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NEWS LETTER
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US CDC Backs Pfizer's Maternal RSV Vaccine To Protect Infants

The U.S. Centers for Disease Control and Prevention (CDC) on backed Pfizer's respiratory syncytial virus (RSV) vaccine for women in the middle of the third trimester of pregnancy to protect their babies from severe illness. The CDC recommendation comes after a panel of advisers voted 11 to 1 for use of the shot in women 32 weeks to 36 weeks into their pregnancy from September to January, paving the way for it to become the first maternal vaccine for the seasonal respiratory virus available in the country. "This is another new tool we can use this fall and winter to help protect lives," CDC Director Dr. Mandy Cohen said in a statement.

The vaccine was approved by the U.S. Food and Drug Administration last month for use during that same window of 32 to 36 weeks into pregnancy to prevent lower respiratory tract infection and severe disease in infants until they are six months old. "RSV throughout my career has been a difficult disease with just supportive care treatment because there have been no options so today is an exciting day," said Dr. Katherine Poehling, a member of the CDC advisory panel and a professor of pediatrics and epidemiology and prevention at Wake Forest School of Medicine.

Getting the vaccine late in pregnancy is likely to reduce a possible risk of preterm births and complications that might arise from taking it earlier, doctors on the panel said. RSV is a common respiratory virus that usually causes mild, cold-like symptoms but can also lead to serious illness and hospitalization. It is typically a seasonal illness, starting in autumn and peaking in the winter in most of the U.S., according to the CDC. Because RSV is a seasonal disease, "year round administration could not benefit children born in April through September," panel member Dr. Sarah Long, professor of pediatrics at Drexel University College of Medicine said. If needed, those babies could receive Sanofi (SASY.PA) and straZeneca's (AZN.L) antibody therapy nirsevimab to prevent RSV in infants and toddlers, which was approved earlier this year, she said.

An estimated 58,000 to 80,000 children below the age of five years are hospitalized each year due to RSV infection in the U.S., according to government data. Pfizer's vaccine, along with another made by GSK (GSK.L), won U.S. approval in May for use in people age 60 and older and are already available around the country. Pfizer said the list price of the maternal shot will be $295 per dose, the same as for older adults. It plans to use a tiered pricing strategy for the shot outside of the U.S. At an advisory meeting in May, FDA staffers had flagged a higher number of pre-term births among participants taking Pfizer's vaccine in a clinical trial compared to those who received a placebo. However, the agency said the difference did not appear to be statistically significant, thus might have been due to chance. A surge in cases of RSV infections coinciding with an increase in COVID transmission and an earlier-than-normal flu season has raised the specter of a so-called 'tripledemic' of respiratory illness across the United States. CDC has said it expects total hospitalizations from the three to be similar to last year. For the first time, vaccines to protect against all

Newer Antibiotic Effective Against Deadly Staph Infection In Trial

An antibiotic already in use in Europe to treat pneumonia controlled deadly bloodstream infections with Staphylococcus aureus bacteria just as effectively as the most powerful antibiotic currently in use, according to data from a late-stage trial.

Ceftobiprole from Swiss drugmaker Basilea Pharmaceutica (BSLN.S) appeared to be equally effective as the older drug daptomycin in the roughly one-in-four patients who had particularly difficult to treat methicillin-resistant S. aureus (MRSA) infections, researchers reported on Wednesday in The New England Journal of Medicine.

"This is an area of true need," study leader Dr. Thomas Holland of Duke University School of Medicine said in a statement. "There has not been a new antibiotic approved for the treatment of S. aureus bacteremia for over 15 years." For the study, 390 patients hospitalized with complicated bloodstream staph infections were randomly assigned to receive infusions of ceftobiprole or daptomycin.

The treatment was successful in 69.8% of the ceftobiprole group and 68.7% of the daptomycin group, according to the report. Success was defined as survival, symptom improvement, clearance of S. aureus from the blood, absence of new complications and no need for other antibiotics.

Gastrointestinal issues were the most common side effect with both drugs.
Daptomycin was the most recently approved new antibiotic for S. aureus bacteremia more than 15 years ago, the researchers noted.

"Despite a lot of work in medical science, complicated staph infections still have a 25% mortality rate at 90 days," study co-author Dr. Vance Fowler Jr. of Duke Health said in a statement. "We need more options for treating these infections." (Source: Reuters)

WHO Recommends Malaria Vaccine Made by Oxford University, Serum Institute; Roll Out Expected in Mid-2024

The World Health Organization (WHO) on Monday recommended a new malaria vaccine, R21/Matrix-M, to curb the life-threatening disease spread to humans by certain mosquitoes. The R21/Matrix-M vaccine is the second malaria vaccine recommended by WHO, following the RTS,S/AS01 vaccine, which received a recommendation in 2021. Both vaccines are shown to be safe and effective in preventing malaria in children and, when implemented broadly, are expected to have high public health impact, WHO said in a statement.

The addition of R21 to the list of WHO-recommended malaria vaccines is expected to result in sufficient vaccine supply to benefit all children living in areas where malaria is a public health risk," it stated. “Demand for the RTS,S vaccine far exceeds supply, so this second vaccine is a vital additional tool to protect more children faster, and to bring us closer to our vision of a malaria-free future,

WHO Director-General Tedros Adhanom Ghebreyesus said. R21/Matrix-M, developed by Britain's University of Oxford, will become available by mid-2024. Each dose would cost between $2 and $4. R21/Matrix-M is mass manufactured by Serum Institute of India and uses Novavax's Matrix M adjuvant. "WHO is now reviewing the vaccine for prequalification, which is WHO stamp of approval, and will enable GAVI (a global vaccine alliance) and UNICEF to buy the vaccine from manufacturers," Tedros said (Source Business Today)

Wegovy Maker Novo Nordisk Becomes Europe’s Most Valuable Firm

The success of the weightloss drug Wegovy has helped its Danish manufacturer to overtake the French luxury group LVMH as Europe’s most valuable company. After Novo Nordisk, which specialises in diabetes and weight loss treatments, launched Wegovy in the UK. its share price rose 0.7% to Danish kroner 1,310.80 (£150).That gave it a market value of £340bn – making it worth more than the entire Danish economy, which is valued at £323bn. LVMH, which comprises 75 luxury brands including Louis Vuitton, Dior and Givenchy, closed down 0.4% at €772.60 a share, giving it a market value of €388bn (£331bn). Novo Nordisk had briefly overtaken LVMH in terms of its market value on Friday, but fell back by end of trading.

On Tuesday, the Danish drugmaker extended its lead, with its shares rising 1.6% by the afternoon while LVMH fell 1%. Soaring demand for Wegovy has led to shortages of the appetite-suppressing drug, which is prescribed for people with obesity and is injected by users once a week. Novo Nordisk said on Monday that the drug would be introduced to the UK “through a controlled and limited launch”. It has restricted global supplies as it tries to ramp up manufacturing. Wegovy is available on the NHS and can also be bought privately at pharmacies. The list price for a month’s supply in the UK ranges from £73.25 to £175.80 depending on the dose,but the NHS negotiated a discount with the manufacturer. Boots said that because of limited stock of Wegovy it will prioritise supply to people using Saxenda – another weight-loss drug made by Novo Nordisk – through its online doctor service. Many other high street pharmacies are waiting for supply of Wegovy.

Several big UK insurers – Aviva, Axa and WPA – will not cover the cost of Wegovy under their private medical insurance policies. Aviva and Axa said they only cover acute conditions while Wegovy would be classified as treatment for a chronic condition, and WPA (Western Provident Association) has an exclusion on obesity. Get set for the working day – we'll point you to all the business news and analysis you need every morning
Novo Nordisk is the world leader in diabetes and weight loss drugs in a market that analysts predict could reach more than £80bn in annual sales within a decade. Experts have warned against seeing treatments as a quick fix for the obesity crisis, stressing the importance of exercise and a healthy diet. (Source: The Guardian)

The U.S. government will stop distributing free doses of Merck & Co's (MRK.N) COVID-19 antiviral treatment molnupiravir by the middle of next month and expects it to be sold on the commercial market instead. The Administration for Strategic Preparedness and Response (ASPR), a division of the U.S. Department of Health and Human Services, said in a statement posted on its website late last week they anticipate transition of the drug, sold under the brand name Lagevrio, from government-managed to traditional commercial distribution in November.

Merck, which developed the drug with Ridgeback Biotherapeutics, said in an emailed statement on Wednesday that it needs an updated letter of authorization from the U.S. Food and Drug Administration to allow it to start selling the drug commercially. Molnupiravir was initially hailed as a potential breakthrough when few treatment options were available but was soon eclipsed by Pfizer's (PFE.N) rival treatment Paxlovid, which had more impressive data. It has taken a backseat to Paxlovid in the United States and the EU regulator recommended against the Merck drug's use in the region. Trial data showed a roughly 30% reduction in hospitalizations and deaths from the illness in people with risk of progression for severe disease with the Merck drug, compared with a roughly 90% reduction in hospitalization for Paxlovid. It has also been linked to potentially transmissable mutations in the COVID-19 virus, according to a study published in the journal Nature last month. Merck said the study was limited and that it is confident in the clinical profile of the drug. (Source: Reuters)

Viatris to Sell India API, Women's Healthcare Biz For $1.2 BN

Viatris Inc., the result of the merger between Mylan NV and Pfizer Inc.'s Upjohn unit in 2020, has sold two of its businesses in India for $1.2 billion as part of a global exercise to exit non-core businesses.

Viatris on Monday said it sold the Indian active pharmaceutical ingredients (API) business to IQuest Enterprises, a local pharma firm owned by Matrix Laboratories founder Nimmagadda Prasad. The deal marks Prasad's re-entry into the API business that he sold to Mylan in 2006. Viatris also sold its women's healthcare business to Insud Pharma of Spain.

The API business in India includes three manufacturing sites and a research lab in Hyderabad, three manufacturing sites in Visakhapatnam and third-party API sales, Viatris said in a statement.

The company will retain some research and development (R&D) capabilities in API. The women's healthcare business, which primarily specializes in oral and injectable contraceptives, includes two manufacturing facilities in Gujarat, one each in Ahmedabad and Sarigam. Mylan acquired the Famy Care women's healthcare business from the Mumbai-based Taparia family in 2015 for $800 million. Mint first reported the company's plans to sell the women's healthcare business on 8 November.

Both transactions, subject to regulatory approvals, are expected to close in the first quarter of 2024. In February 2022, Viatris sold its local biosimilar business to Biocon Biologics for $3.35 billion as part of a plan to exit various businesses in Europe and other markets, including India. At that time, Viatris said it had identified non-core opportunities.

Including the Biocon Biologics deal, that could generate around $9 billion in pre-tax proceeds. "Completion of divestitures will bring a successful conclusion to all Phase 1 efforts and commitments, including prioritizing the use of net proceeds for debt paydown to reach gross leverage target of 3x in the first half of 2024," the company statement said. "It will also set the company up extremely well as we enter into our Phase 2 strategy for 2024 and beyond," it added.

The company said it has achieved its goal of substantially simplifying the organization by increasing focus on areas with the greatest potential to accelerate growth, patient impact and shareholder value. Global investment bank Jefferies, which specializes in pharma deals, and law firm Saraf and Partners, advised Viatris on the transaction.

Viatris is known for its off-patent blockbusters, such as the cholesterol treatment drug Lipitor, erectile dysfunction drug Viagra and antidepressant Zoloft. The drugmaker also sells many lesser-known over-the-counter items like dietary supplements, allergy medicines and cosmetics. (Source: Mint)

Musk's Neuralink to Start Human Trial of Brain Implant For Paralysis Patients

Billionaire entrepreneur Elon Musk's brain-chip startup Neuralink said it has received approval from an independent review board to begin recruitment for the first human trial of its brain implant for paralysis patients.

Those with paralysis due to cervical spinal cord injury or amyotrophic lateral sclerosis may qualify for the study, it said, but did not reveal how many participants would be enrolled in the trial, which will take about six years to complete.

The study will use a robot to surgically place a brain-computer interface (BCI) implant in a region of the brain that controls the intention to move, Neuralink said, adding that its initial goal is to enable people to control a computer cursor or keyboard using their thoughts alone.

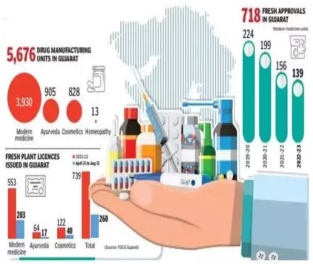
The company, which had earlier hoped to receive approval to implant its device in 10 patients, was negotiating a lower number of patients with the U.S. Food and Drug Administration (FDA) after the agency raised safety concerns, according to current and former employees. It is not known how many patients the FDA ultimately approved.

Musk has grand ambitions for Neuralink, saying it would facilitate speedy surgical insertions of its chip devices to treat conditions like obesity, autism, depression and schizophrenia.

In May, the company said it had received clearance from the FDA for its first-in-human clinical trial, when it was already under federal scrutiny for its handling of animal testing.

Even if the BCI device proves to be safe for human use, it would still potentially take more than a decade for the startup to secure commercial use clearance for it, according to experts. (Source: Reuters)

Gujarat's Pharma Industry Growth Hits 'Fever Pitch'



The pharma industry in Gujarat has grown by 40% in the last four years and is set to hit an annual turnover of Rs 2 lakh crore in three years. Since the 2020 fiscal year, 494 new plant approvals and 1,682 licenses have been granted to new units that began production. As of March 2023, the Gujarat pharma industry's annual turnover was Rs 1.42 lakh crore. Industry leaders say the large numbers of new export-oriented plants will lead to quicker growth in the next five years. H G Koshia, commissioner of Food and Drug Control Administration, Gujarat, said, "Since GST was rolled out, Gujarat has seen massive new investments in pharma. Lots of companies shifted here from northern and northeastern states as taxation became uniform. These numbers multiplied after Covid, given the resilience shown by pharma manufacturers here. "In 2022-23, we approved plans for 139 new modern medicine manufacturing units, and the flow of new investments continued this fiscal year too. The state now has 4,000 conventional medicine manufacturing units. Most of these are oriented towards both the domestic market and exports and have the necessary approvals. Our exports will thus increase significantly in the coming years."

According to the Indian Drug Manufacturers' Association (IDMA), the size of the Indian pharmaceuticals market is Rs 4 lakh crore: Rs 2 lakh crore domestic and Rs 2 lakh crore in exports. The size of the Gujarat pharma industry is around Rs 1.42 lakh crore and IDMA estimates that it will reach Rs 2 lakh crore by 2026.IDMA president Viranchi Shah said, "Indian pharma exports are growing by double digits and more countries are eager to trade with India, so there are greater export opportunities for Gujarat-based pharma companies. Gujarat has a sturdy base in formulations and is set to increase its production of active pharmaceutical ingredients (APIs) with the dedicated bulk drugs park. This will lower material costs and increase our competitiveness. With most new investments in the pharma sector getting regulatory approvals, there will be increased capacity for exports, which will help us corner a larger share of the global pharma market. The Gujarat pharma industry has grown from Rs 1 lakh crore in the 2019 fiscal year to Rs 1.42 lakh crore in 2023."

Shah emphasized that Gujarat companies need to focus more on innovation and R&D. "Currently, almost all our products are either branded generics or generics and are off-patent. We need to develop new products. The US, Vietnam and the UAE are encouraging local production, and our companies will soon face competition from them in general medicines. Innovative products will give us an advantage." Shah emphasized that Gujarat companies need to focus more on innovation and R&D. "Currently, almost all our products are either branded generics or generics and are off-patent. We need to develop new products. The US, Vietnam and the UAE are encouraging local production, and our companies will soon face competition from them in general medicines. Innovative products will give us an advantage." The Indian domestic formulations market is expected to grow at a healthy rate of 10-15% in the next three to five years. Companies that are focused on growing economies and emerging markets could even outpace the industry." Lincoln recently started exports to Canada. TGA-Australia and EU GMP approvals will further strengthen its presence and expand its network to over 90 countries. He said there are some challenges for the industry on the export front. "We are seeing more and more countries now adopting the most stringent regulatory norms, like USFDA, for product and plant approvals. The time taken for inspections, plant approvals, compliance with changing regulatory rules and the costs involved in complying are challenges for growth in the export market. Availability of skilled human resources is also a major challenge in the domestic market," he added.

Pharma majors bullish on US prospects

The state's pharma majors have also seen revivals in their US businesses. Sun Pharmaceuticals saw its US formulations sales grow by 12% in the first quarter. Zydus Lifesciences posted 10% growth in the quarter in its US business, which makes up 48% of its operating revenue, according to the company's quarterly report. Other markets also provided significant revenues. Torrent Pharmaceuticals saw its revenues grow by 21% in other markets – primarily Germany. "Our Germany revenue grew by 21% to Rs 258 crore. Constant currency revenue was 29 million euros, up 11%. Growth momentum continues with new tenders bagged and improved conversion in existing tenders," the company said during its first-quarter results. Industry stakeholders said that to boost their US generics business, most pharma companies are looking to invest heavily in R&D of new drugs while applying for abbreviated new drug applications (ANDAs) to launch new products more aggressively. Some 200 new drugs are slated for launch by the end of the fiscal year. A senior official of Zydus Lifesciences said, "The production-linked incentives (PLI) scheme will play a key role in the coming years. We are focusing more on R&D and innovation and have a strong product line for export markets. The US will remain our key market because it has around a 40% share in the global pharma market."

Quality medical devices for less open new doors

The medical devices industry in Gujarat is also bullish with domestic manufacturing growing strongly. Gujarat is a hub for medical devices and pharma machinery with a 35% share of India's production. The Indian medical devices industry is worth around $11 billion, and is expected to grow to $50 billion by the end of 2023, according to central government data.Dr Manish Doshi, MD of Concept Medical & Envision Scientific, said, "The medical devices industry in India was import dependent, but there has been a surge in domestic manufacturing through innovation. This transformation is attributed to greater healthcare awareness, growing incomes, technological advancement, and government initiatives such as "Make in India" and the PLI scheme for Indian manufacturers. The industry now offers a wide range of medical devices, from basic consumables to advanced imaging and diagnostics equipment, stents, balloon catheters and advanced heart valves. This diversification has enhanced patient care outcomes nationwide. The Covid-19 pandemic underscored the importance of a robust medical devices sector, as demand for vital devices such as ventilators and diagnostic tools had skyrocketed." (Source: Times of India)