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'Brands Don't Die': Cipla Grabs Rights To Novartis' Galvus In India

by Anju Ghangurde

Novartis draws up perpetual license agreement with Cipla for its vildagliptin brand in India. Experts weigh in on some deal nuances and whether the DPP-4 inhibitor can deliver long-term value in an ultra-competitive segment.

<u>Novartis Pharma AG</u> has handed over manufacturing and marketing rights for Galvus, its vildagliptin mother brand and combinations, in India to <u>Cipla Limited</u>, as part of what appears to be a wider portfolio reorientation effort underway at several large foreign firms in the country.

Under the 'perpetual license agreement', Cipla will manufacture and market Galvus and Galvus combination brands used to treat type 2 diabetes, effective 1 January 2026, though the deal is subject to meeting certain conditions precedent.

"During the interim period we would continue to market and distribute Galvus branded products," Cipla said in a filing with the Bombay Stock Exchange.

An industry expert tracking the development told *Scrip* that the deal is expected to entail a sizable payment to Novartis at the end of the three-year transition to 2026 and the interim period will see a significant part of the brand gains accrue to the Swiss firm.

Five Big Pharma Products That Saw Action In India; There's More To Come

By Anju Ghangurde

27 Jan 2023

Scrip spotlights the action around five key big pharma products in India. We track the gains made by Rybelsus and Keytruda, the wave of Januvia and Ibrance generics and on-market



"Thereafter, with own manufacturing in play, Cipla can change cost-dynamics and capitalize. Galvus still commands a premium and patients continue to stay with it despite the flood of cut-price vildagliptin versions in India post patent expiry," the executive said.

and court action for blockbuster Entresto.

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"Squeeze" In Sulfonylureas Market

Others highlighted market shifts and the brand longevity dimension that were perhaps among the factors driving the deal for Cipla.

The former chief of a foreign firm in India said that with sodium glucose co-transporter-2 (SGLT-2) inhibitors and dipeptidyl peptidase-4 (DPP-4) inhibitors becoming more and more affordable in the country, he expects a substantial "squeeze" in the sulfonylureas market in favor of the newer, safer class of diabetes therapies.

"Sulfonylureas still command a high percentage of the prescription share. That will dramatically reduce," he predicted, endorsing Cipla's optimism on Galvus going forward.

An estimated 74.2 million people in India live with diabetes – over 70% are estimated to have poor glycemic control.

The executive further asserted that in India, "molecules have life" but brands have a "bigger life".

"[GSK's] Augmentin (amoxicillin-clavulanic acid) still sells, so does [Pfizer Ltd. (India)'s multivitamin] Becosules. Similarly, Galvus and [MSD's] Januvia (sitagliptin) will continue to sell. Brands in India don't die," the executive declared. (Also see "MSD India Chief On The Now, Next For Januvia, Gardasil And Keytruda's Ascent" - Scrip, 29 Aug, 2022.)

Interestingly, Augmentin, which was launched in India in the 1990s, featured as the leading brand on the Indian pharmaceutical market in March 2023, with sales of INR770m (\$9.4m) and galloping growth of 45% as per IQVIA data.

The industry expert quoted previously, though, also pointed to a potentially delicate area for Cipla, which had earlier bought the rights to Vysov (vildagliptin) - among the co-marketed brand names of the Swiss multinational's DPP-4 inhibitor in India.

Selling two brands of the same product at different price points could be frowned upon by the regulator, the expert maintained, but added that technically speaking Cipla holds a license to



Galvus.

In 2019, Cipla had acquired the brand name and trademark rights for Vysov and Vysov M (vildagliptin+ metformin) for the Indian market. Earlier, trademark rights for other vildagliptin brands such as Zomelis and Jalra/Jalra-M were similarly snapped up by Eris Lifesciences and <u>USV</u> respectively in India. (Also see "<u>Novartis Sheds Vildagliptin Trademark In India Ahead Of Patent Expiry</u>" - Scrip, 5 Dec, 2019.) (Also see "<u>Vildagliptin Prices Fall By Over 70% In India Post Patent Expiry</u>" - Scrip, 10 Dec, 2019.)

Both Cipla and Novartis did not immediately respond to specific queries from *Scrip* around the Galvus deal.

Diabetes Is A Priority Area For Cipla

The deal's strategic rationale for Cipla appears to be clear-cut – diabetes is among the priority areas of the Mumbai-based firm, which has been widening its specialty offerings in the segment over the recent past via alliances with big pharma.

It had earlier cut a deal with <u>Boehringer Ingelheim</u> to co-market the German group's oral antidiabetes treatments Oboravo (empagliflozin), Oboravo Met (empagliflozin+metformin) and Tiptengio (empagliflozin+linagliptin) in India and also has marketing partnerships with <u>Janssen</u> and <u>Eli Lilly and Company</u> in the space.

Cipla had earlier launched Prominad (canagliflozin) in-licensed from Janssen, while 2021 saw the company gain rights to sell, promote and distribute Lilly's Humalog (insulin lispro (rDNA origin) injection) and Trulicity (dulaglutide) in India. Over 100 jobs at Lilly were reported to have been cut following the deal, though the US company clarified at the time that it will continue to maintain its "existing operating model" for the remaining portfolio of products in the country.

Galvus raked in sales of INR2.68bn for the 12-months to February 2023 as per IQVIA data and Cipla believes that the DPP-4 inhibitor has the potential to contribute significantly to its portfolio in the diabetes care continuum space.

"This deal is expected to further bolster Cipla's position in India as one of the top players in the diabetes category," the company added.

IQVIA total sales audit (TSA) moving annual total (MAT) data for May 2022 valued the overall Indian market for DPP-4 inhibitors (considering plain as well as the metformin combination together) at INR36.21bn. The market for plain DPP-4 inhibitors stood at INR12.25bn during the period contributing 34% of the total, but was stagnant in terms of growth whereas the DPP-4 inhibitor + metformin combination market, which contributed 66%, reflected growth of 3.2% at MAT level, the data indicated at the time. (Also see "*Can Novo's Oral Semaglutide Shake Up Indian*



Diabetes Segment?" - Scrip, 23 Jan, 2022.)

Portfolio De-cluttering?

The Galvus deal also appears to be, what some industry honchos termed, part of a portfolio "decluttering" effort in India by Novartis to align more broadly with the Swiss group's global thrust as a pure-play innovative pharma company focused on five key therapeutic areas - cardiovascular, immunology, neuroscience, solid tumors and hematology. However, these experts also pointed out that portfolio reorientation efforts rank high on the agenda of several foreign firms in India. (Also see "*Big Pharma Rescripts India Playbook*" - In Vivo, 17 Nov, 2022.)

"Most multinational companies are hell-bent on doing that. They would rather have 'very established' brands like Augmentin or Becosules or then be very selective with their future pipeline. There is no in-between," the former head of the foreign firm quoted previously maintained.

Firms such as <u>Sanofi</u> have over the recent past also moved out of non-core segments, preferring to focus on areas where it can win in India. (Also see "<u>Sanofi India Chief Departs, Sets Transformative Path</u>" - Scrip, 16 Jan, 2022.)

The French multinational had earlier divested brands such as skin cream Soframycin and Sofradex (framycetin sulfate and gramicidin) manufactured via third-party arrangements to Encube Ethicals Private Limited and also sold it its nutraceuticals business to Universal Nutriscience, a strategic partnership between private equity Kedaara Capital Fund II LLP and Universal Medicare Private Limited, among other initiatives.

<u>Novartis India Ltd.</u> itself had 2022 struck a deal with <u>Dr. Reddy's Laboratories Ltd.</u>, handing over sales and distribution of certain established brands, accounting for 50% of the listed entity's 2020-2021 product revenues, to the Hyderabad-based company. The deal also saw the Swiss multinational let go of around 400 employees in India. (Also see "<u>Novartis-Dr Reddy's Sales Pact, Job Cuts: Are Foreign Firms Altering India Push?</u>" - Scrip, 14 Feb, 2022.) (Also see "<u>BioAsia 2023: Leaders from Novartis, Apple Talk Innovation, Tech, Data Privacy</u>" - Scrip, 28 Feb, 2023.)

Globally, Novartis has unveiled plans to transform into a 'pure-play' innovative medicines company. "Our strategy is focused on five core attractive therapeutic areas, key technology platforms, and the US market, with the aim to increase value per new molecular entity from our deep pipeline", Vas Narasimhan, CEO of Novartis, said in September last year. The other priority geographies for the Swiss group include China, Germany and Japan.

