FDA Approval Secured for IDT's Temozolomide Product

US launch planning underway with Mayne Pharma

Approval Comes Earlier Than Expected - Possible CY 2016 launch

USD200 million addressable US market[1]

13 April 2016, Melbourne: IDT Australia Limited (IDT.AX) has today achieved a major commercial milestone having succeeded in gaining approval from the US Food and Drug Administration (FDA) for its oral brain cancer drug Temozolomide. This approval will pave the way for the commercial launch of what is to be the first product in a portfolio of IDT's own generic drug products into the US market.

The approval is the first for IDT under the Abbreviated New Drug Application (ANDA) system; and has been granted over six months earlier than initially expected. The addressable market for Temozolomide in the US alone is currently over USD 200 million.[1]

A US distribution partner is already in place and commercial launch preparations are now underway. In September 2015 IDT announced the appointment of Mayne Pharma as the distributor for IDT's Temozolomide product in the US (IDT ASX announcement 24 Sept 2015). As a result of this FDA approval, IDT and Mayne will immediately begin planning for a commercial US launch for the product. This is now expected to deliver revenues in CY2016.

"Securing FDA approval for the first of IDT's proprietary products is a major milestone for the Company, and to have this ahead of schedule is a fantastic result," said IDT's chief executive, Dr Paul MacLeman. "We expect this launch to pave the way for the introduction of other IDT products into the US market as we build our manufacturing capabilities and expand our marketed generic drug portfolio."

IDT will provide further updates on the expected US launch date for Temozolomide as details come to hand.

ENDS

For further information please contact:
IDT Australia Limited
Dr Paul MacLeman
Managing Director
(03) 9801 8888

Monsoon Communications
Rudi Michelson
(03) 9620 3333

[1] IMS Health USD MNF sales by quarter up to December 2015

About IDT

IDT (ASX:IDT) is a public Australian pharmaceutical manufacturing company based in Boronia, Victoria, Australia. IDT is commercializing a portfolio of 24 generic drugs to manufacture and sell via US distribution partners. The company is also exploring EU and Japanese sales opportunities. With IDT's 2013 Temozolomide ANDA filing this signifies IDT's move to rapidly become a specialty generics business with near term revenue build up.

IDT has extensive experience in the development and production of high potency and high containment pharmaceutical products for local and international clients. IDT's facilities are fully cGMP compliant and are regularly audited by the US FDA and Australian TGA. With an experienced team of specialists within world-class facilities, IDT provides 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 offering trial packaging, distribution and pharmacy services from the cGMP Boronia facilities.