

Zydus receives two product approvals from the USFDA

Ahmedabad, 15 September 2017

Zydus Cadila has received the final approval from the USFDA to market Modafinil tablets USP, 100 mg and 200 mg. Modafinil tablets are indicated to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnoea or shift work disorder. The sales of Modafinil tablets USP are estimated at \$ 148.66 million. *Source: IMS Health, IMS National Sales Perspective Audit, MAT July 2017, extracted September 2017.*

The group also received the tentative approval for Solifenacin Succinate tablets in strengths of 5 mg and 10 mg. Solifenacin Succinate tablets are indicated for the treatment of overactive bladder associated with symptoms of urinary incontinence and urinary frequency. The sales of Solifenacin Succinate tablets are estimated at \$1.04 billion. *Source: IMS Health, IMS National Sales Perspective Audit, MAT July 2017, extracted September 2017.*

Both the drugs will be manufactured at the group's formulations manufacturing facility at the Pharma SEZ, Ahmedabad.

The group now has more than 150 approvals and has so far filed over 300 ANDAs since the commencement of the filing process in FY 2003-04.
