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NEWS LETTER
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Eisai, Biogen Say Alzheimer's Drug Succeeds In Slowing Cognitive Decline

Eisai Co Ltd (4523.T) and Biogen Inc (BIIB.O) on Tuesday said their experimental Alzheimer's drug significantly slowed cognitive and functional decline in a large trial of patients in the early stages of the disease, marking a rare win in a field littered with failed drugs. The drug, lecanemab, slowed progress of the brain-wasting disease by 27% compared with a placebo, meeting the study's main goal, and potentially offering hope for patients and their families desperate for an effective treatment. "It's not a huge effect, but it's a positive effect," said Ronald Petersen, director of the Mayo Clinic Alzheimer's Disease Research Center in Rochester, Minnesota.

Eisai, leader of the 50-50 partnership's lecanemab program, is seeking FDA approval under an accelerated pathway, with a decision expected in early January. On Tuesday the Japanese drugmaker said it will use the new efficacy results to submit lecanemab for traditional FDA review as well. The company said it will also seek authorization in Japan and Europe during its current fiscal year, ending March 31. Eisai said results from the 1,800-patient trial prove the longstanding theory that removal of sticky deposits of a protein called amyloid beta from the brains of people with early Alzheimer's can delay advance of the debilitating disease. "This means that treating amyloid is a step in the right direction," Petersen said. Shares of Biogen and Eisai were halted, but shares of Eli Lilly & Co , which is also developing an Alzheimer's drug, rose as much as 6.7% in after hours trade. The lecanemab data suggest "a potentially new multi-billion dollar franchise," Jefferies analyst Michael Yee said in a research note. Lecanemab, like the partners' previous drug Aduhelm, is an intravenous antibody designed to remove amyloid deposits. Unlike Aduhelm, lecanemab targets forms of amyloid that have not yet clumped together. "If you can slow a disease by almost 30% that's fantastic. This is what we have been looking for," said Dr. Jeff Cummings, director of the Chambers-Grundy Center for Transformative Neuroscience at the University of Nevada Las Vegas.

The so-called amyloid hypothesis has been challenged by some scientists, particularly after the U.S. Food and Drug Administration's controversial approval of Aduhelm in 2021 based on its plaque-clearing ability rather than proof that it helped slow cognitive decline. The decision came after the FDA's own panel of outside experts had advised against approval. Aduhelm was the first new Alzheimer's drug approved in 20 years after a long list of high-profile failures for the industry. Patient advocacy groups hailed the news of positive lecanemab trial results. "This is important because it demonstrates that each of these drugs is different ... I would hope that the FDA approves the drug in January," USAgainstAlzheimer's Chairman George Vradenburg told Reuters. The Phase III trial evaluated the drug's ability to reduce cognitive and functional decline based on the Clinical Dementia Rating-Sum of Boxes (CDR-SB), a numerical scale used to quantify the severity of dementia in patients in areas such as memory, orientation, judgment and problem solving and personal care.

BRAIN SWELLING

The rate of a brain swelling side effect associated with anti-amyloid treatments was 12.5% in the lecanemab group, versus 1.7% in the placebo group. But many cases did not cause symptoms, with symptomatic brain swelling seen in 2.8% of those in the lecanemab group, the companies said. Micro hemorrhages in the brain occurred at a rate of 17% in the lecanemab group, and 8.7% in the placebo group. Petersen said the side effect rate was much less than with Aduhelm and "certainly tolerable." Aduhelm's approval was a rare bright spot for Alzheimer's patients, but critics have called for more evidence that amyloid-targeting drugs are worth the cost.

The controversy and reluctance by some payers to cover Aduhelm led Biogen to slash the drug's price to $28,000 per year from an initial $56,000. But Medicare, the U.S. government health plan for people 65 and older, this year said it would only pay for Aduhelm and other similar drugs if patients were enrolled in a valid clinical trial, which sharply curtailed the medication's use. Since Alzheimer's is a disease of aging, an estimated 85% of patients eligible for the drug are covered by the government plan. Michael Irizarry, Eisai's deputy chief clinical officer, said on a conference call that the company will have discussions with the Medicare agency regarding coverage of lecanemab.The number of Americans living with Alzheimer's is expected to rise to around 13 million by 2050 from more than 6 million currently, according to the Alzheimer's Association. Globally, that figure could rise to 139 million by 2050 without an effective treatment, according to Alzheimer's Disease International. Other plaque-targeting antibodies in late-stage development for Alzheimer's patients include Roche Holding AG's (ROG.S) gantenerumab and Eli Lilly's donanemab. '(Source: Reuters)

Gilead Widens Battle Against Alleged Counterfeit HIV Drug Ring

A federal judge in New York has frozen the assets of dozens of people and entities accused of operating a massive nationwide scheme to distribute counterfeit bottles of Gilead Sciences Inc (GILD.O) HIV drugs, including two alleged "kingpins.

Gilead, which has been pursuing alleged counterfeiters in a civil lawsuit since last year, said in a court filing unsealed on Wednesday it had uncovered an operation that was "staggering in scope," responsible for sales of hundreds of millions of dollars of counterfeit bottles of its top sellers Descovy, Genvoya and Biktarvy, and other medicines.

U.S. District Judge Ann Donnelly's latest asset freeze order, also unsealed on Wednesday, targets more than 50 defendants newly added to Gilead's lawsuit. Many counterfeit bottles contain antiviral pills manufactured by Gilead but illegally bought off the street and repackaged, while some have been found to contain other, potentially dangerous drugs, including the powerful antipsychotic Seroquel, Gilead has said.

HIV drugs accounted for $7.6 billion of Gilead's $12.6 billion revenue in the first half of the year. The company in January warned that more than $250 million of counterfeit drugs had been sold over the last two years, and said it had identified more than 85,000 bottles that were fake or tampered with. read more.

The newly added defendants include alleged "kingpins" Lazaro Roberto Hernandez, who was arrested on drug counterfeiting and money laundering charges in June as part of a related federal investigation and remains under house arrest, and Armando Herrera, who lives in Florida.

"Gilead's ongoing investigation revealed that these two kingpins directed the initial sale of the counterfeits through suppliers created solely to sell counterfeit medications," the company said in a statement on Wednesday. Gilead said it had identified the two men, who took elaborate steps to conceal their identities, by matching approximate locations of their disposable burner cell phones with flight records.

The Foster City, California-based company first announced it was pursuing counterfeiters in August 2021, shortly after filing its lawsuit. In addition to the alleged kingpins, the case now includes alleged mid-level leaders and a complex web of shell companies, distributors and pharmacies.

It also involves so-called collectors, who pay cash on the street for the bottles used in the scheme, often acquiring them from people who are homeless or suffering from drug addiction, Gilead said. (source: Reuters)

Opioid Crisis Cost U.S. Nearly $1.5 Trillion In 2020 –Congressional Report

WASHINGTON, Fueled by the COVID-19 pandemic, the economic toll of the opioid addiction and overdose crisis on the United States reached nearly $1.5 trillion in 2020 alone and is likely to grow, a congressional report seen by Reuters shows. Opioid-related deaths soared during.

The pandemic, including from the powerful synthetic painkiller fentanyl, exacerbating an already tragic and costly nationwide crisis that accounted for 75% of the 107,000 drug overdose fatalities in 2021, according to U.S. Centers for Disease Control and Prevention (CDC) data.

"It's equivalent to one 737 (jet) every day going down, no survivors. It's a mind boggling number of deaths," said Representative David Trone, who sits on the Congressional Joint Economic Committee (JEC) that issued the report. The committee said in a Wednesday report that after adapting a method used by CDC scientists and adjusting for inflation, it found that the crisis cost the U.S. economy $1.47 trillion in 2020, a $487 billion increase from 2019.

The latest calculation represents a 37% increase from 2017, when the CDC last measured the cost. "JEC is valuing all the various loss that happens with addiction. There's loss of productivity, folks in the job force, all the medical health costs, just a huge number of costs," said Trone, a Democrat who previously chaired the bipartisan U.S. Commission on Combating Synthetic Opioid Trafficking.

The rise in fatal opioid overdoses in 2021 suggests the total cost is likely to continue to increase," the report said. The report also highlighted racial inequalities within the crisis. Although opioid use is more common among white people, Black people accounted for 17% of U.S. fatal opioid overdoses in 2020 despite making up 12.5% of the population.

Black people have a harder time getting addiction treatment because they are less likely to have access to affordable healthcare and prescribed medications that can reduce the risk of fatal opioid overdoses, it said. President Joe Biden announced on Friday nearly $1.5 billion to fund access to medications for opioid overdoses, sanctions against traffickers, and increased funding for law enforcement. (Source Reuters)

End of COVID Pandemic Is 'In Sight' -WHO Chief

The world has never been in a better position to end the COVID-19 pandemic, the head of the World Health Organization said on Wednesday, his most optimistic outlook yet on the years-long health crisis which has killed over six million people. "We are not there yet. But the end is in sight," WHO Director-General Tedros Adhanom Ghebreyesus told reporters at a virtual press conference.

That was the most upbeat assessment from the UN agency since it declared an international emergency in January 2020 and started describing COVID-19 as a pandemic three months later. The virus, which emerged in China in late 2019, has killed nearly 6.5 million people and infected 606 million, roiling global economies and overwhelming healthcare systems. The rollout of vaccines and therapies have helped to stem deaths and hospitalisations, and the Omicron variant which emerged late last year causes less severe disease. Deaths from COVID-19 last week were the lowest since March 2020, the U.N. agency reported. Still on Wednesday, he again urged nations to maintain their vigilance and likened the pandemic to a marathon race.

"Now is the time to run harder and make sure we cross the line and reap the rewards of all our hard work." Countries need to take a hard look at their policies and strengthen them for COVID-19 and future viruses, Tedros said. He also urged nations to vaccinate 100% of their high-risk groups and keep testing for the virus. The WHO said countries need to maintain adequate supplies of medical equipment and healthcare workers. "We expect there to be future waves of infections, potentially at different time points throughout the world caused by different subvariants of Omicron or even different variants of concern," said WHO's senior epidemiologist Maria Van Kerkhove.

With over 1 million deaths this year alone, the pandemic remains an emergency globally and within most countries. "The COVID-19 summer wave, driven by Omicron BA.4 and BA.5, showed that the pandemic is not yet over as the virus continues to circulate in Europe and beyond," a European Commission spokesperson said. WHO's next meeting of experts to decide whether the pandemic still represents a public health emergency of international concern is due in October, a WHO spokesperson said.

GLOBAL EMERGENCY

"It's probably fair to say most of the world is moving beyond the emergency phase of the pandemic response," said Dr Michael Head, senior research fellow in global health at Southampton University. Governments are now looking at how best to manage COVID as part of their routine healthcare and surveillance, he said. Europe, the United Kingdom and the United States have approved vaccines that target the Omicron variant as well as the original virus as countries prepare to launch winter booster campaigns. In the United States, COVID-19 was initially declared a public health emergency in January 2020, and that status has been renewed quarterly ever since. The U.S. health department is set to renew it again in mid-October for what policy experts expect is the last time before it expires in January 2023. U.S. health officials have said that the pandemic is not over, but that new bivalent vaccines mark an important shift in the fight against the virus. They predict that a single annual vaccine akin to the flu shot should provide a high degree of protection and return the country closer to normalcy. (Source: Reuters)

Bayer Brings In Novel Therapy For Worsening Heart Failure

Verquvo is being launched in line with the rest of the world, and is priced at Rs.127 per pill Bayer is rolling-out its new therapy vericiguat, Verquvo, which helps reduce hospitalization and mortality in patients with worsening heart failure. The once-a-day drug is being launched in line with the rest of the world, and is priced at an India-specific price of Rs.127 per pill, which is about 1/15 th the global price, Manoj Saxena, MD, Bayer Zydus Pharma told Business Line. India is estimated to have a crore people with heart failure, occurring in patients that are a decade younger than their Western counterparts. Despite the substantially younger age of patients, three out of five Indian patients will die within five years of diagnosis, company officials said.

About the product

Vericiguat is a soluble guanylate cyclase (sGC) stimulator, indicated with standard care in adults with symptomatic chronic heart failure. The drug works on a pathway not currently targeted by existing heart failure treatments and can reduce the risk of cardiovascular death and heart failure hospitalization, added Dr Ashish Gawde, Country Medical Director. Chronic heart failure occurs.

The heart is not able to pump blood as well as it should. Thickening of arteries (atherosclerosis), heart attack, infections, or rheumatic heart disease make the heart muscle weak or stiff, so it cannot pump blood effectively, the officials explained. The heart failure segment is estimated to be about ₹20,000 crore, while worsening heart failure is about ₹1200 crore.

Commercial rights and FDA approval

Interestingly, Bayer and Merck have a worldwide collaboration in the field of sGC modulators. The vericiguat program is being co-developed by Bayer and Merck. Merck has the commercial rights to vericiguat in the US and Bayer has exclusive commercial rights in the rest of world. Bayer received approval of vericiguat in India based on results of its Phase III VICTORIA trial, published. The New England Journal of Medicine (NEJM) in March 2020. The drug is not given to pregnant women. Vericiguat was approved for use by the US FDA in January 2021, and by the European Commission in July 2021. (Source: Business Line)

34 Drugs Added, 26 Dropped From List of Essential Medicines

Bleaching powder and ranitidine, a common antacid sold under some of the most popular medicine brands in India, were amongst the ones dropped from the list of National List of Essential Medicines (NLEM) 2022 even as nicotine replacement therapy (NRT) and TB & diabetics treatment drugs were among the latest addition to the list. As per data released by Union Ministry of Health and Family Welfare on Tuesday Ranitidine — sold under brands Rantac, Zinetac, among others — was taken off the list reportedly following safety concerns.

Nicotine replacement therapy focusses on providing the user with nicotine through gums, patches, sprays, inhalers or even lozenges; but it does not include the harmful chemicals of tobacco. The nicotine replacement therapy is used to relieve physical withdrawal symptoms that some experience. The government terms "essential medicines" as those that satisfy the priority healthcare needs of most of the population. The NLEM effectively mentions medicines which are to be available at affordable costs. Many of these are used in various national health programmes, treating emerging and re-emerging infections and so on.

The NLEM 2022 includes 384 medicines spread across 27 categories that include cardiovascular ones, those used in anaesthesia, those for neurological disorders, anti-infective medicines, ear, nose, throat and gastrointestinal medicines, hormones, other endocrine medicines and contraceptives, among others. "Several antibiotics, vaccines, anti-cancer drugs and many other important drugs will become more affordable & reduce patients' out-of-pocket expenditure," Mansukh Madaviya, the Union Health Minister, wrote on Twitter as he launched NLEM 2022.

Amongst the medicines 34 new medicines added are some used to treat TB such as amikacin (used for anti-bacterial infections in joints, urinary tracts and also for multi drug resistant TB) and bedaquiline. India has nearly 13 lakh TB patients.
Other additions were cefuroxime – to treat bacterial infections; dabigatran – used as anticoagulant to treat and prevent blood clots after hip or knee surgeries and also prevent stroke, diabetes medicines like insulin glargine (for Type I and Type II diabetes); ivermectin (an anti parasitic drug), montelukast (ashtma treatment); valganciclovir (an anti-viral used to treat cytomegalovirus infection in those with HIV/AIDS or following organ transplant), among others.

According to Vikas Bajpai, Centre of Community Medicine, JNU, none of these medicines (ones removed from essential medicines list) are required for disease control programmes in the country.

Medicines Removed

As many as 26 medicines were deleted from NLEM 2015.

Apart from bleaching powder, medicines like procarbazine – a chemotherapy medicine used to treat lymphoma; rifabutin – used as an antibiotic in TB treatment; sucralfate – to treat ulcers, stress ulcers; were among the other major medicines removed. Suranjit Chatterjee, Senior Consultant, Internal Medicine, Indraprastha Apollo Hospital-New Delhi, said

"The list of medicines added to the essential list is a welcome move. If the purpose is to get these medicines available and manufacture at a generic level then the Government also needs to ensure that strict quality is maintained in their manufacture." According to Sudarsan Jain, Secretary General, Indian Pharmaceutical Alliance.

The NLEM 2022 looks to strike a balance between patient centricity and public health concerns. "Anti-microbial resistance is a critical issue NLEM has attempted to address," he said. (Source: Business Line)

U.S. Starts Enrollment In Trial Testing Siga's Antiviral For Monkeypox

The National Institutes of Health (NIH) it had started enrolling monkeypox patients in a late-stage study testing Siga Technologies Inc's (SIGA.O) antiviral pill Tpoxx against the disease. The oral and intravenous formulations of Tpoxx are approved by the U.S. Food and Drug Administration for the treatment of smallpox, but does not yet have clearance to treat monkeypox.

It is, however, currently accessible by clinicians for treating monkeypox under a compassionate use request. The NIH aims to enroll more than 500 patients, including both adults and children, who will then be randomized to receive either Tpoxx or placebo pills for 14 days. Investigators will evalutate if participants receiving Tpoxx heal more quickly compared to placebo, as well as provide critical data on the optimal dosing and safety of the drug in children and people who are pregnant.

The United States has recorded more than 21,000 confirmed cases of monkeypox, according to data from the Centers for Disease Control and Prevention. (Source Reuters)