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Bangladesh Pharma Giant To Sell First Generic Version of Remdesivir for Covid-19

Beximco Pharmaceuticals to give drug, which has been authorised by the US for emergency use in the treatment of coronavirus patients, for free to state-run hospitals.

One of Bangladesh's largest drug-makers, Beximco Pharmaceuticals, says it has become the world's first company to start selling the generic version of Gilead Sciences Inc.'s anti-viral drug, remdesivir, which has shown promise in fighting the new coronavirus. The Dhaka-based Beximco, which counts Norges Bank as one of its investors, will sell remdesivir for about 6,000 taka (Dh261) a vial to private clinics but will give it free to state-run hospitals treating Covid-19 patients, it was confirmed on Friday.

Beximco is branding the drug bemsivir, the launch of which was announced during a simple ceremony at the Health Ministry in the presence of Zahid Maleque MP, Minister for Health and Family Welfare, Government of the People's Republic of Bangladesh.

While handing over the first batch of medicine, Managing Director of Beximco Pharma, Nazmul Hassan MP, said: "We have decided to provide bemsivir free of cost to all those severely ill patients of government hospitals." U.S. drug authorities granted emergency use authorisation at the end of April, paving the way for its broader use in U.S. hospitals, after Gilead provided data showing the drug had helped Covid-19 patients. Beximco says the drug can be given via intravenous infusion. Beximco's Chief Operating Officer Rabbur Reza told Reuters that a patient might need anywhere between 5 and 11 vials.

Recent clinical trials have shown evidence that remdesivir helps severe Covid-19 patients recover faster. The Japan government has also granted special approval for remdesivir in emergency treatment of Covid-19.

The emergency approvals will help broaden use of remdesivir in hospitalised patients, especially in developing and less-developed countries where access to breakthrough, advanced drugs remains a major challenge, added the Beximco Pharma MD. "We are pleased to be the first generic company in the world to introduce this very important drug for treating the hospitalised Covid-19 patients. This reinforces our commitment to playing our part in ensuring access to breakthrough therapies despite facing many challenges amid this unprecedented pandemic.

"We express our gratitude to the regulatory authorities for extending their wholehearted support for making this potential drug available to our patients at the earliest possible time. As a responsible company, we will continue to extend our support to the government in all possible ways during this national emergency," Hassan said.

He said Beximco Pharma will supply bemsivir to Government-designated hospitals for Covid-19 treatment, and not make it available through pharmacies, in compliance with tdirectives from Bangladesh drug regulatory authorities. On the very first day of receiving regulatory approval, Beximco Pharma has donated large quantities of the drug to the Bangladesh Government for the treatment of Covid-19 patients. Zahid Maleque MP, Minister for Health and Family Welfare, Government of the People's Republic of Bangladesh, lauded Beximco Pharma for its initiatives during this time of the pandemic.

He said: "Beximco Pharma has taken various proactive measures to provide the latest, evidence-based treatment options for Covid-19 patients. The company is committed to fighting this unprecedented pandemic, in all possible ways, employing its competitive R&D and manufacturing skills.

"Beximco Pharma has already launched another anti-viral drug, favipiravir, under the brand name viraflu, as well as repurposed anti-malarial drug, hydroxychlorquine, under the brand name kovicin, and anti-parasitic drug, ivermectin (under the brand name Ivera) as potential Covid-19 treatment. Beximco Pharma is a leading exporter of pharmaceuticals in Bangladesh and it has a geographic footprint in more than 50 countries. In August 2016, Beximco Pharma became the first Bangladeshi pharmaceutical company to export medicine to the US market following its manufacturing site approval by the U.S. FDA in June 2015. (Source; Khaleej Times)

Emergent Biosolutions, BARDA reach $628M Deal to Manufacture COVID-19 Vaccine Hopefuls

The U.S. government has shelled out big money to help develop a possible COVID-19 vaccine and boost manufacturing of COVID-19 drugs stateside. Now, in order to amp up production of its chosen vaccine hopefuls, the government will enlist a Maryland CDMO to get production quickly up to speed.

Emergent BioSolutions has won a $628 million deal with the U.S. government to scale production of targeted COVID-19 vaccine candidates to make "tens to hundreds of millions" of doses available through 2021, the CDMO said Monday. The contract is part of the government's "Operation Warp Speed" development initiative to speed promising COVID-19 vaccines through clinical trials and into mass production before the end of 2020.

As part of the agreement, the government will shell out $542.7 million to reserve bulk manufacturing capacity at Emergent's Baltimore Bayview facility, which was constructed as part of a Biomedical Advanced Research and Development Authority (BARDA) pandemic preparedness contract signed in 2012. The remaining $85.5 million will be spent expanding fill/finish capacity at two Emergent plants at Camden in Baltimore and Rockville, Maryland. The massive order will allow Emergent to set aside the needed manufacturing space to mass-produce what could be two or three promising vaccine candidates identified by BARDA and the U.S. Department of Health and Human Services (HHS), Emergent CEO Robert Kramer said Monday.

The Maryland-based CDMO previously signed manufacturing deals with Johnson & Johnson, Novavax and Vaxart to produce their COVID-19 vaccine candidates at scale, but the BARDA contract would take precedent if other hopefuls beat those three companies to the punch.

"The government has the right to prioritize what work we do in the Baltimore facility," Kramer said. "We're having a very close dialogue with 'Operation Warp Speed,' HHS and BARDA to make sure we are 100% aligned." That could mean that Emergent's private partners have to wait their turn at the company's Baltimore facility, but Kramer noted that J&J had already signed an agreement with BARDA to co-develop a possible vaccine. In a deal valued at $135 million, Emergent agreed to set aside some of its manufacturing capacity at the Baltimore Bayview plant to help J&J reach its stated goal of producing up to 1 billion doses of a potential vaccine each year.

But all of the reservations Emergent is taking are ultimately dependent on one thing: Will a vaccine be ready to go in the next couple years? Kramer said the likelihood the U.S. government will identify at least one promising candidate for production later this year is "entirely possible and likely," and the CDMO said it would be ready to roll on scaled-up production immediately. Emergent, a "public health threat solutions provider" that has most of its manufacturing in the U.S. , sees BARDA's order as a continuation of its sustained business with the government.

"When we say as a company that we are made to do what we are doing right now, that's exactly what it is," Kramer said.
Emergent will aim to help "Operation Warp Speed" meet its stated manufacturing goals of 100 million doses within the year and up to 300 million doses by the end of 2021, when the order comes to a close, Kramer said.

The government's Emergent deal is only the most recent of the massive contracts BARDA has shelled out in recent weeks to produce COVD-19 drugs and potential vaccines. In late May, the Trump administration floated a four-year, $354 million contract with a fledgling company, Phlow Corporation, to build a generic medicine and active pharmaceutical ingredient (API) plant in Richmond, Virginia, and supply COVID-19 treatments produced there.

That deal can be expanded up to 10 years and a total of $812 million, making it among the largest in BARDA's history. It's part of the administration's push to boost drug manufacturing on U.S. soil, HHS said in a release at the time. To fulfill the government deal, Phlow has teamed up with CivicaRx, a generics maker started by hospitals fed up with rising drug prices and API supplier AMPAC, among others. CivicaRx and its partners will manufacture the finished dosage forms of essential medications, including vials and syringes.

The U.S. partnership "immediately enabled" the company to deliver 1.6 million doses of five generic drugs used to treat hospitalized COVID-19 patients, including sedatives for patients on ventilators, to the U.S. Strategic National Stockpile, Phlow said in a release. Aiming to hedge its bets on a potential vaccine, BARDA has also shelled out big bucks to another drugmaker, AstraZeneca. In late May, BARDA agree to pay $1.2 billion to access 300 million of AstraZeneca's vaccine doses starting in the fall. AstraZeneca has signed up to deliver 400 million doses through its initial supply agreements, including a U.K. pact for 100 million total doses. BARDA also agreed in mid-April to pay out $483 million to Moderna to support development of its mRNA vaccine for COVID-19. (Source: Fierce Pharma)

Scientists to Carry Out a Larger Trial of Favipiravir and Other Combination Drugs: CSIR Director General

New Delhi (India): Even as the country's drug regulator has approved Glenmark's FabiFlu, the generic version of antiviral drug Favipiravir, CSIR (Council of Scientific and Industrial Research) and Cipla will carry out a larger, multicentre clinical trial of the drug to check its efficacy and safety among Covid-19 patients.

The CSIR is also going to submit before the Drug Controller General of India (DCGI) new proposals to conduct trials on combination drugs, Director General-CSIR Dr Shekhar Mande told News18. The autonomous body under the Ministry of Science and Technology has focused on repurposing of existing drugs that have been used globally as antiviral medicine. The CSIR has partnered with pharmaceutical companies such as Cipla and Sun Pharma.

The scientific body and its partners have got clinical trial approvals for four repurposed drugs – Sepsivac, ACHQ (a phytopharmaceutical plant based drug), Favipiravir and Umifenovir. Sepsivac and Favipiravir are in Phase III of the trials.

"Results on repurposed drugs are showing promise and we have some good leads. Cipla is already carrying out Favipiravir trials. The earlier trials had a limited number of people. But now we need a much larger trial on 600-700 people and we will approach the DCGI on that issue," said Dr Mande.

"In addition, we have also prepared proposals on trials about three to four combinations of drugs. Our emphasis from now on will be on combinations. One of the drugs would be an antiviral drug. We will be submitting these proposals to the DCGI in the coming days to seek approvals for trials," Dr Mande added.

As per the Clinical Trials Registry – India website Glenmark Pharmaceuticals Ltd. is carrying out a randomised open-label study to evaluate efficacy and safety of Favipiravir and Umifenovir combination as compared to Favipiravir alone. This is being tested on moderate hospitalized adult Covid-19 patients.

Meanwhile, Cipla is currently in Phase-3 of Favipiravir trials which are being carried out in eight centres in the country. Five of these eight centres have approved the Phase-3 trials. These randomised, open label, prospective, comparative parallel group clinical trials will evaluate efficacy and safety of Favipiravir with supportive care versus supportive alone among patients with mild to moderate Covid-19.

While Glenmark worked independently, CSIR worker on the research and actual synthesis of Favipiravir drug. "Favipiravir is a compound and to make the chemical structure in large quantities you need key starting materials. Through a series of chemical synthesis steps, you have to generate the final compound. We generated the end-to-end process and it was handed over to Cipla," Dr Mande said. "We understand our limitations of scaling up beyond our labs while companies can scale up but they need our technical know-how. This is a perfect win-win situation," he added. (Source: News18)

The Indian Pharmaceutical Industry Might Be A Ray of Hope In the Feared Economic Slowdown

The coronavirus pandemic has hit us hard, socially, financially and emotionally. By now, we are familiar with the need to flatten the curve by practicing social distancing. But what will happen after the lockdown?

While there are fears about an economic slowdown and unemployment, could the Indian pharmaceutical industry blossom in the post Covid-19 world? Sritama Pramanik got a job offer while India is in lockdown and has started working from her home in Berhampore, Murshidabad. "We track all phases of drug development from discovery through clinical trials to launch. We help the global pharmaceutical companies gain insight into the drug development trends across the industry and identify new business opportunities," says Pramanik who has just completed her MBA in healthcare management from the Goa Institute of Management and is now working as an external consultant, Pipeline Intelligence, IQVIA, Bangalore. While it is a time of nail-biting anxiety for most finalyear students, people like Sritama might gain an upper hand as demand in the pharma and allied industries is likely to spike.

Researchers in laboratories all over the world are working to develop a cure to the novel coronavirus. Prasanta Kumar Das, associate manager of R&D at Zydus Wellness Products Limited in Ahmedabad, too is busy researching new products. "We are working from home and at the laboratory on alternate days as our core work is laboratory-based. While working from home, we focus on documentation, strategy planning and studying research papers.

We work in the lab with 3050 per cent strength to maintain physical distance," says the man who did his MPharm from the Bengal Institute of Pharmaceutical Sciences in Kalyani.

A degree in pharmaceutical or life sciences may help students get absorbed by the industries now at the frontline in the Covid19 battle -- whether it be making diagnostic kits, drugs or vaccines. Avishek Shah is a researcher at a top multinational IT company in Noida and is currently working from his home in Kanchrapara, North 24-Parganas, on drug repurposing for Covid-19. "I basically deal with in silico [using the computer] drug discovery, especially drug repositioning and drug repurposing using artificial intelligence and machine learning. (Source: The Telegraph)

Medtech Company Granted £225k to Develop Drug-Releasing Eye Lens

VisusNano was awarded the funding for its drug-eluting MEDILens product, which is being developed to release anti-inflammatory drugs directly into the patients' eye following cataract surgery.

Cataracts are the most common cause of blindness worldwide and can only be cured by surgery. More so, post-surgery inflammation can cause pain and loss of vision if left untreated. Currently, this is prevented through the administration of eye drops, three-to-four times a day for a month.

Since MEDILens can release anti-inflammatory drugs directly into the eye, this removes the need for eye drops. VisusNano will now use the Innovate UK funding to test the safety and efficacy of MEDILens in animal models. Following this, the company aims to develop a commercial veterinary product and a prototype for humans within the next 18 months.

VisusNano CEO, Dr Joanna Gould, commented: "We are thrilled to receive this funding from Innovate UK to develop our technology further, possibly changing the lives of thousands of cataract patients. The potential of MEDILens is substantial; not only is the intraocular lens market growing because of the ageing population, but our product can be easily modified to incorporate other drugs to treat different diseases. We are delighted to be fast-tracking our veterinary cataract product and prototype for humans in the next 18 months." (Sourvcce: Eurpean Pharmaceutical Manufacturer)

Will the Launch of Favipiravir Mark the Turnaround for Glenmark Pharma?

Glenmark Pharma became the first Indian company to receive approval for manufacture and marketing of Favipiravir for the treatment of mild-to-moderate symptoms of Covid-19, in what is a positive development for the investors of the one of the most under-performing pharma stocks.

If the drug proves to be efficacious over the next few months, Glenmark will enjoy first mover advantage at a time when the country is reporting record number new coronavirus cases.

It will likely to boost the company's local sales in the near term, increase its visibility among doctors and patients and, above all, vindicate the company's sustained focus on R&D.

Currently, there is no visibility on the impact of the drug launch on the company's business. Glenmark's management has not provided any estimate on the possible sale of this drug. The company has begun manufacturing the drug – which is due to be rolled out by early next week and is likely to be available pan-India within 8-10 days.

The ramp up in drug sales is dependent on the load of patients and how the pandemic develops. At Rs 103 a tablet and Rs 3,500 for the complete course of medication – it is moderately priced as compared with the competing drug Remdesivir, which too has received emergency drug approval for treatment of coronavirus patients with severe conditions and is likely to be made available by June end at around Rs 5,000 a dose.

Debt on the books, high expenses towards R&D, and headwinds to its US business have adversely impacted the company's valuations on the Street in recent years. The Glenmark stock is trading at a historically lower valuation of 16 times its trailing four quarters consolidated earnings. This is less than half of the price-to-earnings multiple of 35 of the ET Pharma Index.

Despite the price more than doubling during the period of the lockdown, the Glenmark stock is the only one in the pharma sector to trade 20% lower than its year-ago level. It is still trading at one-third the level of its record high in 2015.

The company has been on a restructuring mode with reduction in R&D expenses and employee cost. The launch of this antiviral drug has the potential to be a game-changer for Glenmark's fortunes on the Street as well as off it. Reduction in debt is going to be the key confirmation for the Street to buy into the company's turnaround story. The fourth quarter numbers, to be announced next week, will provide a clue to the Street about the debt reduction levels achieved and the company's growth trajectory. (Source: Economic Times)