IDT Finalises Partnership with Mayne Pharma for Exclusive Distribution of Temozolomide in the US

IDT finalizes appointment of Mayne Pharma Group Limited as US partner in the distribution of IDT's Temozolomide drug product
Temozolomide had US annual sales at June 2015 of over USD220m
Targeting launch of the products in late calendar 2016 to early 2017

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24 September 2015, Melbourne: IDT Australia Limited (IDT.AX) has completed another major commercial milestone, finalizing an agreement with a US subsidiary of Mayne Pharma Group Limited (ASX: MYX "Mayne Pharma") to distribute IDT's generic Temozolomide product in the United States of America.

IDT filed an Abbreviated New Drug Application ("ANDA") for Temozolomide in late 2013 (ASX announcement 18 November 2013). Temozolomide is indicated for the treatment of melanoma and glioblastoma multiforme and had US sales of approximately USD 220 million in the 12 months ending 30 June 2015[1].

The Distribution Agreement has an initial term of ten years, with Mayne Pharma as the exclusive distributor for IDT's Temozolomide in the US, subject to certain minimum order requirements. Mayne Pharma will pay certain upfront payments totalling just over USD1.06 million to IDT upon: filing of IDT's Temozolomide Abbreviated New Drug Application ("ANDA"), execution of this Distribution Agreement, acceptance of the ANDA by the US Food and Drug Administration ("FDA") and upon IDT's first commercial supply of Temozolomide to Mayne Pharma. The Agreement also contains a product pricing and profit share arrangement based on IDT's manufacture and Mayne Pharma's US sales of IDT's Temozolomide product respectively. The exact commercial terms regarding the product pricing and profit share arrangements are confidential between the parties

Mayne Pharma operates a full-service speciality pharmaceutical business in the US that develops, manufactures, markets and distributes over 25 products and also has an impressive pipeline of products under development. Headquartered in Greenville, North Carolina, Mayne Pharma's US operations complies with all relevant state licensing and FDA requirements and has substantial commercial and distribution capabilities that can service all US pharmaceutical accounts.

"We are pleased to finalise the details of our arrangements with Mayne Pharma, and look forward to a mutually beneficial relationship supplying this valuable and important drug to US patients." said Dr Paul MacLeman, Managing Director of IDT.

IDT's Temozolomide ANDA has been "Accepted for Review" by the US FDA and is currently progressing through the FDA's review process. The parties are targeting a commercial launch of Temozolomide in the US in late calendar 2016 to early 2017.

ENDS

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

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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 IDT is commercialising a portfolio of specialty generic drugs with aggregate addressable markets of over US$800 million.

With extensive experience in the development and production of high potency and high containment pharmaceutical products for local and international markets, 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 also committed to providing international pharmaceutical customers services in drug development, scale-up, clinical services and commercial drug manufacture.

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.