to deliver better patient care, train future generations of doctors more effectively and bring innovative treatments to patients through groundbreaking research.

For more information about the NUHS, please visit www.nuhs.edu.sg

About the National University Cancer Institute, Singapore  
The National University Cancer Institute, Singapore (NCIS) offers a broad spectrum of cancer care and management covering both paediatric and adult cancers, with expertise in prevention, screening, diagnosis, treatment, rehabilitation and palliative care. The Institute's
strength lies in the multi-disciplinary approach taken to develop a comprehensive and personalised plan for each cancer patient and his or her family.

NCIS draws on the expertise of its specialists in the fields of haematology-oncology, radiation oncology, gynaecologic oncology, paediatric oncology, surgical oncology, oncology nursing, oncology pharmacy, palliative care, pathology, radiology, medical specialties including gastroenterology and hepatology, infectious diseases, pulmonary and critical care, psychiatry, epidemiology and public health as well as other allied health sciences.

With several award-winning clinician-scientists and clinician-investigators, NCIS has an international reputation in translational research and clinical trials, providing patients with access to promising breakthroughs in cancer diagnostics, technology and therapies. NCIS is also closely affiliated with the Cancer Science Institute of Singapore, National University of Singapore.

For more information about the NUHS, please visit www.ncis.com.sg

About the National University Hospital
The NUH is a tertiary specialist hospital and major referral centre for over 35 medical and surgical specialty services. These include Cardiology, Gastroenterology and Hepatology, Obstetrics and Gynaecology, Oncology, Ophthalmology, Paediatrics, Orthopaedic Surgery and Hand and Reconstructive Microsurgery.

Staffed by a team of healthcare professionals who rank among the best in the field, the NUH offers quality patient care by embracing innovations and advances in medical treatment.

In 2004, the NUH became the first Singapore hospital to receive the Joint Commission International (JCI) accreditation, an international stamp for excellent clinical practices in patient care and safety. Today, patient safety and good clinical outcomes remain the focus of the hospital as it continues to play a key role in the training of doctors, nurses and allied health professionals, and in translational research which paves the way for new cures and treatment, offering patients hope and a new lease of life.

A member of the National University Health System, it is the principal teaching hospital of the NUS Yong Loo Lin School of Medicine and the NUS Faculty of Dentistry.

For more information, please visit www.nuh.com.sg
Process Overview of FACT Accreditation

**Preparation**
Review the current standards and accreditation manual to determine eligibility requirements.

**Application**
Submit the eligibility application describing the organization and accreditation goals.

**Submission**
Complete the Compliance Application to indicate compliance with the appropriate standards within 12 months of Eligibility Application approval.

**Coordination**
Additional documentation, dates for on-site inspection, selection of inspection team and determination of onsite inspection agenda.

**On-site Inspection**

**Outcome**
Organization notified of inspection results.
Submission of documentation to verify initial and in-process enhancements.

**Response**
Inspection findings are reviewed. If all FACT Standards have been met, the organization will receive a certificate indicating FACT Accreditation.
Factsheet on hematopoietic stem cell transplants at NCIS

What is a hematopoietic stem cell transplant?
Hematopoietic stem cell transplantation (HSCT) is a procedure in which multipotent stem cells collected from bone marrow, peripheral blood or umbilical cord blood are administered to a patient to reconstitute normal bone marrow function. It is usually given to patients with damaged or defective bone marrow or immune systems and is used to treat malignant diseases such as leukaemia, lymphoma and myeloma as well as non-malignant diseases such as thalassaemia, Fanconi’s anaemia and aplastic anaemia.

What are the processes involved in a transplant?
Stem cell transplant in a cancer patient involves the collection and storage of blood-forming stem cells, either from a suitably matched donor or from the patient himself/herself, in a process known as stem cell harvest. The patient is then given high doses of chemotherapy with/without radiotherapy to eliminate remaining cancer cells. This also kills the patient’s normal blood producing stem cells. Following this treatment, the harvested stem cells are immediately introduced back into the patient. This allows the bone marrow to recover its blood forming capacity and immune system. During the transplant, the patient is required to be hospitalized for about 3-4 weeks and nursed in an isolated room where he will be observed and treatment for infections that occurs. He/she will also require regular blood and platelet transfusions until his/her counts recover.

What is the recovery time?
The transplant process takes about 3-4 weeks. However, the time taken for patients to return to normal daily activity and work is variable and depends on the patient’s speed of recovery. Some patients may take as few as 6 months, while others may take a year or even longer.

What is the typical cost of such a transplant?
An autologous stem cell transplant (uncomplicated), where the patient’s own stem cells are used, costs between S$40,000-S$50,000. However, in patients where the autologous stem cell transplant can be performed as an outpatient procedure, the cost can be reduced to S$20,000 - S$25,000.

An allogeneic stem cell transplant (uncomplicated), where the stem cells are used from a suitably matched stem cell donor, the cost is between S$60,000 and S$130,000, depending on the type of donor.

In a peripheral blood stem cell harvesting, where chemotherapy with growth factors are used to mobilise stem cells from the bone marrow into the blood circulation for collection, the cost of this procedure is between S$10,000 - S$15,000.

Transplant programmes at NCIS
The hematopoietic stem cell transplantation programme at NUHS is one of the biggest in Singapore. Almost 60-65 transplants (adult and paediatric inclusive) are performed at NUHS.
each year. The programme takes referrals from within Singapore, the surrounding Asian countries, and also from afar.

The programme is the only comprehensive and fully equipped centre in Singapore which treats both adult and paediatric patients on one site. All stem cell transplant related facilities, i.e. the clinical unit, collection unit and processing unit are conveniently located on a single site. The programme is also fully supported by having all medical and surgical specialties for both adult and paediatrics in one hospital which are essential for transplant care.

The programme offers all types of transplants: autologous, allogeneic, unrelated donor, cord blood, haplo-identical transplants. It treats both cancer and non-cancer conditions. For non-complex cases such as multiple myeloma, the programme now offers an outpatient autologous stem cell transplant service.

The transplant programme is formed by a multi-disciplinary adult and paediatric team comprising transplant physicians, haemato-oncologists, specially-trained bone marrow transplant nurse coordinators and nurses, pharmacists and other healthcare professionals such as medical social workers and dietitians.

The adult stem cell transplant clinical facility at NUHS include:

Inpatient Care
- 6 Hepa-filtered rooms
- 20 isolation rooms

Outpatient Care
- 5 BMT clinic sessions
- Day therapy unit
- Outpatient transplant
- Cellular Therapy eg. Donor lymphocyte infusion
- Transfusions/Infusion Therapies
- Daily Walk-in/direct access service

As part of its commitment to providing holistic care to patients, the programme also runs a thriving support group for transplant patients as well as to help them cope with lifestyle changes that they would have to undergo following a transplant and leading up to one. The group, started in 2009, organises regular meetings to facilitate sharing among patients, doctors and caregivers as well as social activities to foster social support. It has around 100 members.
Factsheet on NUH paediatric bone marrow transplant programme

The Blood and Bone Marrow Transplantation (BMT) programme in the NUH Division of Paediatric Haematology-Oncology started in 1983. It is the oldest and largest paediatric BMT service providing unrelated donor stem cell transplantations in Singapore. The division performs bone marrow transplants, peripheral blood transplants, cord blood transplants and complicated transplants such as mismatched adult donors and mismatched dual cord blood donors. The division also uses cellular therapies in collaboration with St Jude investigators to treat highly aggressive cancers.

Conditions treated under the BMT programme include acute and chronic leukemia, lymphoma, eurablastoma and other solid tumors, aplastic anemia and other marrow failure syndromes and thalassemia, among many others.

The BMT team consists of doctors and nurses who are trained and experienced in paediatric BMT and provide round-the-clock care to patients and their families. The team is supported by a larger team of specialists in Intensive Care, Apheresis Service, Nephrology, Hepatology, Gastroenterology, Pulmonology, Cardiology, Neurology, Endocrinology, Otolaryngology, Ophthalmology, Emergency Care, Surgery and Orthopedic Surgery.

Patients also benefit tremendously from services of the on-site Blood Donation Centre, Blood Bank and Stem Cell Laboratory. These facilities are American Association of Blood Banks-accredited since May 2006.

Bone marrow transplants are conducted at the Viva-University Children's Cancer Centre located in NUH. The centre has 17 beds with five stem cell transplant rooms and three isolation rooms. The Stem Cell Transplantation Suite comprises five individually High Efficiency Particulate Air (HEPA)-filtered positive pressure rooms which provides the highest quality of isolation for BMT patients. It also has a dedicated HEPA-filtered exercise corridor, motion-activated double-door, play area and nursing counter.
Factsheet on Department of Laboratory Medicine at NUH

The Department of Laboratory Medicine provides laboratory based testing services to support all the clinical disciplines at NUH. In addition, we provide reference laboratory testing for other hospitals, polyclinics, clinical research organizations, researchers locally as well as from overseas.

Our Core Laboratory has a fully automated line system with automated analytical modules for chemistry, haematology, immunoassay and coagulation testing. Samples are generally untouched by human handling throughout the entire testing cycle. In addition, all results are reported back to the clinicians electronically, a paperless system.

We have four clinical divisions: Clinical Chemistry, Haematology, Microbiology and Molecular Diagnosis Centre with a menu of more than 500 test type. For the detailed tests, kindly refer to our intranet eService Guide.

Accreditation
Under NUH wide accreditation, we are accredited to the following standards:

- ISO 14001 and OHSAS 18001 certification
- Joint Commission International (JCI) Accreditation

The Department of Laboratory Medicine is also accredited by the following laboratory specific standards:

- College of American's Pathologist (CAP) - Laboratory Accreditation Programme 
  (Full laboratory accreditation including Molecular Pathology and Flow Cytometry)
- Singapore Accreditation Council (SAC) - Singapore Laboratory Accreditation Scheme 
  to ISO15189
- FACT (Foundation for the Accreditation of Cellular Therapy – first in Asia to obtain 
  this in 2012)
- AABB (American Association of Blood Banks – first in Asia to be accredited for 4 
  areas, ie donor centre, blood banking, cord blood, stem cells.
- MOH's National Public Health Unit for our HIV and Malaria testing testing facilities