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Economic Times , Delhi
Saturday 9th January 2016, Page: 12
Width: 25.19 cms, Height: 32.55 cms, a3, Ref: pmin.2016-01-09.44.23

ON A THRESHOLD OF DRUG INNOVATION

Four anti-infective drugs that Wockhardt is developing have been accorded priority review status by the US regulator, putting them on the fast track of development. The company's contrarian bet, which may be paying off after a two-decade wait, puts it in a league of select global drug makers. Vikas Dandekar reports

Mumbai: Indian drug maker Wockhardt has quietly been conducting discovery research in a narrow range of potent anti-infective compounds, which, if successfully developed, promise to fight life-threatening pathogens and vindicate the company's perseverance in staying on course through the past two decades.

The signs have been encouraging, although late in terms of the lengthy drug development cycle. Over the past 15 months, the US Food and Drug Administration has granted four of Wockhardt's experimental antibiotic drugs a priority review status called Qualified Infectious Disease Product (QIDP), which accelerates the drug development cycle in addition to providing a five-year extension of the exclusivity period, post approval.

This has fuelled Wockhardt's ambitions to go full throttle into further developing the drugs, vaulting it into the pack of A-listers of select global drug makers including Roche, Merck, Pfizer and AstraZeneca that have stepped up interest in the same area lately. Wockhardt increased its investment in research & development to 11.5% of sales during FY15 at Rs 515 crore from 9.3% of sales in FY14 at Rs 450 crore.

Although the risks of late-stage failures cannot be ruled out, the low-profile yet ambitious leads have shown safety and effectiveness in treating bacterial infections such as klebsiella (a form of pneumonia), MRSA (methicillin-resistant staphylococcus aureus) and metallo beta lactamase, among others. International experts forecast that these infections can invariably lead to catastrophic medical consequences if no timely treatment options are developed.

Somewhat coincidentally, Wockhardt's pipeline is maturing at the right time. The FDA's initiative on faster approvals, enacted as part of the Generating Antibiotic Incentives Now (GAIN) Act of 2012, underlined the urgency to develop new antibiotics.

Against roughly 18 approvals for antibiotic drugs granted by the FDA between 1980 and 1984, data culled from prominent scientific journals suggest the number dwindled to six between 2010 and 2014. So far, the US regulator has granted QIDP status to about 35 products and encouragingly, the list is expanding. Wockhardt is upbeat about the prospects of the compounds in the pipeline, Chairman Habil Khorakiwala, 73, told ET. Although a market launch may be three to four years away, the company has tasked management consulting firm McKinsey & Co. with evaluating the potential of the drugs once they reach the last mile of regulatory clearance and commercialisation.

In the near term, Wockhardt plans to accelerate the development of its earliest lead called WCK 771 - an intravenous injection - into phase III clinical studies. The drug's efficacy will be tested on a large set of patients in select international markets.

Khorakiwala noted that WCK 771 will be targeted primarily at emerging markets and if conditions are suitable, the company may explore local partnerships since it may not have the capability to conduct studies and take up regulatory filings at the local level. Another compound, WCK 2349, delivered in oral form, offers significant benefits over its peers as most products currently under development are delivered to patients as injections.

For another set of drugs - WCK 4873, WCK5222 - Wockhardt plans to go solo in conducting global studies. Khorakiwala categorically said he has no plans to out-license his products. Filing for registration of the drugs in the US and Europe will form an important step in the overall game plan.

For Wockhardt, the renewed optimism in the global outlook for anti-infective products vindicates its long-term strategy. Choosing anti-infective drugs was not an impromptu decision. Khorakiwala recalls his visits to some leading research facilities of large global drug makers to evaluate their potential and risks. The interest at that time was waning, he said, but the market dynamics still looked favourable and two decades later, his contrarian bet may prove to be right.

"Antibiotics formed about 25% of the (pharmaceutical industry) turnover in emerging markets like India and China. From a pure competitive analysis, there was hope of a product either for the global market or at least for the emerging market and that was our conceptual framework. We stuck to our core over the last two decades and we did not get into any other areas," he remarked.

Researching anti-infective drugs was considered less commercially viable than products for neurology, respiratory or oncology disorders. The price of cancer drugs jumped, while those of antibiotics stayed in a low band. Further, with pathogens mutating rapidly, newly approved drugs were fraught with the risk of becoming resistant and losing their effectiveness. Sensing the impending crisis, the Centers for Disease Control and Prevention, the top US health agency, declared in 2013 that the human race is now in the "post-antibiotic era" and a year later, the World Health Organization sent out a stern cautionary signal that the crisis of antibiotic resistance is becoming dire. MRSA causes the death of an average 11,285 patients a year in the US alone, recent data showed. With the alarming rise in the incidence of drug-resistant infections, multinational pharma companies are signing up deals at a fast clip.

In January 2015, Swiss giant Roche struck a $750 million deal with Japan's Meiji Seika for an early-stage compound to battle multiple drug-resistant infections. A month before that, US major Merck & Co. lapped up antibiotic specialist Cubist in a $9.5 billion merger to spruce up its antimicrobial research programme.

In February 2015, Anglo-Swedish drug maker AstraZeneca said it will spend $40 million to create a new stand-alone subsidiary focussed on early-stage R&D of small molecule anti-infective drugs. Last June, New York-headquartered behemoth Pfizer said it will spend as much as $1.9 billion to acquire Vicuron, a company developing novel anti-infective drugs for hospital-based and community-acquired infections.

Not to rest on its four aces, Wockhardt is matching up globally. Khorakiwala said the regulators have approved an abridged pathway for his drugs but his company will continue to seek new leads in the sphere of anti-infective drugs.

Global Hot Chase

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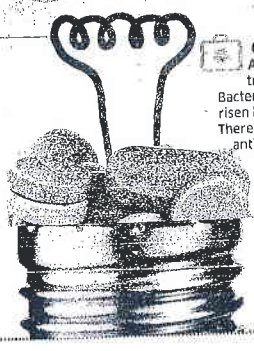
FDA's QIDP: Proposed from 2012, Qualified Infectious Disease Product is a regulatory intervention that accelerates the drug development cycle for anti-infective candidates, in addition to providing a five-year extension of the exclusivity period, post approval.

The renewed optimism in the global outlook for anti-infective products vindicates the company's long-term strategy

QIDP-SEPT. 2014 - WCK 2349 Developed in an oral form and can claim significant benefits over injections if developed successfully.

Wockhardt's Germ Fighting Aces:

QIDP-SEPT. 2014-WCK 771 Acts against one of the globally rising class of pathogens, MRSA (Methicillin-Resistant Staphylococcus Aureus), which causes a range of diseases from skin infection to severe respiratory infection. In the case of severe infections such as Hospital Acquired Pneumonia (HAP), there is currently limited medical reach, causing a high unmet need and mortality. Effective against MRSA, it has shown potential in treatment of HAP.



QIDP-MAY 2015 - WCK 4873 A new class of antibiotic drugs for treatment of Community Acquired Bacterial Pneumonia (CABP), which has risen by alarming proportions globally. There is a global crisis of availability of antibiotics to fight resistant bacteria.

QIDP-DEC. 2015 - WCK 5222 A new class of antibiotics for gram negative bacteria for complicated urinary tract infection, Hospital Acquired Bacterial Pneumonia (HABP) and Ventilator-Associated Bacterial Pneumonia (VABP).