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# Progen PG500 Series Pty Ltd Completes Phase I Monotherapy Trial

**Melbourne, Australia, 22 July 2016.** TBG Diagnostics Ltd (ASX:TDL, the Company) today announces that its wholly-owned subsidiary Progen PG500 Series Pty Ltd (the former R&D team at Progen Pharmaceuticals Ltd), has successfully completed the primary objective of a Phase 1 clinical trial of PG545 in patients with advanced solid tumours.

The PG545102 Phase I study was a dose-escalating study conducted to assess the safety and tolerability of PG545 in patients with advanced solid tumours at sites across Australia. The study completed four dose cohorts, with a total of 23 patients, as a once-weekly intravenous infusion. In July 2016, Progen PG500 Series Pty Ltd held an end-of-cohort meeting with the study investigators and medical monitor after the completion of an expansion cohort evaluating a dose of 100mg. This dose was declared the maximum tolerated dose (MTD).

Keith Dredge, Director of Drug Development said, "We have now established a safe and well tolerated dose for PG545 which is considered to be a therapeutic dose. We are currently analysing biomarker samples, the results of which will be reported in due course. We are very grateful to the patients and their treating physicians involved in the study".

One patient remains on-study and full results of the Phase I study will be presented at a major international cancer conference in due course.

### **ENDS**

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### **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 MDx market which is increasing from 10% (\$6Bn USD) to 25.2% (\$25Bn USD) of total IVD market share by 2024. Targeting further growth in China – the 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

#### **About PG545**

PG545 is a new multifunctional anti-cancer drug designed to target the tumour microenvironment and developed inhouse by Progen Pharmaceuticals. PG545 has been demonstrated in a variety of cancer models to slow the growth rate and/or destroy cancer cells directly, block the growth of new blood vessels within tumours (angiogenesis), stop the spread of cancer (metastasis), and modulate specific immune cells known to interact with cancer cells. These complementary mechanisms are uniquely targeted by PG545 to block key processes in cancer development and represent a novel approach to the treatment for several cancer types.

This release contains forward-looking statements that are based on current management expectations. These statements may differ materially from actual future events or results due to certain risks and uncertainties, including without limitation, risks associated with drug development and manufacture, risks inherent in the extensive regulatory approval process mandated by, amongst others, the United States Food and Drug Administration , the China Food and Drug Administration and the Australian Therapeutic Goods Administration, delays in obtaining the necessary approvals for clinical testing, patient recruitment, sample collection, delays in the conduct of clinical trials, market acceptance of TBG products, future capital needs, general economic conditions, and other risks and uncertainties detailed from time to time in the Company's filings with the Australian Securities Exchange and the United States Securities and Exchange Commission. Moreover, there can be no assurance that others will not independently develop similar products or processes or design around patents owned or licensed by the Company, or that patents owned or licensed by the Company will provide meaningful protection or competitive advantages.