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NEWS LETTER
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Antibodies In Children Last At Least 6 Months After COVID; SK Bioscience Vaccine Shows Promise Vs Omicron

The following is a summary of some recent studies on COVID-19. They include research that warrants further study to corroborate the findings and that has yet to be certified by peer review. Antibodies in kids after COVID last 6 months or more Most children and adolescents with COVID-19 antibodies after SARS-CoV-2 infection usually still have the antibodies in their blood more than half a year later, new data shows.

Starting in October 2020, researchers in Texas recruited 218 subjects between the ages of 5 and 19. Each provided three blood samples, at three-month intervals. More than 90% were unvaccinated when they enrolled in the study. The first blood test showed infection-related antibodies indicating recovery from COVID-19 in one-third of the children, the researchers reported online Friday in Pediatrics. Six months later, 96% of those with the antibodies still had them. The study was designed to detect the presence of antibodies, which are only one component of the immune system's defenses, not the amount of antibodies. The level of protection even in those with antibodies is unclear. Researchers found no differences based on whether a child was asymptomatic, severity of symptoms, when they had the virus or due to weight or gender.

"It was the same for everyone," Sarah Messiah of UTHealth School of Public Health Dallas, said in a statement. "Some parents... think just because their child has had COVID-19, they are now protected and don't need to get the vaccine," Messiah said. "We have a great tool available to give children additional protection by getting their vaccine." A small study published earlier this month in JAMA Network Open suggested that most children infected with the coronavirus do not have antibodies in their blood afterward. Only 37% of children appeared to develop antibodies, compared to 76% of adults, even though viral loads were similar in the two groups, those researchers found. Experimental SK vaccine shows promise against Omicron A booster shot of an experimental vaccine being developed by SK Bioscience Co (302440.KS) has shown "durable protection" against the Omicron variant in Rhesus macaques, according to new data.

The monkeys had received two initial doses of the vaccine plus a booster 6 or 12 months later. Blood samples from the boosted primates showed "remarkably high" levels of antibodies that could neutralize both the original strain of the virus and the Omicron variant that caused infections to soar, the researchers reported on Sunday on bioRxiv ahead of peer review. The animals' second-line immune defenses were also "substantial and persistent," they said. The vaccine, called GBP510, triggers responses from the immune system by delivering copies of a key part of the spike protein from the surface of the coronavirus. The protein "subunits" are studded onto nanoparticles to resemble the virus itself. These components are supplemented with an adjuvant from GSK (GSK.L) that boosts the immune system's responses, explained Bali Pulendran of Stanford University in California.

"Vaccination with two doses... followed a year later by a booster shot... plus adjuvant, led to highly durable antibody responses and protection against Omicron infection, even six months later," Pulendran said. Large late-stage trials of GBP510 in humans are underway. AstraZeneca drug less protective vs Omicron in transplant patients The AstraZeneca (AZN.L) antibody shots given to prevent COVID-19 in high-risk children and adults with weakened immune systems do not adequately protect organ transplant recipients from the Omicron variant, researchers found. The drug, Evusheld, did protect against the Delta variant in kidney transplant recipients, and lab test results released on Monday show Evusheld can neutralize Omicron in mice, including the highly contagious BA.2 version. But among 416 kidney recipients treated with Evusheld after Omicron became the predominant variant, 9.4% developed symptomatic breakthrough infections, with one-in-three of those patients requiring hospitalization, researchers reported on Saturday on medRxiv ahead of peer review.

Two patients died of COVID-19. In lab experiments, the researchers exposed the BA.1 version of Omicron that caused the massive winter surge to blood samples from 15 Evusheld-treated patients. None of the samples could neutralize the virus. The U.S. Food and Drug Administration recently advised that higher doses of Evusheld are likely needed to prevent Omicron infections, and that patients who received the originally approved shots should receive booster doses. The researchers said kidney transplant recipients "should be advised to maintain sanitary protection measures and undergo vaccine boosters." (Source: Reuters)

Mylab to Open New Manufacturing Facility In Visakhapatnam For Advanced Diagnos-

The new facility to manufacture a wide range of high-quality molecular diagnostic products Mylab Discovery Solutions, India's leading biotech company, announced the opening of a new manufacturing facility at Andhra Pradesh MedTech Zone (AMTZ) in Visakhapatnam.

The new facility would utilise the latest technology to manufacture a wide range of high-quality molecular diagnostic products and increase the company's manufacturing capacity. Spread over 43,000 square feet, the facility will be set up to cater to the increasing demand for transformative molecular testing in India and across the world for early and accurate diagnosis.

Debarshi Dey, Director of Mylab Discovery Solutions, said , " Mylab is entering an exciting period of growth and we are committed to delivering innovative diagnostic solutions to people around the world.

Expanding our manufacturing footprint enables us to strengthen indigenous production capacity and continue to produce the diagnostic kits of tomorrow. We are pleased to join forces with AMTZ to develop new diagnostics to better serve patients and address health challenges across the globe."

Jitendra Sharma, Managing Director and CEO, Andhra Pradesh MedTech Zone said, "Mylab have been a game changer in the field of diagnostics and has been at the forefront of the fight against Covid-19.

The addition of Mylab's facility further reinforces AMTZ's pioneering position as an ecosystem that supports new innovations in healthcare and boost manufacturing of home-grown diagnostic solutions."

After obtaining necessary approvals, the under-construction manufacturing facility will officially start operations from June this year. The facility would increase the production capacity to 500,000 per day, and create jobs for skilled workers.

Mylab Discovery Solutions is an Indian biotech firm focused on developing and commercialising Molecular, Serological, Immunology testing solutions and equipment for applications in clinical diagnostics.

AMTZ is India's premier medical technology park with common manufacturing and scientific facilities, including specialized laboratories, warehousing, and testing centres. (Source: Business Line)

Germany Speaks Out Against COVID-19 Vaccine Patent Waiver

BERLIN, March 28 (Reuters) - German Chancellor Olaf Scholz said on Monday he did not agree with a planned intellectual property waiver for COVID-19 vaccines as patents are a crucial way of encouraging companies to continue pushing ahead with new research.

The waiver drafted by the United States, European Union, India and South Africa earlier in March would need formal approval from the WTO's 164 member countries, including Germany, before being adopted.

The potential waiver deal followed months of negotiations over how to accelerate COVID-19 vaccine production in developing countries, where vaccination rates have lagged wealthy countries. Scholz, speaking at a news conference, said that a better way of making vaccines accessible in emerging economies would be to transfer vaccine production facilities to Africa. (Source: Reuters)

Rhode Island Reaches $107 mln Opioid Settlements With Teva and Allergan

Rhode Island's attorney general on Monday announced settlements he valued at $107 million against the drugmakers Teva Pharmaceutical Industries (TEVA.TA) and AbbVie's (ABBV.N) Allergan unit to resolve claims over their roles in fueling an opioid epidemic in the state.

Attorney General Peter Neronha said the settlements include $28.5 million in cash, plus the delivery to Rhode Island of anti-overdose treatments - 1 million Naloxone sprays and 67,000 bottles of Suboxone pills - over 10 years.

"While no amount of money will ever be enough to undo the harm suffered by Rhode Islanders throughout the ongoing opioid epidemic, these additional recoveries will further support public health efforts to respond to the challenges," Neronha said.

Israel-based Teva, the world's largest generic drug company, called its settlement "a critical step forward in getting life-saving treatments to the people who need them."

It said it was still "actively" negotiating a national settlement. Teva Chief Executive Kåre Schultz told Reuters last month the company will likely end up paying $2.7 billion to $3.6 billion in cash and drugs to settle all U.S. state and local government claims.

AbbVie, which acquired Allergan in 2020, did not immediately respond to a request for comment. The settlement was reached just as Rhode Island was prepared to take Teva to trial. Jury selection began last week, and opening arguments were set to begin on Monday.

The Rhode Island lawsuit is one of more than 3,300 filed by state, local and Native American tribal governments across the country accusing drugmakers of minimizing the addiction risks of opioid pain medications. More than 500,000 people have died due to opioid overdoses in the past two decades, according to the U.S. Centers for Disease Control and Prevention.

Rhode Island valued Teva's contributed medicines at $78.5 million. The company reached a similar $225 million settlement recently with Texas which included $75 million in contributed drugs.

Concerns about the value of those drugs have been a sticking point in Teva's attempt to reach nationwide settlement agreement. Hunter Shkolnik, a lawyer who represents opioid plaintiffs in other cases, called the use of the list price a "smoke and mirrors" technique that artificially inflates the settlement's value. Vincent Greene, an attorney who represented Rhode Island in the Teva case, said the inclusion of treatment drugs will "save lives immediately and in the years to come." Rhode Island has reached all-cash settlements from other defendants, giving the state more flexibility to accept non-cash contributions from Teva, Greene added.

Other defendants in the Rhode Island case settled long before the trial, including the largest U.S. drug distributors McKesson Corp (MCK.N), AmerisourceBergen Corp (ABC.N) and Cardinal Health Inc . Those three companies joined a nationwide $21 billion settlement. (Source: Reuters)

U.S. Drug Supply Is Even More Reliant On India Than Thought

Amid the first Covid-19 lockdowns in 2020 and worries that critical drugs could run low, a 200-year-old nonprofit, little known outside the drug industry, took it upon itself to meticulously map the supply chain of medications Americans take. It was an ambitious undertaking that not even the Food and Drug Administration had tried before. U.S. Pharmacopeia has long played a critical role in the drug industry, which relies on its chemical samples to help ensure quality. The results of its huge data-mining probe were startling: Indian factories, the data showed, provide a vast amount of ingredients that go into the generic drugs Americans take.

USP Chief Executive Officer Ron Piervincenzi says that before his organization sought to map the supply chain during the lockdowns, he was surprised by the paucity of data. “We were just frustrated—not just frustrated, truly annoyed,” he says.

Active ingredient production, the USP found, is far more concentrated in India than was previously understood given the FDA’s limited data, which had made China look like a more dominant player in the pharmaceutical supply chain than it really is. Active ingredients are what make a drug effective against a particular disease or condition.

It’s well known that Indian factories have struggled with quality issues over the years. What’s more, there’s nothing stopping the Indian government from cutting off supplies of certain drugs to protect its domestic stockpile. That’s exactly what India did early in the pandemic, when it temporarily banned the export of certain antibiotics and acetaminophen, the active ingredient in Tylenol, to ensure it had enough to meet domestic needs.

Add to that India’s close ties to Russia at a time of fraught relations between the Kremlin and the West. India has expressed interest in obtaining more oil from Russia, and Prime Minister Narendra Modi has so far avoided criticism of President Vladimir Putin’s invasion of Ukraine.

“I’m not saying India is averse to the U.S.,” says Stephen Schondelmeyer, co-lead of the Resilient Drug Supply Project at the University of Minnesota’s Center for Infectious Disease Research & Policy. Yet, “they’re somewhat Russia-friendly. They have a lot of trade with Russia.”

The Biden administration recently warned about the preponderance of drug supplies that come from China and India, and members of Congress have introduced legislation to protect the pharmaceutical supply chain from what they perceive as China’s dominance of the industry. Those positions will need to be reassessed after USP’s determination that India accounts for the lion’s share of the world’s active ingredient manufacturing plants for generic drugs, which account for 90% of the drugs Americans take.

USP found that brand-name drugmakers are more likely to turn to Europe for their active ingredients. Many issues can lead to shortages but without good data on where drugs come from, large buyers, particularly hospitals, can’t anticipate them as well as they’d like. USP’s findings could change that. For a price, they can help those in charge of keeping medical centers well-stocked anticipate drug shortages and give policymakers a tool for identifying the cause of a shortage.

Federal incentives could encourage the creation of new production lines in the U.S., and investment in factories in Canada and Mexico would help diversify supplies so that if a given company were knocked out, another making the same drug elsewhere could step in.

Rising transportation costs are also straining the drug supply chain, adding an incentive to bring production closer to home. In an October survey of its members, the Association for Accessible Medicines, a lobbying group, found that air cargo costs had increased an average of 227% since before the pandemic, says Jonathan Kimball, AAM’s vice president for trade. Ocean cargo costs were up 193%. Kimball said costs have probably worsened with rising oil and gas prices triggered by Russia’s invasion of Ukraine.

The industry has a lot of work to do. Of the 100 drugs Americans use most, 83 have no production source in the U.S. for their active ingredients, says Tony Sardella, a senior research adviser at the Center for Analytics & Business Insights at Washington University in St. Louis. About 75% of 52 drugs used to treat Covid that Sardella analyzed, including analgesics as well as pulmonary and cardiology drugs, don't have a U.S. source for active ingredients.

With its close ties to the industry, USP was able to gather details on what factories supply which ingredients—information that major drug companies carefully guard. USP mapped factories all over the world to determine active ingredient output for the U.S. market.

Getting that wide-angle view of the global supply chain required cross-referencing 40 external datasets in what Vimala Raghavendran, who heads USP’s Pharmaceutical Supply Chain Center, says was “a massive undertaking.” That gave USP a level of detail and timeliness that far exceeds the FDA’s data. USP intends to keep its data up to date for sale to hospitals and government agencies. “Bottom line is that you can’t have a one-size-fits-all solution to this big problem,” Raghavendran says. “Our medical supply chain is not as resilient as we need it to be.” (Source: AFP)

Second Booster Shields Elderly From COVID But Protection Wanes Quickly - Study

A fourth dose of the Pfizer/BioNTech vaccine lowered rates of COVID-19 among the elderly but the protection against infection appeared short-lived, a large study in Israel has found. The second booster's protection against infection dwindled after four weeks, Israeli researchers showed in their study published on Tuesday in the New England Journal of Medicine.

Protection against severe illness did not wane during the six weeks after the dose but more follow-up study was needed to evaluate its longer-term protection, the researchers said.

The study on 1.3 million people aged 60 and older looked at data from the Israeli Ministry of Health database between Jan. 10 and March 2, when the Omicron variant was predominant. It comes ahead of a meeting by the U.S. Food and Drug Administration on Wednesday to discuss the need for additional boosters, a week after the United States authorised a second booster shot for people aged 50 and older amid a spread of the Omicron sub-variant BA.2.

European health ministers have also urged the bloc's governments to back a fourth dose for people over 60. In Asia, South Korea started giving out fourth doses of COVID-19 vaccines in February and Singapore has said a second booster dose is planned for those aged 80 and older. (Source: Reuters)

US FDA Inspections Back In Full Swing For Pharma Cos

Surge in audit inspections could be periodic or could also be linked to evolving standards in manufacturing US FDA plant inspections seem to be coming back strongly after a two-year hiatus, going by the just-concluded inspection at Zydus Lifesciences on March 10 and a warning letter to Aurobindo earlier this year, in mid-January.

FDA officials commented in February 2022 that FDA is keen on restarting inspections, including surprise inspections in India.

FDA could be set for a busy year in India as the backlog of redressals from previous inspections and pending applications for plants and products become pressing. Earlier, the total number of US FDA plant audits for drug quality assurance in India peaked in 2019 at 239. Another 80 inspections were completed in January-March 2020 prior to Covid and slid to 5 inspections in 2021.

The surge in audit inspections could be periodic or could also be linked to evolving standards in manufacturing. In such waves, 'OAI (Source: Business Line)

WHO Suspends U.N. Supply of Bharat Biotech's Covaxin Vaccine for COVID-19

The World Health Organization said on Saturday it has suspended supply through United Nations agencies of COVID-19 vaccine Covaxin, produced by India's Bharat Biotech, to allow the manufacturer to upgrade facilities and address deficiencies found in an inspection.

The WHO asked countries that have received the vaccine to take appropriate actions, according to the statement, but did not specify what the appropriate actions would be.

The WHO said the vaccine is effective and no safety concerns exist, but the suspension of production for export will result in the interruption of Covaxin supply.

It said the suspension is in response to the outcomes of WHO post emergency use listing (EUL) inspection conducted from March 14 to 22, and the vaccine maker has indicated its commitment to suspend production of Covaxin for export.

Bharat Biotech did not immediately respond to a request for comment sent outside business hours. (Source: Reuters)

Bharat Serums and Vaccines to Invest ₹200 crore in Genome Valley

Bharat Serums and Vaccines Limited (BSV) has announced an investment of ₹200 crore in the state-of-the-art injectable and vaccine manufacturing facility at Genome Valley in Hyderabad.

The facility will produce women health products, rabies vaccines, immunoglobulins and hormones, among others. Sanjiv Navangul, Managing Director and Chief Executive Officer, BSV met Telangana Industries Minister KT Rama Rao on Tuesday and informed of his company's commitment to invest.

'm delighted to announce the entry of Bharat Serums in Genome Valley, Hyderabad," Rama Rao said. Telangana Government would extend all the support required by Bharat Serums and would also partner with BSV in areas like improving women's health, he added. BSV is amongst the top 10 biotech companies in India. It has in its portfolio over 145 brands.

The company has over 1,000 employees selling its products across the country with their brands being marketed all over India and exported to over 70 countries across the world. (Source: Business Line)