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PRESS RELEASE
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DUKE-NUS AND HEALTH SCIENCES AUTHORITY (HSA) SUCCESSFULLY CONDUCTED THE FIRST-IN-WORLD PILOT PROGRAMME ON MULTI-REGIONAL CLINICAL TRIALS

The first-in-world pilot programme on Multi-Regional Clinical Trials (MRCT) was successfully concluded on 19 March 2014 in Singapore. Endorsed by APEC (Asia-Pacific Economic Cooperation), this programme was organised by Singapore's Health Sciences Authority (HSA) and the Duke-NUS Graduate Medical School Singapore (Duke-NUS).

2 Conceptualised and endorsed by APEC and the Regulatory Harmonization Steering Committee at the beginning of 2013, the programme comprises on-line learning modules coupled with face-to-face meetings that provide the platform to discuss and address issues faced by regulators and to form supporting professional networks. The programme was developed for clinical trials regulators to enhance their understanding of the acceptance of MRCT results for review by regulatory authorities; facilitate training in internationally recognised technical guidance; and promote science-based review and evaluation of MRCTs. 50 participants from health products regulatory agencies from 19 out of 21 members of the APEC forum underwent the training.

3 MRCT - the simultaneous conduct of a clinical trial in multiple geographical regions - plays a major role in providing patients with access to innovative new medicines. It is particularly important for APEC economies to have relevant skilled human capacity in regulating this area as APEC is an increasingly important destination for MRCTs because of the growth of drug development and clinical trials across the region.

4 "Duke-NUS was established for the purpose of training the next generation of leaders, including regulators, to develop a vibrant biomedical hub for Asia. We are honored to have hosted nearly 50 regulators from 19 APEC member economies for this ground-breaking pilot project and to play a role in levelling up competencies in clinical trials regulation" said Prof. Ranga Krishnan, Dean of Duke-NUS.

5 Assoc Prof John Lim, CEO of HSA, said, "As a national health products regulator protecting and advancing national health and safety, HSA also aims to facilitate a conducive regulatory environment supporting biomedical development. Patients look for faster access to safe, efficacious and good quality health products. It is essential to promote and align regulatory excellence in the conduct and regulation of clinical trials to enable expeditious access to innovative and safe new medicines. We would like to thank our colleagues from the US Food and Drug Administration, Health Canada and the University of Virginia for helping to develop the content for this pilot programme.

6 "APEC accounts for over 40% of the world's population, 54% of world GDP and 44% of world trade. I am delighted to see APEC member economies working alongside our colleagues

in academia and regulatory agencies with the aim of facilitating MRCTs that ultimately will benefit patients," said Mike Ward, Chair of APEC's Life Sciences Innovation Forum Regulatory Harmonization Steering Committee.

7 With the success of this pilot programme, APEC is exploring with Duke-NUS and HSA further programmes or "Centres of Excellence" for MRCT and other regulatory science topics to enhance the capacity of regulatory agencies across the region. In future, such programs could also accommodate clinical trials professionals from industry and healthcare institutions to promote greater regulatory convergence.

8 "This MRCT Center of Excellence is the type of collaboration that is needed among academia, industry, and government to facilitate biomedical innovation. I salute APEC member economies, Duke-NUS, HSA, and their industry partners for their vision in piloting such a program," said faculty member Dr. Robert J. Meyer, MD, Director of the Virginia Center for Translational and Regulatory Sciences at the University of Virginia's School of Medicine.

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About Duke-NUS Graduate Medical School
The Duke-NUS Graduate Medical School Singapore (Duke-NUS) was established in 2005 as a strategic collaboration between the Duke University School of Medicine, located in North Carolina, USA and the National University of Singapore (NUS). Duke-NUS offers a graduate-entry, 4-year M.D. (Doctor of Medicine) training programme based on the unique Duke model of education, with one year dedicated to independent study and research projects of a basic science or clinical nature. Duke-NUS also offers M.D/PhD and PhD programmes. As a player in Singapore's biomedical community, Duke-NUS has identified five Signature Research Programmes: Cancer & Stem Cell Biology, Neuroscience and Behavioural Disorders, Emerging Infectious Diseases, Cardiovascular & Metabolic Disorders, and Health Services and Systems Research.

Duke-NUS and SingHealth have established a strategic partnership in academic medicine that will guide and promote the future of medicine, tapping on and combining the collective strengths of SingHealth's clinical expertise and Duke-NUS' biomedical sciences research and medical education capabilities.

For more information, please visit www.duke-nus.edu.sg

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 and 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. As the national blood service, it is

responsible for providing a safe and adequate blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice.

For more details, visit http://www.hsa.gov.sg/.

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