Australian Securities Exchange
Company Announcements

18 November 2013

IDT Moves to Build Generic Drug Portfolio, Files ANDA for Temozolomide in the US

- **IDT Australia Limited (ASX:IDT) has filed an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (FDA) seeking approval to market temozolomide capsules**
- **The temozolomide market is large (US$996 million) and IDT seeks to capitalise the opportunity to manufacture generic products as temozolomide comes off patent next year**
- **This initiative harnesses IDT's competitive advantage in specialised pharmaceutical capabilities, formulation expertise, and know-how in relation to difficult to manufacture drugs.**
- **This is the first product in a series of potential IDT registered generic products**

18th November 2013, Melbourne: IDT Australia Limited (ASX:IDT) today advised that it has filed an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (FDA) seeking approval to market 6 different strengths of temozolomide capsules. Temozolomide is indicated for the treatment of melanoma and glioblastoma multiforme, and comes off patent in the US in 2014, being already off patent in some other jurisdictions.

For the year ending 31 March 2013, the global market for temozolomide was approximately US$996 million.[1]

The ANDA submission for Temozolomide leverages the specialist manufacturing plant, formulation expertise, handling and know-how that have been built up at IDT to handle difficult to manufacture drugs.

With 30 years of experience in specialised pharmaceutical manufacturing, IDT possesses a wide body of manufacturing expertise and know-how relating to a number of drug classes. Many of these products, have now become available for generic registration as their patents expire. Using this knowledge, IDT therefore has a suite of potential generic products with substantial markets and short timelines to market.

As has been achieved with temozolomide, the process of building an ANDA using IDT's knowledge base and facilities consists of (i) the manufacture of three finished dose stability batches and (ii) demonstration of bioequivalence. Intravenous drugs are automatically deemed to be equivalent, while oral drugs may require *in vitro* studies, or in some cases a small human or animal equivalence study. Thus, this is a far simpler, quicker and less costly path to market than the development of new chemical entities.

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[1] Newport Premium: cited electronically at https:newport.thompson-pharma.com/newport/Product/profile.do?apiGrpId=11400

"IDT's strategy is to maximise the value of our substantial infrastructure, experience and intellectual property to selectively grow our own generic drug portfolio." said Dr Paul MacLeman, Managing Director of IDT. "IDT is now in the process of moving up to a greater share of the industry value chain as the owner of a range of registered and marketed drugs rather than solely as a contract manufacturer of pharmaceutical ingredients. This change could potentially take our share of the value chain for such products from single digit percentages to tens of percentages of the wholesale price."

The Company is in regular discussions with several large generic pharmaceutical distributors in the US and elsewhere who have expressed interest in partnering for the sales and marketing of IDT generic products. IDT's supply of turnkey products with marketing approvals, materially de-risks deals for these companies, so delivering more value to IDT.

IDT is commencing with this first oncology drug filing but plans to file for selected additional generic drugs over the next 12-18 months. The drug target prioritisation will be focussed on those where IDT possesses a clear competitive advantage, encompassing existing tight API supply, a difficult to manufacture or difficult to handle drug, which is off or coming off patent and where there is strong market demand. Many of these are likely to be further oncology drugs, which in addition to being high value, often require the specialized manufacturing facilities and skills that IDT possesses.

The global generics market was estimated at about $225 billion in 2011. By 2016, it is expected that the value of the total global generics sector will have risen to $358 billion, representing more than 18% of all pharmaceuticals, a projected compound annual growth rate (CAGR) of 9.7% between 2011 and 2016[2]. Drivers for this are patent expiries in large product categories, falling rates of innovation productivity and cost pressures for private and government payers. Backward and forward integration in the generics industry has also made the segment a target of high levels of mergers and acquisition activity.

IDT is grateful for assistance provided by the Victorian State Government early in the development of this project, which assisted in the feasibility assessment for the program.

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About IDT

IDT Australia Ltd (ASX:IDT) is a public Australian pharmaceutical manufacturing company. Based in Boronia, Victoria and with 30 years' experience in the development and production of high potency and high containment pharmaceutical products for local and international clients, IDT's extensive facilities are fully cGMP compliant and are regularly audited by the US FDA and Australian TGA. With an experienced and professional team, operating within world-class facilities, IDT is committed to providing a full-scale service for new drug development and scale-up, commercial active drug manufacture as well as a variety of oral and injectable finished drug dose forms.

Through CMAX, its clinical research services business based at the Royal Adelaide Hospital in South Australia, IDT also provides full Phase I clinical trials management and delivery, recruitment in specific disease states for Phase II and Phase III trials as well as being able to offer trial packaging, distribution and pharmacy services from the cGMP Boronia facilities.

[2] BCC Research: cited electronically at http://www.bccresearch.com/market-research/pharmaceuticals/generic-drugs-global-market-phm009f.html