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Jubilant receives ANDA approval for Spironolactone

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Jubilant Life Sciences receives ANDA approval for spironolactone

Jubilant Life Sciences, an integrated Pharmaceuticals and Life Sciences Company announced that it has received Abbreviated New Drug Application (ANDA) approval from the US Food and Drug Administration (US FDA) for Spironolactone Tablets, 25 mg, 50 mg and 100 mg, the generic version of Aldactone (of GD Searle), which is used as a diuretic to treat fluid retention (edema) caused by congestive heart failure and cirrhosis of the liver. We expect to launch this product in Q1 FY15.The total market size for Spironolactone Tabletsas per IMS is US$ 87Million per annum.

Jubilant has also received a tentative approval from the USFDA for Memantine Tablets, 5 mg and 10 mg, the generic version of Namenda (of Forest Labs), which is used for treatment of moderate-to-severe Alzheimer's disease. We expect to launch this product post patent expiry in 2015. The total market size for Namenda as per IMS is US$ 1.85 Billion per annum.

As on December 31, 2013, Jubilant Life Sciences had a total of 689 filings for formulations of which 230 have been approved in various regions globally. This includes 60 ANDAs filed in the US and 42 Dossier filings in Europe.