FDA Confirms Change of Ownership of 23 US Generic Drugs and IDT Successfully Manufactures First Batch of Tablets

U.S. FDA receipts notice from IDT as the new registered owner of note of the recently acquired 23 generic drug products.

IDT successfully manufactured its first engineering batches of tablets (Doxazosin Mesylate 1mg and 8mg) in its Boronia manufacturing facility.

13 April 2015, Melbourne: IDT Australia Limited (IDT.AX) announces that the U.S. Food and Drug Administration (FDA) has confirmed receipt of the change of ownership letters formally transferring ownership of the 23 generic drug products to IDT.

Formalising change of ownership is a process whereby the vendor and the purchaser both submit correspondence informing the FDA that the transfer of a drug registration has occurred. The FDA's "Orange Book", the register kept by the FDA listing all US approved drug products and their owners, will be updated in due course.

Integration of the 23 Generic Drug Products

The process of integrating these 23 US generic drug products is well underway with the successful manufacture of engineering batches of 1mg and 8mg Doxazosin Mesylate tablets in IDT's Boronia manufacturing facility. Engineering batch manufacture involves matching the formulation and manufacturing process contained within the original drug registration dossier. It is an important milestone for IDT to show regulators that it can make these drug products according to the original FDA approved registration.

Figure 1: Doxazosin tablet manufacture IDT Boronia

Figure 2: Doxazosin Mesylate 1mg (left) and 8mg (right)

Following the success of the engineering batches, IDT will now move on to the manufacture of exhibit batches of drug product that will be placed on stability studies. The data from the exhibit batch manufacture and stability work form the basis of a submission to the FDA to re-activate the marketing approval of the products.

Dr Paul MacLeman, Managing Director and CEO of IDT Australia, said: "*I am pleased to say that IDT is now the registered owner of these US generic drug products.*"

"The successful manufacture of Doxazosin in IDT's Boronia solid oral dosage form facility is a turning point for the Company in that we have now shown that IDT has the personnel, equipment and resources required to manufacture these newly acquired products in-house."

"We are focused on getting these drug products back on the market as quickly as possible using established and strong distribution partners."

The Company will update shareholders as further progress occurs.

ENDS

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About IDT

Established in 1975, IDT Australia Ltd (ASX:IDT) is a public Australian pharmaceutical manufacturing company. Based in Boronia, Victoria and with 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 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.