Lupin CEO On ProAir Generic Site Transfer, Digital Plans

Amazon Entry Not A Near-term Worry

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- **INTERVIEWS**
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*Source: Lupin Ltd.*LUPIN CEO VINITA GUPTA IS ONE OF THE FEW WOMEN LEADERS IN INDIAN PHARMA

Lupin Limited CEO Vinita Gupta is busy readying plans these days for the company's next big product – a generic to Teva Pharmaceutical Industries Ltd.'s ProAir HFA (albuterol sulfate) – after an August roll out of its first biosimilar in Europe.

The Indian firm might, however, delay launches of a few other branded products given reduced face-to-face interactions with physicians and patients post COVID-19.

A growing but still rare breed of women leaders in pharma, Gupta, who was named Vogue and IBM "Businesswoman of the Year 2018" and one of the “Top 50 Most Powerful Women in Business 2018” by Fortune India, spoke on a wide range of topics in an interview with *Scrip*.

Under her leadership, the company focused on complex generics and specialty products has been aggressively pursuing the US and other developed markets, a process that began yielding results with the launch of Solosec (secnidazole) in the US, though progress has been slow so far.

Hopes are now pinned on Nepexto, a biosimilar to Amgen, Inc./Pfizer Inc./Takeda Pharmaceutical Company Limited.’s Enbrel (etanercept), launched in Germany via an alliance with Mylan N.V. as well as Lupin’s albuterol generic, which is set for a launch soon. (Also see "Lupin Optimistic On Albuterol Given COVID-19 Demand" - Scrip, 2 Jun, 2020.)]

The company’s tie up with Nichi-Iko Pharmaceutical Co., Ltd. for etanercept in Japan is still operational, despite Lupin having sold its stake in subsidiary Kyowa Pharmaceutical Industry Co. Ltd. (Also see "Lupin Offloads Kyowa Pharma For $525m But Not Exiting Japan " - Scrip, 11 Nov, 2019.)

IQVIA data puts the moving average total sales of the albuterol sulfate inhalation aerosol market in the US at $2.9bn in June 2020, of which the ProAir HFA market accounted for $1.3bn. While launch conditions are currently tough due to the ongoing pandemic, the company hopes the drug's off-label use in COVID-19 patients will be a blessing in disguise.

Meanwhile, Lupin will continue to leverage digital partnerships put in place during the pandemic to accelerate its virtual marketing efforts in the US and other markets, while concurrently leveraging its field force in India to drive sales across geographies. (Also see "Four Digital Saviors Of Indian Pharma During COVID-19" - Scrip, 3 Jun, 2020.)

You said earlier that the ProAir generic will be launched in September – does that timeline hold? Also, what has been the early response to Nepexto?
Yes, it does. Originally, we were to launch generic ProAir in the second half of the year but we tried to do it a little bit earlier. So, we’re on track to launch the product next quarter. It’s too early to talk about Nepexto though as we just launched week before last.

Given the market conditions due to COVID-19, do you feel the need to recalibrate launch strategies for either of them?
The approval for ProAir is timely given that albuterol is a rescue medication and asthma patients are at increased risk to COVID-19. We are making the product available to our generic customers/partners, so don’t really see any impact. The market is back to a normalized level for albuterol overall and for the ProAir brand and we believe that the

generic will expand access to the therapy. We have a track record of delivering strong market share, so we expect to be able to turn it into a material product for the company. Now, the market for etanercept has also been really stable given that two indications - rheumatoid arthritis and psoriaris – represent a significant need and Mylan has commercial plans and tactics to maximize presence within the current market conditions. It's early days, but really no recalibration. We are excited about these launches.

Could you give us some indication of the revenue potential of these two products for FY2021 and can consumers expect any price advantage from Lupin's products?

Pricing of albuterol is fairly stable and we plan to take our share in a responsible manner to be able to grow the product on a profitable basis. I can't give a revenue guidance except that they represent an opportunity for us given a limited number of players and high barriers to entry. We know how long it takes to get the product developed and approved. We expect the advantage in the product to continue and add to profitability on a sustainable basis over the next few years.

Do you have an update on the Somerset facility? Do you expect to shift some products from the Indian facilities to the US?

We are building flexibility of manufacturing products in the US around essential medicines that we believe are high on the government list in the US. The Coral Springs facility [in Florida] is approved by the FDA and we are looking at the possibility of manufacturing albuterol in the US. We also hope to get the Somerset unit [in New Jersey] inspected soon and have already started tech transferring from some of our sites in India. We hope to build flexibility, but also to access some of the government channel business which will be incremental to our revenues as we don't have much of a presence in that space.

Is there a relook at ANDAs and upcoming launches given that the environment is not conducive due to COVID-19?

With ANDAs on the generic side of business, we are basically accessing an existing market so unless the branded product's performance limits the potential of the generic, we would not change our launch plans. Our ANDAs are very much around the loss of exclusivity of the brand and we will continue to work hard to make such products available and maximize their potential. The approach is to ensure that we get approved in time. In some cases where due to the COVID-19 situation, we don't expect approval like at OAI [Official Action Indicated] sites very soon, we are looking to do a tech transfer to our other sites like Nagpur and Aurangabad that could enable us to get to the market in time. On the brand front, wherever we are launching around the world, given that physical face-to-face interaction is down significantly, we are weighing options to determine if it makes sense to delay our launch to make sure that we maximize and don't have lost opportunities through inefficiencies in the launch phase.

You had rationalized your marketing force in US. Is there any move to do that in India?

Not yet. We have started to see very strong action over the last two months. 90% of our field force is back in the field calling up doctor's offices compared to other countries, like for example in the US only 15% of doctors' offices in the obstetrician/gynecologist segment are open to seeing patients. In India, we have a very strong track record and we will continue to build on this to maximize our revenues. We will continue to engage with the digital and virtual efforts wherever they are not open. Now, we have good experience on this front, so we will leverage this as much as we can. We don't intend to change our tactic from face-to-face interaction, but interactions will continue both virtually and physically.

What are the changes as far as digital initiatives are concerned given that patient care has moved to teleconsulting and "at home" point of care? Is any acquisition planned in this space?

The whole COVID-19 situation has got us to come up with creative ways of engaging with a customer, both physicians as well as direct-to-patient. So, in almost every country in the world we have gone into a virtual interface with our customers, leveraging digital. For example, in the US our sales force went completely virtual at the start of the pandemic in March and these interactions have grown week after week with reps having achieved a strong share of voice in the remote model. For women's health in the US, we have partnered with a company called PlushCare to leverage the telehealth model so we can send a message to patients when they can't access consult an obstetrician/gynecologist and have Solosec dispensed when they need it. We have seen a number of interactions convert into active contact with our customers leading to prescription generation, so we have started to see the momentum. We are going to continue to explore what is the best way to do it – it's a new experience for us and for our industry. Certainly, there is a very bright future for digital engagement and the question is to what extent we can partner with companies to access their capabilities as also build some of these in-house. So, we will see if it makes sense to continue with a partnership model or get involved in a more material manner.

On The Entry Of Amazon, Reliance In India's E-Pharmacy Business

Q: Amazon and Reliance have entered the e-pharmacy space in India. Do you think pharma companies will have to lower their margins to accommodate bulk purchasers like these players?

A: It's early days and we will have to see. E-pharmacies in the pandemic world and with lockdowns can potentially gain momentum in the future. We are yet to see what impact the model is going to have, but the primary source of prescriptions in India is still the physician, so we think the e-pharmacies are going to increase access to products. We see physicians driving the bulk of prescriptions and don't see that changing in any material manner in the near future.

Q: Would in-house brands by these players be a threat given that in India once a physician prescribes a brand, you don't necessarily have to stick to it and a switch is possible at the pharmacy or at consumer's end?

A: We haven't seen Amazon get into the branding side in the US yet given that there a lot of considerations, certainly from the GMP (Good Manufacturing Practices) supply perspective. One has to make sure the product is of good calibre. From that standpoint, if you look at the generic segment it's still small. The image of a company is very closely linked to the quality and calibre of a product and this certainly drives prescription behavior as we have seen so far. So, we don't see any material shift in the near term.

(Also see "Amazon Pharmacy Starting Up In India: What Pharma Could Gain Or Lose" - Scrip, 18 Aug, 2020.)

A US FDA (Food and Drug Administration) guidance says if a pre-approval inspection can't be done for a product pending marketing approval and there is concern regarding a manufacturing facility relevant to it, the agency could issue a complete response letter (CRL). Is this a concern?

FDA has started conducting desktop reviews, especially in lieu of prior approval inspections, under quarantine. So, we would expect the momentum of review of products through desktop and other means to continue and as part of the review, if the FDA is not satisfied, they would issue a CRL and if they are satisfied we expect them to issue an approval. (Also see "Complete Response Letters In Lieu Of Inspections: What To Expect During COVID-19" - Pink Sheet, 19 Aug, 2020.)

Have you seen such inspections happening where there were prior objections or concerns raised? Are facilities which have received FDA observations also getting cleared?

We haven't seen that yet. FDA is evolving their approach because they realize travel is going to be a challenge in the near term, so they are looking at possible approaches to ensure that they can continue to review applications and ensure that affordable products come to market. It's evolving and we certainly have seen momentum around first applications. Whether they will consider applications and approve products out of sites where official action is indicated, we've yet to see.
(Also see "What The FDA's Inspections Q&A Guidance Really Means: It's Time To Offer Virtual Inspections" - Pink Sheet, 25 Aug, 2020.)

A recent Capgemini report has indicated a consumer preference against injectables. Could this preference or need at the consumer's end change the overall environment in any manner?

I don't believe so. According to IQVIA, the prescription base has been fairly stable for the injectables segment, especially in oncology. Within this segment, we have seen auto injectors that can be administered easily, grow. I would certainly see more trend towards convenience devices like auto injectors, which has grown overall in the injectables segment, but I don't see a significant shift. In some therapies where medicines are not critical, you could see some drop-off but for all essential ones for which people take injectables, I would expect the trend to continue and perhaps go towards more convenient devices. (Also see "Post-COVID-19 Consumer Preferences A Guide For Pharma Strategy" - Scrip, 31 Aug, 2020.)

There have been a few product recalls of late, for example lisinopril and Mibelas 24 Fe (norethindrone e.estradiol-iron). Could you clear the air over why this is happening and how much of an impact do you foresee?
We do a recall any time we feel there is even a small risk from a patient's perspective and we always want to ensure patient safety. As much as you try, there are always situations where you must take corrective action and we try to ensure that we do that as soon as possible. In terms of a major recall, it really has been metformin where the NDMA [N-nitrosodimethylamine] issue has been a major challenge. I'm very pleased to say that we have worked through the challenge. We believe we have a path to get the product back into the market within this quarter and have got clearance for our strategy.

Are you considering the use of block chain technology or continuous manufacturing to lower the risk of such incidences going forward?
We are certainly looking at continuous manufacturing wherever it makes sense and digitization also on the quality front in terms of in-process digital controls to reduce the number of errors. Overall, we have seen good trends in terms of catching any deviations or out-of-specification issues, but we continue to look at leveraging technology on top of our systems, practices and people to try to reduce the number of deviations and errors.

Detailed Phase III results on the success of Solosec to treat trichomoniasis have been released. How soon do you expect to receive a supplementary ANDA (abbreviated new drug application) for it?
We will file the supplementary ANDA later this year and hope to get approval by the middle of next year. This would expand the market for Solosec significantly. (Also see "String Of Positives For Lupin Lifts Outlook" - Scrip, 6 May, 2020.)

What impact do you foresee from the entry of Strides in the levothyroxine market in the US?
We don't think there is going to be a material shift. Just being in the market for over a year now, we know how difficult it is to shift customers and patients from one product. Our ramp-up has been slow given the nature of the product and high volumes but our position in the product is very strong and any new entrant in the market will take long for a material shift.