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## **TBG ExProbe™ Real Time PCR Based Typing Kit receives Taiwan FDA approval and CE Mark, immediately opens markets**

### **Key highlights**

- **TBG Typing Kit, ExProbe™ receives CE Mark and Taiwan FDA approval**
- **One of fastest test products available for Human Leukocyte Antigen diagnostics**
- **ExProbe™ Typing Kits are also planned for production in TBG Xiamen facility and China FDA registration.**
- **Key certification for a new TBG product line to enhance HLA IVD pipeline**
- **Global HLA market is worth roughly \$700m AUD and growing at 7% CAGR**

**Melbourne, Australia, July 24 2017.** The Board of TBG Diagnostics Limited (ASX: TDL) (the **Company** or **TBG**), an emerging leader in Molecular Diagnostics in the Asian Pacific region, is pleased to announce that our **ExProbe™ SE HLA ABCDRDQ (ExProbe™)** Typing Kit has received the European CE-Mark as well as the Taiwan TFDA market approval. Receiving these certifications immediately allows access to existing and new markets with a unique TBG Diagnostics product.

The **ExProbe™** system is developed based on the real-time PCR (polymerase chain reaction) technology platform. With less than 80 minutes from purified DNA to clinical report, this is one of the fastest molecular Human Leukocyte Antigen (HLA) testing products available. TBG is the first to receive CE-Mark as well as Taiwan TFDA clearance for a real-time PCR test with 5 HLA loci in a single 96 well tray.

Real-time PCR platform testing has been widely adapted in nearly all molecular diagnostics laboratories. In addition to transplantation and transfusion, new roles for HLA typing have been discovered in drug hypersensitivity and other auto-immune diseases. The need to perform HLA typing has reached beyond the traditional transplant laboratories. With TBG's new real-time PCR product, molecular HLA testing is now easy for any laboratory to adopt and perform.

Previously, TBG has been selling its real-time products to the market as RUO (research use only). Now that the products are CE and Taiwan TFDA certified, they can now be used in clinical settings across a larger market. Once certification is attained, the products are released to market immediately. Manufacture of the **ExProbe™** kit has to date been in Taiwan. However, with the plan to achieve regulatory approval in China, TBG will soon be able to commence manufacture from its state of the art facility in Xiamen, mainland China.

TBG sees the development of new diagnostics products such as the **ExProbe™** Typing Kit and Next Generation Sequencing (NGS) as crucial as these new HLA technologies overtake traditional platforms which are much slower and inefficient. TBG now offers a range of HLA IVD products with four technology platforms: SSP (Sequence Specific Primers), SBT (Sequence Based Typing), Real Time PCR and NGS.

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**About TBG Diagnostics**

Listed on the Australian Stock Exchange (ASX: TDL), TBG Diagnostics is a global Molecular Diagnostics (MDx) company operating in the In-vitro Diagnostics (IVD) 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 manufacturing facility 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

TBG products are distributed to more than 22 countries including major hospital and laboratory clients in USA, Taiwan, Germany, Portugal, China, Hong Kong and Singapore. Operating in the rapidly growing molecular diagnostics (MDx) market which is growing at 7% CAGR and estimated to be valued at approximately US\$10Bn by 2021.

TBG Diagnostics is targeting further growth in China - fastest growing MDx market at CAGR of 27.9%. TBG has an extensive research and development pipeline targeting products for oncology, infectious diseases, transplants, transfusions, pharmacogenetics, autoimmune diseases and genetic diseases