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ASX Announcement
TBG Biotechnology First to Receive China FDA Approval for High Resolution HLA Genotyping for Hematopietic Cell Transplantation

Melbourne – October 23th, 2017 - TBG Biotechnology Corp. have received today the approval from the China Food and Drug Administration (CFDA) for a portfolio of high resolution Human Leukocyte Antigen (HLA) genotyping kits widely used in hematopoietic cell transplantation (HCT) in the treatment of leukemia, lymphoma, aplastic anemia and myelodysplastic syndromes. It is the first approval of its intended use in China and by law, once a CFDA approved product is available, all clinical laboratories should use CFDA approved products for clinical testing. Currently, TBG's HLAssure™ SE SBT Kits will be the only marketed products that can fulfill the requirement for high resolution HLA genotyping.

The CFDA approved HLAssure™ SE SBT Kit portfolio covers HLA loci A, B, C, DRB1 and DQB1. These are the primary genetic targets currently used for assessing the compatibility between donors and the recipient. Other clinical applications for HLA high resolution typing include disease association with autoimmune diseases and prediction of susceptibility to drug hypersensitivity.

"China has one of the fastest growing allogeneic HCT markets with a CAGR of over 18.9%. We were determined to be the first to provide a CFDA approved high resolution typing solution for the HLA typing laboratories in China," said Ifan Chiu, President of the TBG Biotechnology Xiamen.

The rapid growth in the number of HCT is partially due to the increasing availability of compatible donors. As all donors require HLA typing, it also makes up one of the larger segments of the HLA typing market. These donors can either be from related family members, China bone marrow registry, or the cord blood registries. Since 2003, the China bone marrow registry has accumulated 2,370,569 register donors and over 170,000 donor samples are HLA typed and added to the registry every year.

The TBG subsidiary in Xiamen China is currently in discussion with several top tier HCT laboratory distributors and service providers to ensure that the products can be rapidly and properly implemented across China.

"Since the incorporation of our TBG Xiamen subsidiary in 2014, TBG has always focused on China as one of the key markets in becoming a global supplier for clinical diagnostics. Being privileged as the first to receive CFDA approval for high resolution HLA typing kit is only the first step. TBG will continue to lead the market with developments of biomarkers in HCT diagnostics as well as key partnerships in next generation sequencing platforms." Said Eugene Cheng, Group COO of TBG Diagnostics Limited.

About TBG Diagnostics

TBG Diagnostics is a global molecular diagnostic (MDx) company operating in the IVD (in vitro diagnostics) industry. TBG is focused on the development, manufacture and marketing of molecular diagnostic kits, instruments and services

TBG Diagnostics is an established brand with a strong presence in the Asian market. From its plant in Xiamen, China it develops and manufactures:

- Nucleic Acid Test (NAT) products

- HLA typing reagents based on NAT technologies
- Automation systems for NAT operations
- IVD-related NAT kits and services

Products distributed to more than 22 countries. Major hospital and laboratory clients in USA, Taiwan, Germany, Portugal, China, Hong Kong and Singapore. Operating in the rapidly growing IVD market - US$53 billion in 2013 and expected to reach US$74.7 billion by 2020.

Targeting further growth in China - fastest growing MDx market at CAGR of 27.9%. Extensive research and development pipeline targeting products for oncology, infectious diseases, transplants, transfusions, pharmacogenetics, autoimmune diseases and genetic diseases.