

Shilpa Decade 3: 2005-2014: Oncology Consolidation:2015....New Frontiers

Shilpa Medicare History 2005 -2015

The Oncology Decade 2005-2014

2007

- Shilpa Medicare Ltd has entered into a memorandum of understanding (MoU) with LOBA Biochemie AG, Austria, to acquire 100% shares of LOBA in an all-cash deal; - Company splits its face value from Rs10/- to Rs2/-, Company is a recognized "Star Export House". During the year the Company has received COS from EDQM for products Oxaliplatin, Carboplatin, Baflomed HCL.

2008

- Shilpa Medicare being one of the niche players in oncology products will certainly have good prospectus in the years to come as the demand for these drugs is expected to grow faster than other drugs. The Company will be one of the largest Oncology API manufacturers once the 100% EOU is fully operational

2009

- Shilpa Medicare Ltd has informed that the Company has signed a MOU to form a joint venture company to manufacture drugs and pharmaceuticals with ICE S.r.l and PCA S.p.a. of Italy. Filed USDMF of Anastrozole with USFDA (23123), Ambroxol MF Holder & Site Registered with PMDA, Japan;

2010

- Shilpa Medicare Limited has been granted certificate of GMP Compliance of Manufacturer for Gemcitabine Hydrochloride. Filed USDMF of Temozolamide with USFDA (23479); Patent Filed for Novel Polymorphic Form of Bortezomib (160/CHE/2010). Filed USDMF of Irinotecan HCl with USFDA (23562). Filed USDMF of Oxaliplatin with USFDA (23563); Received approvals for Oncology products from TGA Australia, PMDA Japan, Health Canada,

2011

- Shilpa Medicare Ltd acquired Controlling Stake in Nu Therapeutics. Thrust on filing DMFs in various countries including Canada, EU Countries, USA and China for marketing Company's products in these Countries. Obtained EUGMP Certificate for Gemcitabine HCl EP from AFSSAPS, France; Obtained EUGMP Certificate for Temozolomid (Unit-1) & Capcitabine (Unit-2) from BSC, Hamburg. Obtained EUGMP Certificate for Anastrozole, Irinotecan & Oxaliplatin from INFARMED, Portugal; In-House R & D recognised by DSIR India;

2012

- Shilpa Medicare Limited (SML) produced five key HIV medicines i.e. Tenofovir, Emtricitabine, Cobicistat, Elvitegravir and a combination of the four, known as the Quad for sale in over 100 countries, depending on the medicine. - Shilpa Medicare Ltd has announced the Company's State of art facility at Pharma Park Jodhpur (SEZ), near Mahaboobnagar (AP) for undertaking Contract Research & Forward Integration i.e. Own Formulation (Manufacturing of Oral & Injectables (Onc) Products) has started functioning partially; 18 patents filed in India, 4 in US, 3 in Europe, 1 in Japan. DMFs filed for Imatinib in China, Rendamustine in Europe several countries, Busulphan in Austria, Irinotecan Hung, V, Romania, Slovenia, Tomozolamide in Korea, Sweden, Capcitabine in Austria

2013

- Shilpa Medicare Limited (SML) produced five key HIV medicines i.e. Tenofovir, Emtricitabine, Cobicistat, Elvitegravir and a combination of the four, known as the Quad for sale in over 100 countries, depending on the medicine. Company has filed about 40 Patent applications, of which about 15 International Patent Applications (PCT), ~ 20 Indian Patent Applications (IN) and few US Patent Applications. In our endeavor for "Innovating for Affordable Healthcare" the Company successfully crossed mark of 100 patent applications entirely with in house efforts and has also successfully filed four US-DMFs. At present the Company has 13 Nos of US DMFs available as CA (Complete assessment)

2014

- Company spent about R- 2703.28 lacs on R&D. Projects of five products transferred successfully, other projects of eight products have been completed and advised for transfer to plant.

2015
Higher-Risk-Appetite?? - Newer-Frontiers? - Accelerating-Growth

- Shilpa filed 45 patent applications - cumulative total 189 patent applications in India and other countries. Received grants for 13 patents, 11 oncology APIs and 4 non-oncology APIs have been developed in R&D and successfully transferred to plant. Another 18 new oncology drugs are under development. Considering the developments in the pharma industry the Company has started focusing on development of new process and new products. Shilpa filed two ANDA with paragraph IV certifications and out of which one ANDA did not receive any notice from brand company.

2016

- Signals intent on moving faster on Biosimilars. Acquires Navya Biologicals share swap deal ~77 Cr - NBPL engaged in development of bio-similars and bio-process technology platforms.

The latest acquisition is 2% equity dilution.