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NEWS LETTER
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Biden Told it Will Take Two Weeks to Have Definitive Data On Omicron Variant

WASHINGTON - The top U.S. infectious disease official, Dr. Anthony Fauci, told President Joe Biden on Sunday it will take about two weeks to have definitive information on the new coronavirus variant Omicron that has sparked new travel restrictions and shaken financial markets. Biden, returning to Washington following the Thanksgiving holiday weekend, was briefed in person by his coronavirus response team on Sunday afternoon as officials expect the new variant to reach the United States despite an impending ban on travelers from Southern Africa, where it was first detected. Fauci said he believes existing vaccines are likely to provide "a degree of protection against severe cases of COVID", and officials reiterated their recommendation for vaccinated Americans to get booster shots, according to a readout of the briefing.

Biden was due to update the public on the new variant and the U.S. response on Monday, the White House said. Omicron, which was first detected in Southern Africa, has now been confirmed in Australia, Belgium, Botswana, Britain, Denmark, Germany, Hong Kong, Israel, Italy, the Netherlands, France, South Africa, and the United States' neighbor to the north, Canada. Earlier on Sunday, Fauci told ABC News' "This Week" that the new variant would "inevitably" reach the United States. "It clearly is giving indication that it has the capability of transmitting rapidly. That's the thing that's causing us now to be concerned," he added on NBC. U.S. officials were seeking more information from South Africa about the new variant. Health and Human Services Secretary Xavier Becerra spoke to South Africa Health Minister Joe Phaahla on Sunday, praising the country's transparency, according to a readout of the meeting.

Its appearance in the United States, where 30% of the population has not received a single dose of vaccine, could threaten to undermine the nation's recovery nearly two years after COVID-19's emergence and further pressure local healthcare systems already taxed by the recent Delta variant. Rising cases as colder weather forces more people indoors has also caused some hospital systems and U.S. states, including New York, to declare emergencies. So far, nearly 782,000 people have died in the United States from COVID-19 since early 2020, the most of any country in the world, amid over 48 million infections, Reuters data show.

TRAVELERS BANNED, NOT FLIGHTS

The United States is joining other nations in seeking to block transmission by imposing travel restrictions. Beginning at 12:01 a.m. ET (0501 GMT) on Monday, it will bar entry of nearly all foreign nationals who have been in any of eight southern African countries within the last 14 days and has warned Americans against traveling to those nations. U.S. citizens and lawful U.S. permanent residents who have traveled to the countries will still be able to enter the United States and no new screening or tracing requirements have been introduced.

Flights by Delta Air Lines (DAL.N) and United Air nes (UAL.O) have continued from South Africa to the United States since the variant was discovered. Fauci and other top officials said the sudden burst of cases made Omicron worrisome and it remained unclear how current vaccines or therapeutics could be impacted. "We need more data there before we can say confidently that this is not a severe version of the virus, but we should find that out in the next couple weeks," outgoing National Institutes of Health Director Dr. Francis Collins told "Fox News Sunday." Vaccine makers Pfizer/BioNTech (PFE.N), (22UAy.DE) and Moderna (MRNA.O) have said they expect more information soon. "We have to go through a couple of weeks yet of uncertainty," Moderna Chief Medical Officer Dr. Paul Burton told CNN, saying Omicron's transmissibility and severity were also still unknown along with current vaccines' effectiveness against it.

'CLARION CALL' FOR SHOTS

Fauci pressed Americans to continue to get COVID-19 vaccines and boosters while experts evaluate Omicron. "This is a clarion call ... (to) get vaccinated," he told NBC. The United States has recorded over 1.1 million new COVID-19 cases in the last 14 days, up 9% from the prior two weeks, Reuters data shows, with Michigan and Minnesota leading the nation in new cases, based on infections per 100,000 residents. The proportion of COVID-19 tests coming back positive in New York state had doubled since last month to 4.23%, underscoring the need for vaccinations, Governor Kathy Hochul said in a statement. "Cases are rising throughout New York State, and the new Omicron variant poses a very real threat to the progress we've made," Hochul said. The variant could cast a pall over the rest of the U.S. holiday season and potentially impact companies' return-to-office plans. (Source: Reuters)

Without Innovation Indian Pharma Cannot Touch $130 Bn by 2030: Industry

Sun Pharma says it eyes $1.5 bn from innovative products in 3-4 years The leading names of the Indian pharmaceutical industry said that the target of touching a $130 billion size for the Indian drug industry by 2030 would not be possible without focus on innovation. India is a leading player globally when it comes to generic or copy cat drugs.

but has failed to move up in the value chain when it comes to innovative drugs. Speaking at the Global Innovation Summit 2021, Dilip Shanghvi, managing director of Sun Pharmaceuticals, the largest domestic drug maker by market share, said that they expect to touch a turnover of $1.5 billion from innovative products in the next three to four years. “Because of the investments that we have made in the past, our innovative products business is growing three times faster than the generics and branded generics business.

Hopefully, in the next three to four years we can look at this business crossing $1.5 billion,” he said. Similarly, Nilesh Gupta, MD of Lupin claimed that they expect to draw 20 per cent of their turnover from innovative products. “The innovation story should be 20 per cent of our total revenues. I think it’s going to take a good ten years to get there but that is the intention,” he said. If India wants to be relevant in the pharma space, we have to be innovative, Gupta quipped. Pankaj Patel, chairman of Cadila Healthcare agreed, saying, “As a generic industry we have reached here, can we grow from here? Without innovation we cannot.” India roughly accounts for 30 per cent of the global generic drugs market. Patel added that without innovation the Indian industry cannot aspire to touch $130 billion turnover by 2030.

India’s big pharma has already begun focusing on developing new products in the laboratory. Satish Reddy, chairman of Dr Reddy’s Laboratories (DRL) pointed out that they have 13 products in the clinic. Reddy felt that new technologies will play a major role to determine the way forward. The industry, however, was unanimous that the initial impetus for creating an ecosystem for innovation would come from the government. Glenn Saldanha, MD, Glenmark Pharmaceuticals said, “Initial impetus of formation of hubs (for innovation) comes from the government. The US is in a league of its own when it comes to innovation. For the rest of the world, impetus from the world is important,” Saldanha said. At the same time, the industry feels that regulatory clearances and process need to speed up here.

Patel pointed out that in case of the Covid19 vaccine, the US majors went to clinic very fast. “Can we imagine that kind of speed here? Can one regulator give me all the necessary approvals? All these areas are still very open and we lose time. In innovation one has a limited patent life, and if one loses time then there is very little time to reap the rewards,” Patel reasoned.

Christopher Viehbacher, founding partner Gurnet Point Capital and former CEO of Sanofi pointed out that so far no Indian vaccine has every been approved outside of India. “There is a need to have a global standard regulator,” Viehbacher said. Attracting the right kind of talent is a key area, and the industry felt that despite having half a million STEM graduates (Science, Technology, Engineering and Mathematics) novel research has been on a slow lane. However, when this talent goes and works in other countries, there is no dearth of research. Patel said that while companies try to bring talent from overseas back to India, it is still limited.

What one needs is to have a national level policy, or some kind of incentive to bring talent back. “For example, if a person of Indian origin comes back to the country for research etc, he or she does not need to pay income taxes for a certain number of years,” Patel suggested. Some others in the industry like Samina Hamied, executive vice chairperson of Cipla said that putting up shops where the talent is very important. “One thing Covid19 taught us is that talent can work from anywhere,” she said. (Source: Business Standard)

Generic Pharmacy Chain Medkart Valued at ₹140 Crore

Ahmedabad-based chain of generic medicines pharmacy, Medkart informed that the company has raised ₹40 crore in Series A round of fundraising. This puts the company’s post-money valuation at ₹140 crore. The funding round was co-led by Alkemi Growth Capital and Insitor Partners with participation from angel investors including Prashant Poddar and other professionals from UAE and ex-CEO of IIFL Asset Management.

The investors collectively will hold 28 per cent in the company, while the promoter holding will be 72 per cent post transaction. Founded in 2014 by Ankur Agarwal and Parsharan Chari, Medkart has recorded a turnover of ₹25 crore for the fiscal 2021. Medkart offers generic versions of the drugs thereby making medicines affordable for the people. Reduced cost It reduces the cost of medicines by up to 85 per cent. Medkart has doubled its store strength during the Covid-19 era from 34 in a pre-pandemic era to 75 stores now, mostly across Gujarat and Rajasthan.

“The need for fundraise was felt to further expand our reach in Gujarat and Rajasthan. We look to increase our store strength to 250 by end of 2023,” said Ankur Agarwal, Co-founder, Medkart. Through its offering of generic alternative medicines, the company claims to have saved over ₹200 crore for its customers and enjoys a loyal customer base of about 600,000 chronic patients. “We want to take our stores where the customers are. To increase our store count we will offer franchisees to the new entrepreneurs or fresh pharmacy graduates,”

Agarwal said adding that against the initial investment is ₹10 lakh per store. He said the earning potential is immense considering the growing awareness about the generic versions of the drugs which are authentic, affordable and effective. The company has a large repeat revenue profile with 80 per cent revenue coming from the repeat business. The company has focused on building a robust supply chain and improving end delivery to customers. Medkart also offers door-step delivery based on the value of the orders. Also, in its next endeavour the company looks to explore online consultancy using digital platforms. (Source: Business Line)

U.S. CDC Says All Adults Should Get COVID-19 Booster Shots

The U.S. Centers for Disease Control and Prevention (CDC) said on Monday everyone aged 18 years and older should get a booster shot, as it looks to tackle a new and highly infectious strain of the coronavirus that is quickly spreading across the globe. The update comes after President Joe Biden on Monday called for wider vaccination to curb the spread of the Omicron coronavirus variant, which was first detected in southern Africa.

The U.S. health regulators last week expanded the eligibility for booster shots of COVID-19 vaccines to all adults aged 18 and older either six months after their initial Pfizer (PFE.N) or Moderna (MRNA.O) vaccine doses or two months after their Johnson & Johnson (JNJ.N) shot. The CDC had, however, stopped short of saying all adults aged 18 to 49 should get the additional shots. The agency is taking a more cautious stance as Omicron's emergence further emphasizes the importance of vaccination and boosters, CDC Director Rochelle Walensky said in a statement on Monday.

Amid the renewed emphasis, Pfizer and partner BioNTech (22UAy.DE) are expected to ask the U.S. Food and Drug Administration (FDA) in the coming days to authorize their booster shots for those aged 16 and 17 years, the Washington Post reported on Monday, citing sources. Separately, the Wall Street Journal reported that the FDA could approve booster doses for 16 and 17 year-olds as soon as next week.

Pfizer, BioNTech and the FDA did not respond to Reuters' requests for comment. Omicron, which the World Health Organization said carried a very high risk for fueling infection surges, has now been confirmed in several countries including Germany, Hong Kong, South Africa and Canada. Scientists in the United States and around the world are urgently examining vaccine effectiveness related to this variant, the CDC said. The agency also said the 47 million adults who are not yet vaccinated are encouraged to get vaccinated as soon as possible. (Reuters)

Pharmacy Chains Including CVS Helped Fuel Opioid Epidemic, U.S. Jury Finds

A federal jury on Tuesday found that pharmacy chain operators CVS Health Corp (CVS.N), Walgreens Boots Alliance Inc (WBA.O) and Walmart Inc (WMT.N) helped fuel an opioid epidemic in two Ohio counties, in the first trial the companies have faced over the U.S. drug crisis. Jurors in Cleveland federal court after six days of deliberations concluded that actions by the pharmacy chains helped create a public nuisance that resulted in an oversupply of addictive pain pills and the diversion of those opioids to the black market. Mark Lanier, a lawyer for Ohio's Lake and Trumbull counties, called the verdict a "landmark decision" that paved the way for them to each seek more than $1 billion from the companies to help address the deadly epidemic's toll in their communities. U.S.

District Judge Dan Polster will decide how much the companies owe to abate the epidemic in the counties and is expected to hold a trial on that question in April or May. The verdict bolstered efforts by state and local governments to negotiate settlements resolving thousands of other cases against the pharmacy chains. Joe Rice, a lead lawyer for the plaintiffs, said he looked forward to discussing potential settlements. "You can be sure the message from this jury is going to be talked about in the boardrooms of every corporation involved in the pharmaceutical chain that's involved in this litigation," he said.

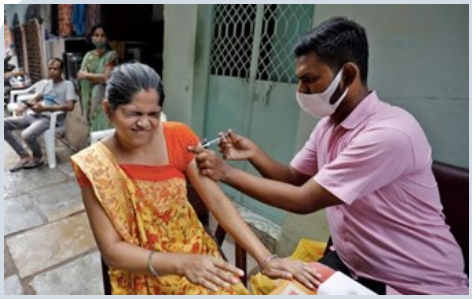
Stock prices for the companies briefly fell after the verdict but quickly rebounded and closed up less than 1%. CVS, Walgreens and Walmart said they would appeal the verdict, arguing it ran contrary to the facts and that it misapplied public nuisance law to hold them liable under a novel legal theory that courts in California and Oklahoma have recently rejected in similar cases against drugmakers. "We will appeal this flawed verdict, which is a reflection of a trial that was engineered to favor the plaintiffs' attorneys and was riddled with remarkable legal and factual mistakes," Walmart said.

U.S. officials have said that by 2019, the health crisis led to nearly 500,000 opioid overdose deaths over two decades.Over 100,000 people died from drug overdoses during the 12-month period ending April 2021, the U.S. Centers for Disease Control and Prevention said in a report last week, a record driven in large part by deaths from opioids like fentanyl. More than 3,300 opioid lawsuits have been filed nationally against drug manufacturers, distributors and pharmacies, culminating with many of the companies - though not the pharmacies - agreeing to proposed global settlements. The three largest U.S. distributors that supply pharmacies and hospitals - McKesson Corp (MCK.N), Cardinal Health Inc (CAH.N) and AmerisourceBergen Corp (ABC.N) - and drugmaker Johnson & Johnson (JNJ.N) in July proposed paying up to $26 billion to settle most of the lawsuits against them.

A bankruptcy judge in September approved a settlement by OxyContin maker Purdue Pharma LP and its wealthy Sackler family owners that the company values at more than $10 billion. The pharmacies, however, went to trial despite the urging of the judge to settle. At trial, lawyers for Lake and Trumbull counties argued that the pharmacies failed to ensure opioid prescriptions were valid and allowed excessive quantities of addictive pain pills to flood their communities. The pharmacy operators denied the allegations.

They said they took steps to guard against diversion of pills and blamed others, including doctors, regulators and drug traffickers, for the epidemic. The verdict followed recent setbacks for plaintiffs pursuing some of the other opioid cases nationally. Oklahoma's top court on Nov. 9 overturned a $465 million judgment against J&J, and a California judge this month ruled in favor of four drugmakers in a case brought by several large counties. Other trials are underway in New York involving drugmakers Teva Pharmaceutical Industries Ltd (TEVA.TA) and AbbVie Inc (ABBV.N), and in Washington state with the three distributors. (Source: Reuters)

Covaxin 50% Effective When Delta Was Dominant, Shows Lancet Study



New Delhi: Two doses of Covaxin are 50 per cent effective against symptomatic disease, according to the first real-world assessment of India's indigenous COVID-19 vaccine published in The Lancet Infectious Diseases journal. Results of an interim study recently published in The Lancet showed that two doses of Covaxin, also known as BBV152, had 77.8 per cent efficacy against symptomatic disease and present no serious safety concerns. The latest study assessed 2,714 hospital workers at the All India Institute of Medical Sciences (AIIMS) in Delhi, from April 15–May 15, who were symptomatic and underwent RT-PCR test for COVID-19 detection.

Researchers noted that the Delta variant was the dominant strain in India during the study period, accounting for approximately 80 per cent of all confirmed COVID-19 cases. Covaxin, developed by Hyderabad-based Bharat Biotech in collaboration with the National Institute of Virology, Indian Council of Medical Research (NIV-ICMR), Pune, is an inactivated whole virus vaccine administered in a two-dose regimen, 28 days apart. In January this year, Covaxin was approved for emergency use in India for people aged 18 and above. The World Health Organization (WHO) added the vaccine to its list of approved emergency use COVID-19 vaccines earlier this month. The latest study was conducted during India's second COVID-19 surge and in healthcare workers who were primarily offered Covaxin.

"Our study offers a more complete picture of how BBV152 (Covaxin) performs in the field and should be considered in the context of COVID-19 surge conditions in India, combined with the possible immune evasive potential of the Delta variant," said Manish Soneja, Additional Professor of Medicine at AIIMS New Delhi. "Our findings add to the growing body of evidence that rapid vaccine rollout programmes remain the most promising path to pandemic control while public health policies must continue to include additional protective measures, such as mask-wearing and social distancing," Soneja said in a statement.

The COVID-19 vaccination centre at AIIMS New Delhi exclusively offered Covaxin beginning January 16 this year to all of its 23,000 employees. Researchers evaluated the effectiveness of the vaccine against symptomatic RT-PCR confirmed SARS-CoV-2 infection. Of the 2,714 employees in the study population, 1,617 people tested positive for SARS-CoV-2 infection, the virus that causes COVID-19, and 1,097 tested negative.

Positive cases were matched to negative RT-PCR tests (controls). The odds of vaccination with Covaxin were compared between cases and controls and adjusted for occupational exposure to COVID-19, previous SARS-CoV-2 infection, and infection dates. The study found that the vaccine effectiveness against symptomatic COVID-19 after two doses of Covaxin with the second dose administered 14 or more days before undergoing RT-PCR testing was 50 per cent. (Source: NDTV)

WHO Advises Against Blood Plasma Treatment For COVID-19

Convalescent plasma showed some early promise when given intravenously to people sick with Covid-19, but recent advice made a "strong recommendation" against the use of blood plasma in people who do not have serious symptoms.

Paris: Covid treatments using plasma taken from the blood of recovered coronavirus patients should not be given to people with mild or moderate illness, the World Health Organization said Tuesday. Convalescent plasma showed some early promise when given intravenously to people sick with Covid-19.

But in advice published in the British Medical Journal, the WHO now says that "current evidence shows that it does not improve survival nor reduce the need for mechanical ventilation, and it is costly and time-consuming to administer".

It made a "strong recommendation" against the use of blood plasma in people who do not have serious Covid-19 symptoms and said that even for patients with severe and critical illness, the treatment should only be given as part of a clinical trial. Convalescent plasma is the liquid part of blood from a recovered Covid patient that contains antibodies produced by the body after being infected.

It was one of the array of potential treatments investigated early in the pandemic, but has shown limited benefit in clinical trials. The WHO said its latest recommendations were based on evidence from 16 trials involving 16,236 patients with non-severe, severe, and critical Covid-19 infection. (Source: NDTV)