Medical News in Brief

Lecanemab Gains FDA Approval for Early Alzheimer Disease
A treatment that may moderately slow mild cognitive decline and reduce amyloid-β plaques in patients with early Alzheimer disease gained accelerated approval from the US Food and Drug Administration (FDA). Lecanemab-irmb, marketed as Leqembi by Eisai and Biogen, is indicated for patients with mild cognitive impairment or mild dementia due to Alzheimer disease.

In a clinical trial involving 1795 patients, those receiving lecanemab showed slower cognitive decline than those receiving a placebo after 18 months of treatment. In a sub-study of 698 patients, those receiving lecanemab also showed greater reductions in amyloid-β plaques, which was the basis for the FDA’s accelerated approval.

Lecanemab’s label warnings include the possibility of amyloid-related imaging abnormalities, such as edema or effusions, and infusion-related reactions. It is the second monoclonal antibody approved for Alzheimer disease. Continued approval may be subject to verification of clinical effect in a confirmatory trial.

Published Online: January 18, 2023. doi:10.1001/jama.2022.24490

Substance Use, Mental Health Challenges Widespread in 2021
More than 46 million people (16.5%) aged 12 years or older in the US met clinical criteria for substance use disorders in 2021, whereas nearly 1 in 4 adults aged 18 years or older reported a mental illness, according to the 2021 National Survey of Drug Use and Health conducted by the federal government.

Alcohol use disorder was the most common substance use disorder, affecting 29.5 million people; 24 million people were classified with drug use disorders. Most people with a substance use disorder did not think they needed treatment and 94% received none.

Nearly 1 in 3 adults had either a substance use disorder or any mental illness. At 46%, the rate was highest among young adults aged 18 years to 25 years, although they were the least likely to be treated. Trend data were not available due to differences in data collection during previous years.

Gene Edited Tumor Cells Kill and Prevent Cancer in Mice
Live cancer cells genetically altered to both attack cancer tumors and stimulate immunity eliminated established glioblastoma tumors and prevented recurrence in mice, according to a report in Science Translational Medicine. The results suggest that cell-based immunotherapies for treating solid tumors in humans may be possible, according to the authors.

The modified tumor cells actively seek out unmodified tumor cells in the body. There, the engineered cells secrete a programmed death factor that directly kills active tumor cells as well as factors that stimulate T cells to attack the tumor.

In addition, the engineered cells express antigens that teach the immune system to recognize the tumor cells, stimulating long-term antitumor activity. The engineered cells also incorporate a 2-layered safety switch that eliminates them if needed.

The therapy transformed the tumor microenvironment from suppressing immunity to stimulating it, the authors wrote.

Published Online: January 18, 2023. doi:10.1001/jama.2022.24492

NIH Pilots Telehealth Program for COVID-19
A pilot program that allows telehealth consultation and antiviral treatment for COVID-19 without leaving home launches this January in Pennsylvania.

A collaboration among the National Institutes of Health (NIH) and local public health agencies, the Home Test to Treat program is intended to expand access to COVID-19 services in vulnerable communities and potentially reduce community spread. The NIH plans to enroll about 100,000 participants nationwide this year.

Telehealth services—including registration, access to telehealth-enabled test kits, consultations, and the delivery of antiviral treatments—will be provided by eMed
through a central website for eligible patients who test positive for COVID-19. UMass Chan Medical School researchers will assess data on patient attitudes, responses, and clinical outcomes. The data will help refine the program, identify specific local issues affecting service delivery, and support design of similar programs to prepare for future pandemics.

**Published Online:** January 18, 2023.
doi:10.1001/jama.2022.24494

**AAP Recommends Immediate, Intensive Treatment for Child Obesity**

In its first comprehensive guidance in 15 years on childhood overweight and obesity, the American Academy of Pediatrics (AAP) recommends comprehensive assessment and immediate, intensive treatment for children and teens who are at or above the 85th percentile of body mass index (BMI) for their age and sex.

The clinical practice guideline advises considering the child’s health status, family system, community context, and resources to create a child-centered, evidence-based treatment plan. Recommended treatments include motivational interviewing and intensive health behavior and lifestyle treatment. Pharmacotherapy may be considered for patients aged 13 years or older whose BMI is at or above the 95th percentile, and bariatric surgery may be considered for patients aged 13 years or older whose BMI is 120% or more than the 95th percentile.

“There is no evidence that ‘watchful waiting’ or delayed treatment is appropriate for children with obesity,” Sandra Hassink, MD, an author of the AAP guideline, said in a statement.

**Published Online:** January 18, 2023.
doi:10.1001/jama.2022.24495

**Sickle Cell Disease Gene Therapy Trial Paused**

A phase 1 and 2 clinical trial of a new gene editing technique to treat sickle cell anemia was voluntarily paused by its sponsor after a severe, likely treatment-related, adverse event occurred with the first patient treated.

The patient experienced prolonged low blood cell counts requiring ongoing transfusion and growth factor support after receiving nulabeglogene autogedtemcel, or nula-cel, produced by Graphite Bio. The investigational treatment is intended to correct a mutation in the β-globin gene to decrease sickle hemoglobin production and restore adult hemoglobin expression, potentially curing sickle cell disease. It uses a new gene editing technology thought to be more precise than earlier methods.

Although the event did not require pausing the trial, Graphite Bio did so based on evolving data, according to a company statement. The firm is assessing the adverse event, risk factors, and mitigation strategies, including potential modifications to the product manufacturing process.

**Published Online:** January 18, 2023.
doi:10.1001/jama.2022.24496

**Letters to Clinicians May Promote Better-Informed Opioid Prescribing**

Letters reminding clinicians of a mandate to check a state prescription tracking database before prescribing opioids significantly increased clinician participation in the program. The approach may promote better-informed and potentially safer opioid prescribing, according to a study in *Health Affairs.*

The study enrolled 12,000 clinicians, all of whom practiced in Minnesota and prescribed opioids with benzodiazepines or gabapentinoids. Each clinician was assigned to a control group that received no letter or to a group that received 1 of 3 letters: one focusing on a new state requirement to check the database before prescribing opioids; another with information about coprescribing opioids with other drugs; or a third combining the 2 messages.

Among those receiving mandate letters, database use increased by 4.5% over 8 months. The combined letters had a similar effect, but the letter that only provided coprescribing information did not. Although the letters made no detectable difference in prescribing, the authors noted such letters could be a cost-effective way to encourage safer prescribing.

**Published Online:** January 18, 2023.
doi:10.1001/jama.2022.24497

**Patients With Mild COVID-19 at Risk of Some Post–COVID-19 Condition Symptoms**

Patients who were diagnosed with mild COVID-19 were up to 4.6 times more likely than uninfected patients to have some symptoms associated with post–COVID-19 condition (PCC) for 6 to 12 months, according to a study in *The BMJ.*

The study examined electronic health records from 1.9 million patients in a nationwide health care system in Israel who received polymerase chain reaction testing for SARS-CoV-2 over 19 months ending October 1, 2021. It compared outcomes of nearly 300,000 patients who tested positive with matched patients who tested negative.

The excess risks for infected patients were highest for altered senses of smell and taste, cognitive impairment, shortness of breath, weakness, and palpitations. Lower but significant excess risk was found for dizziness. The risk differences were higher 30 to 180 days after infection than 180 to 360 days after infection, and symptoms subsided among most patients with PCC within a year. The study’s findings were similar regardless of virus variants, age, and sex.

“This nationwide study suggests that patients with mild COVID-19 are at risk for a small number of health outcomes, most of which are resolved within a year from diagnosis,” the authors wrote. — Howard D. Larkin

**Published Online:** January 18, 2023.
doi:10.1001/jama.2022.24498

**Note:** Source references are available through embedded hyperlinks in the article text online.