

Pharmaceutical Sector

04 December 2020

Evaluating gCopaxone opportunity for potential new entrants – impact of novel drugs, therapeutic substitutes and generic competition

Prior to the approval of first generic copy (Sandoz – Glatopa) in 2015, the Copaxone brand had annual sales of US\$3.5bn in the US. However, we have seen the opportunity erode faster than expectations as we have witnessed an overall decline in the Copaxone prescription volumes in multiple sclerosis markets where it is positioned. Between 2015 and now, the product has lost about 700bps in market share and seen a ~20-25% decline in volumes. Emergence of new treatment options is the primary contributor to the decline in Copaxone's market share. We estimate the current Copaxone market size to be ~US\$1.35bn, which includes both branded and generics drugs. The generic market share is ~40%. Adjusting for the decline in prescription volume, we estimate value erosion on account of generic competition so far to be around 50%. With Dr. Reddy's and Biocon also in the fray for the launch of generic Copaxone, we evaluate how the opportunity would shape up for these potential new entrants.

Broadly we expect the declining trend in Copaxone volume to sustain as there are multiple pressure points.

- 1) Emergence of new therapeutic options
- 2) Growing share of oral therapies
- 3) Cheaper therapeutic substitutes
- 4) Potential launch of once a month gCopaxone is the most relevant threat

New therapeutic options are gaining share from incumbents as they come with better efficacy: Since the genericisation of Copaxone, we have seen the USFDA approve five new treatment options that directly/indirectly compete with Copaxone. The new treatment options include Ocrevus (Ocrelizumab) from Roche in 2017, Kesimpta (Ofatumumab) from Novartis in August 2020, Zeposia (Ozanimod) in 2020 from Bristol Myers, Mavenclad (Cladribine) from EMD Serono in 2019 and Mayzent (Siponimod) in 2019 from Novartis. The new treatment options that have emerged in the past few years are showing promising efficacy levels along with a very good safety profile, which is leading to a wider usage of these therapies.

With growing number of oral treatment options, use of injectable therapy is declining: Over 2015 to 2020, the share of oral treatments in multiple sclerosis has expanded from 35% to 45%. Recently approved Zeposia (Ozanimod) from Bristol Myers is positioned as the best-in-class oral treatment option and we expect it to be a major threat to Copaxone's market share. Zeposia positioning in the multiple sclerosis market is unique and strong, as it has demonstrated a very robust efficacy profile along with a best-in-class safety profile. The combination of very strong efficacy, best-in-class safety and convenience of oral dosing positions it as a treatment of choice in the first line setting. Apart from Zeposia, other recently approved oral treatment options include EMD serono Mavenclad and Novartis Mayzent.

Genericisation of Tecfidera – widely used treatment option will lead to cannibalization of alternative therapy: Tecfidera, which is currently the most widely used oral treatment option, has seen its patents being invalidated recently and generic versions being launched. Tecfidera has a 23% share in the multiple sclerosis market and with the price of the treatment expected to decline significantly (being a plain vanilla generic) we should expect the drug to cannibalize alternatives including Copaxone.

Mylan/Mapi Pharma is developing a long acting Copaxone (once a month glatiramer acetate) which may be launched in 2023: We see this is a very significant threat, as Mylan has initiated Phase 3 trials for once a month dosing of glatiramer acetate. Considering the fact that the active ingredient is same as Copaxone, we believe that there is a high probability of a successful launch. In phase 2 studies, once a month depot produced strong efficacy and safety inline with the thrice weekly version.

Sandoz struggling to gain market share: Sandoz, which launched generic copies in 2018, is still struggling with high single digit market share of the Copaxone pie, which implies new entrants might also see a gradual ramp up, since generic players will look to offer very limited discounts.

Conclusion: We estimate the Copaxone pie to contract by about 20% amidst the aforementioned challenges. Assuming that the new entrants would take a 20% discount to existing prices the market size would contract to approximately \$600mn to \$700mn from \$1350mn now. Considering the limited price discounts (20%) that generic players would be willing to pass, low teens market share may be a probable scenario. These assumptions translate to a sales opportunity of \$60mn to \$80mn for the new entrants. The ramp-up should be gradual considering the limited discount that generics would be looking to offer.

Vishal Manchanda

Research Analyst

 vishal.manchanda@nirmalbang.com
 +91 9737437148

Gaurang Sakare

Research Associate

 gaurang.sakare@nirmalbang.com
 +91 22 6273 8093

DISCLOSURES

This Report is published by Nirmal Bang Equities Private Limited (hereinafter referred to as "NBEPL") for private circulation. NBEPL is a registered Research Analyst under SEBI (Research Analyst) Regulations, 2014 having Registration no. INH000001436. NBEPL is also a registered Stock Broker with National Stock Exchange of India Limited and BSE Limited in cash and derivatives segments.

NBEPL has other business divisions with independent research teams separated by Chinese walls, and therefore may, at times, have different or contrary views on stocks and markets.

NBEPL or its associates have not been debarred / suspended by SEBI or any other regulatory authority for accessing / dealing in securities Market. NBEPL, its associates or analyst or his relatives do not hold any financial interest in the subject company. NBEPL or its associates or Analyst do not have any conflict or material conflict of interest at the time of publication of the research report with the subject company. NBEPL or its associates or Analyst or his relatives do not hold beneficial ownership of 1% or more in the subject company at the end of the month immediately preceding the date of publication of this research report.

NBEPL or its associates / analyst has not received any compensation / managed or co-managed public offering of securities of the company covered by Analyst during the past twelve months. NBEPL or its associates have not received any compensation or other benefits from the company covered by Analyst or third party in connection with the research report. Analyst has not served as an officer, director or employee of Subject Company and NBEPL / analyst has not been engaged in market making activity of the subject company.

Analyst Certification: I, Vishal Manchanda, research analyst and Gaurang Sakare, Research Associate the author of this report, hereby certify that the views expressed in this research report accurately reflects my personal views about the subject securities, issuers, products, sectors or industries. It is also certified that no part of the compensation of the analyst was, is, or will be directly or indirectly related to the inclusion of specific recommendations or views in this research. The analyst is principally responsible for the preparation of this research report and has taken reasonable care to achieve and maintain independence and objectivity in making any recommendations.

Disclaimer

Stock Ratings Absolute Returns

BUY > 15%

ACCUMULATE -5% to 15%

SELL < -5%

This report is for the personal information of the authorized recipient and does not construe to be any investment, legal or taxation advice to you. NBEPL is not soliciting any action based upon it. Nothing in this research shall be construed as a solicitation to buy or sell any security or product, or to engage in or refrain from engaging in any such transaction. In preparing this research, we did not take into account the investment objectives, financial situation and particular needs of the reader.

This research has been prepared for the general use of the clients of NBEPL and must not be copied, either in whole or in part, or distributed or redistributed to any other person in any form. If you are not the intended recipient you must not use or disclose the information in this research in any way. Though disseminated to all the customers simultaneously, not all customers may receive this report at the same time. NBEPL will not treat recipients as customers by virtue of their receiving this report. This report is not directed or intended for distribution to or use by any person or entity resident in a state, country or any jurisdiction, where such distribution, publication, availability or use would be contrary to law, regulation or which would subject NBEPL & its group companies to registration or licensing requirements within such jurisdictions.

The report is based on the information obtained from sources believed to be reliable, but we do not make any representation or warranty that it is accurate, complete or up-to-date and it should not be relied upon as such. We accept no obligation to correct or update the information or opinions in it. NBEPL or any of its affiliates or employees shall not be in any way responsible for any loss or damage that may arise to any person from any inadvertent error in the information contained in this report. NBEPL or any of its affiliates or employees do not provide, at any time, any express or implied warranty of any kind, regarding any matter pertaining to this report, including without limitation the implied warranties of merchantability, fitness for a particular purpose, and non-infringement. The recipients of this report should rely on their own investigations.

This information is subject to change without any prior notice. NBEPL reserves its absolute discretion and right to make or refrain from making modifications and alterations to this statement from time to time. Nevertheless, NBEPL is committed to providing independent and transparent recommendations to its clients, and would be happy to provide information in response to specific client queries.

Before making an investment decision on the basis of this research, the reader needs to consider, with or without the assistance of an adviser, whether the advice is appropriate in light of their particular investment needs, objectives and financial circumstances. There are risks involved in securities trading. The price of securities can and does fluctuate, and an individual security may even become valueless. International investors are reminded of the additional risks inherent in international investments, such as currency fluctuations and international stock market or economic conditions, which may adversely affect the value of the investment. Opinions expressed are subject to change without any notice. Neither the company nor the director or the employees of NBEPL accept any liability whatsoever for any direct, indirect, consequential or other loss arising from any use of this research and/or further communication in relation to this research. Here it may be noted that neither NBEPL, nor its directors, employees, agents or representatives shall be liable for any damages whether direct or indirect, incidental, special or consequential including lost revenue or lost profit that may arise from or in connection with the use of the information contained in this report.

Copyright of this document vests exclusively with NBEPL.

Our reports are also available on our website www.nirmalbang.com

Access all our reports on Bloomberg, Thomson Reuters and Factset.

Team Details:			
Name	Email Id	Direct Line	
Rahul Arora	CEO	rahul.arora@nirmalbang.com	-
Girish Pai	Head of Research	girish.pai@nirmalbang.com	+91 22 6273 8017 / 18
Dealing			
Ravi Jagtiani	Dealing Desk	ravi.jagtiani@nirmalbang.com	+91 22 6273 8230, +91 22 6636 8833
Michael Pillai	Dealing Desk	michael.pillai@nirmalbang.com	+91 22 6273 8102/8103, +91 22 6636 8830

Nirmal Bang Equities Pvt. Ltd.

Correspondence Address

B-2, 301/302, Marathon Innova,
Nr. Peninsula Corporate Park,
Lower Parel (W), Mumbai-400013.

Board No. : 91 22 6273 8000/1; Fax. : 022 6273 8010