

COVID-19

Sputnik V 91pct effective

GSK, CureVac shots to target new variants

LONDON, Feb 3, (AP) — Drugmaker GlaxoSmithKline said Wednesday it will work with a German biopharmaceutical company to develop new vaccines targeting emerging variants of COVID-19 amid concerns that some mutations are making the virus harder to combat.

GSK plans to invest 150 million euros (\$181 million) to support the research of the Tubingen, Germany-based CureVac, which is developing vaccines that use messenger RNA to attack the disease. GSK also said it will help make up to 100 million doses of the company's existing COVID-19 vaccine candidate this year.

"The increase in emerging variants with the potential to reduce the efficacy of first generation COVID-19 vaccines requires acceleration of efforts to develop vaccines against new variants to keep one step ahead of the pandemic," the companies said in a statement.

The announcement comes as public health officials around the world raise concerns about new virus variants that are more contagious or resistant to existing vaccines. While viruses mutate constantly, most of the changes cause little concern. But scientists are closely tracking these mutations to make sure they quickly identify variants of concern.

Authorities in England this week are conducting house-to-house coronavirus testing in targeted communities in a bid to snuff out a new variant before it spreads widely and undermines a nationwide vaccination program.

British authorities want to test about 80,000 people in eight areas where the variant, first identified in South Africa, is believed to be spreading after a handful of cases were found in people who had no contact with the country or anyone who traveled there.

Public health officials are concerned about the variant first identified in South Africa because it contains a mutation of the virus' characteristic spike protein targeted by existing vaccines. The mutation may mean the vaccines offer less protection against the variant.

"We believe that next generation vaccines will be crucial in the continued fight against COVID-19," GSK Chief Executive **Emma Walmsley** said in the statement. "This new collaboration builds on our existing relationship with CureVac and means that together, we will combine our scientific expertise in mRNA and vaccine development to advance and accelerate the development of new COVID-19 vaccine candidates."

Effective

Meanwhile, Russian scientists say the country's Sputnik V vaccine appears safe and effective against COVID-19, according to early results of an advanced study published Tuesday in a British medical journal.

The news is a boost for the vaccine, which governments around the world increasingly are purchasing in the race to stop the devastation caused by the coronavirus pandemic.

Researchers said that based on a fall trial involving about 20,000 people in Russia, the vaccine is about 91% effective and appears to prevent inoculated individuals from becoming severely ill with COVID-19. But it is unclear if Sputnik V can stop transmission. The study was published online Tuesday in *The Lancet*.

Scientists not linked to the research acknowledged that the speed at which the vaccine was made and rolled out had brought criticism of the Russian effort's "unseemly haste, corner cutting and an absence of transparency."

"But the outcome reported here is clear," British scientists **Ian Jones** and **Polly Roy** wrote in an accompanying commentary. "Another vaccine can now join the fight to reduce the incidence of COVID-19."

The vaccine was approved by the Russian government with much fanfare on Aug. 11. President **Vladimir Putin** personally broke the news on national television and said one of his daughters had already received it. At the time, the vaccine had only been tested in several dozen people, and the move elicited criticism from experts both at home and abroad.

Kirill Dmitriev, CEO of the Russian Direct Investment Fund that bankrolled the development of the shot, called the study in *The Lancet* "check and mate to the critics of the Russian vaccine."

"Russia was right from the very beginning," he said. Outside Russia, Sputnik V has received authorization in over a dozen countries, according to the fund - including the former Soviet republics of Belarus, Armenia and Turkmenistan; Latin American nations including Argentina, Bolivia and Venezuela; African nations such as Algeria as well as Serbia, Iran, Palestine and UAE.

Batches of the vaccine have already been supplied to six countries. In all, more than 50 countries have submitted applications for 2.4 billion doses, an RDIF spokesman told *The Associated Press*.

The latest study is based on research involving about 20,000 people over 18 at 25 hospitals in Moscow between September and November, of whom three-quarters got two doses of the Russian vaccine 21 days apart and the remainder got placebo shots.

Serious side effects were reported rare in both groups and four deaths were reported, although none were considered to be the result of the vaccine.

The study included more than 2,100 people over age 60 and the vaccine appeared to be about 92% effective in them. The research is ongoing, but Russia's Health Ministry said in December it was cutting the size of the study from the planned 40,000 subjects to about 31,000 already enrolled volunteers, with developers citing ethical concerns about using placebo shots.

Modified

The Russian vaccine uses a modified version of the common cold-causing adenovirus to carry genes for the spike protein in the coronavirus as a way to prime the body to react if COVID-19 comes along. That's a similar technology to the vaccine developed by AstraZeneca and Oxford University. But unlike AstraZeneca's two-dose vaccine, the Russians used a slightly different adenovirus for the second booster shot.

"This aims to drive higher immune responses to the target 'spike' by using two slightly different jabs," said **Alexander Edwards**, an associate professor in biomedical technology at Britain's University of Reading, who was not connected to the Russian research. He said if you have two identical shots, it's possible the immune system doesn't get as big a boost from the second injection.

Roy, a professor of virology at the London School of Hygiene and Tropical Medicine, said there should no longer be any doubts about the Russian vaccine. She said the high level of antibodies produced by Sputnik V suggest that it could also protect against some of the new COVID-19 variants that have been detected recently, but more studies are needed to verify that.

"Initially, I had some concerns about what they were saying and thought they were getting too much publicity, but the data are now very strong," **Roy** said.

Sputnik V was rolled out in a large-scale vaccination campaign in Russia in December, with doctors and teachers the first in line. Last month, Putin ordered mass immunizations to start.

In early January, the Russian Direct Investment Fund said over 1 million Russians had already been vaccinated. Some Russian media questioned the number, suggesting that the roll-out had been much slower, with many Russian regions reporting small numbers of vaccinations.

The production of Sputnik V will span several countries, including India, South Korea, Brazil, China. "We will also manufacture vaccines in Kazakhstan, develop (production) in Belarus, in Turkey, and possibly even in Iran," **Dmitriev** said, adding that the production in China will start at the end of the month.

"In less than two brief years under **David Bernhardt's** leadership, the depart-



Joe DiMeo and his plastic surgeon Dr Eduardo Rodriguez pose for a portrait, Jan 25, 2021, in New York. In the months since his face and double hand transplant, DiMeo has not shown any signs of rejecting his new face or hands, said Rodriguez, the director of NYU Langone's Face Transplant Program. (AP)

Health

'New chance at life'

Man gets face, hands in rare surgery

NEW YORK, Feb 3, (AP) — Almost six months after a rare face and hands transplant, **Joe DiMeo** is relearning how to smile, blink, pinch and squeeze.

The 22-year-old New Jersey resident had the operation last August, two years after being badly burned in a car crash.

"I knew it would be baby steps all the way," DiMeo told *The Associated Press* recently. "You've got to have a lot of motivation, a lot of patience. And you've got to stay strong through everything."

Experts say it appears the surgery at NYU Langone Health was a success, but warn it'll take some time to say for sure.

Worldwide, surgeons have completed at least 18 face transplants and 35 hand transplants, according to the United Network for Organ Sharing, or UNOS, which oversees the US transplant system.

But simultaneous face and double hand transplants are extremely rare and have only been tried twice before. The first attempt was in 2009 on a patient in Paris who died about a month later from complications. Two years later, Boston doctors tried it again on a woman who was mauled by a chimpanzee, but ultimately had to remove the transplanted hands days later.

"The fact they could pull it off is phenomenal," said **Dr. Bohdan Pomahac**, a surgeon at Boston's Brigham and Women's Hospital who led the second such attempt. "I know firsthand it's incredibly complicated. It's a tremendous success."

DiMeo will be on lifelong medications to avoid rejecting the transplants, as well as continued rehabilitation to gain sensation and function in his new face and hands.

In 2018, DiMeo fell asleep at the wheel, he said, after working a night shift as a product tester for a drug company. The car hit a curb and utility pole, flipped over, and burst into flames. Another driver who saw the accident pulled over to rescue DiMeo.

Afterward, he spent months in a medically induced coma and underwent 20 reconstructive surgeries and multiple skin grafts to treat his extensive third-degree burns.

Once it became clear conventional surgeries could not help him regain full

vision or use of his hands, DiMeo's medical team began preparing for the risky transplant in early 2019.

"Within the world of transplantation, they're probably the most unusual," said **Dr. David Klassen**, UNOS chief medical officer.

Almost immediately, the NYU team encountered challenges including finding a donor.

Doctors estimated he only had a 6% chance of finding a match compatible with his immune system. They also wanted to find someone with the same gender, skin tone and hand dominance.

Then during the search for a donor, the pandemic hit and organ donations plummeted. During New York City's surge, members of the transplant unit were reassigned to work in COVID-19 wards.

In early August, the team finally identified a donor in Delaware and completed the 23-hour procedure a few days later.

They amputated both of DiMeo's hands, replacing them mid-forearm and connecting nerves, blood vessels and 21 tendons with hair-thin sutures. They also transplanted a full face, including the forehead, eyebrows, nose, eyelids, lips, both ears and underlying facial bones.

Possibility

"The possibility of us being successful based on the track record looked slim," said **Dr. Eduardo Rodriguez**, who led the medical team of more than 140 people. "It's not that someone has done this many times before and we have a kind of a schedule, a recipe to follow."

So far, DiMeo has not shown any signs of rejecting his new face or hands, said Rodriguez.

Since leaving the hospital in November, DiMeo has been in intensive rehabilitation, devoting hours daily to physical, occupational and speech therapy.

"Rehab was pretty intense," DiMeo said, and involves a lot of "retraining yourself to do stuff on your own again."

During a recent session, he practiced raising his eyebrows, opening and closing his eyes, puckering his mouth, giving a thumbs up and whistling. DiMeo can feel his new forehead and hands get cold, and often reaches up to push his long hair off of his face.

DiMeo, who lives with his par-

ents, can now dress and feed himself. He shoots pool and plays with his dog **Buster**. Once an avid gym-goer, DiMeo is also working out again - benching 50 pounds and practicing his golf swing.

"You got a new chance at life. You really can't give up," he said.

As with any transplant, the danger of rejection is highest early on, but lasts indefinitely. The medications he takes also leave him vulnerable, for the rest of his life, to infections.

"You're never free from that risk," **Klassen** said. "Transplantation for any patient is a process that plays out over a long period of time."

Still, Rodriguez said he's amazed to see that DiMeo has been able to master skills like zipping up his jacket and putting on his shoes.

"It's very gratifying to all of us," Rodriguez said. "There's a tremendous sense of pride."

Also:

NEW YORK: US regulators have approved the first long-acting drug combo for HIV, monthly shots that can replace the daily pills now used to control infection with the AIDS virus.

The approval of the two-shot combo called **Cabenuva** is expected to make it easier for people to stay on track with their HIV medicines and to do so with more privacy. It's a huge change from not long ago, when patients had to take multiple pills several times a day, carefully timed around meals.

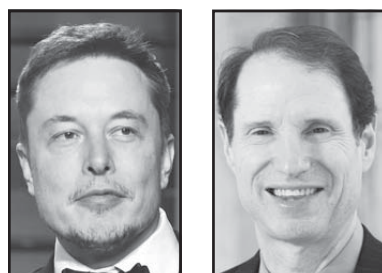
"That will enhance quality of life" to need treatment just once a month, said **Dr. Steven Deeks**, an HIV specialist at the University of California, San Francisco, who has no ties to the drug's makers. "People don't want those daily reminders that they're HIV infected."

Cabenuva combines **rilpivirine**, sold as **Edurant** by **Johnson & Johnson's** Janssen unit, and a new drug — **cabotegravir**, from **ViiV Healthcare**. They're packaged together and given as separate shots once a month. Dosing every two months also is being tested.

The US Food and Drug Administration approved Cabenuva for use in adults who have had their disease well controlled by conventional HIV medicines and who have not shown signs of viral resistance to the two drugs in Cabenuva.



SpaceX's bullet-shaped Starship prototype explodes after crashing while attempting to land following a successful test launch, Feb 2, in Boca Chica, Texas. (AP)



Musk

Wyden

Discovery

Starship explodes on landing: SpaceX's second full test flight of its futuristic, bullet-shaped Starship ended in another fiery crash landing Tuesday.

Elon Musk's company launched its latest Starship prototype from the southeastern tip of Texas, two months after the previous test ended in an equally explosive belly flop.

The full-scale stainless steel rocket reached its intended altitude of 6.2 miles (10 kilometers), slightly lower than the last one. Everything seemed to be going well as the 160-foot (50-meter) Starship flipped on its side and began its descent. But it did not manage to straighten itself back up in time for a landing and slammed into the ground.

"We've just got to work on that landing a little bit," said SpaceX launch commentator **John Insprucker**. "Reminder - this is a test flight."

The next Starship stood nearby at the launch site in Boca Chica, Texas, during Tuesday's test, which lasted 6 1/2 minutes.

Musk is developing Starship to carry people to Mars, perhaps in as little as several years. It's the upper stage of his intended moon- and Mars-ships, meant to launch atop a mega rocket called **Super Heavy** that is still being developed.

SpaceX tried to launch Starship last week, but failed to get the necessary approval from the Federal Aviation Administration, prompting a Twitter outburst from Musk.

SpaceX did not comply with safety regulations for the Dec 9 flight, an FAA spokesperson said Tuesday, and needed to take corrective action before proceeding with launch operations. Tuesday's flight met all safety criteria, according to the FAA. (AP)



'Probe owl protections removal':

Eight Democratic lawmakers called Tuesday for an investigation into "potential scientific meddling" by the Trump administration in its rule to remove critical habitat protections for the imperiled northern spotted owl in the Pacific Northwest.

The group of federal lawmakers, led by **Sen. Ron Wyden** of Oregon, says former Interior Secretary **David Bernhardt** "appeared to unilaterally act" on his way out of office to remove millions of acres of protected habitat designated for the owl.

"In less than two brief years under **David Bernhardt's** leadership, the depart-

ment has been mired in one ethical scandal after another," the lawmakers said in a letter to Interior Department Inspector General **Mark Greenblatt** seeking a re-

view. "Bernhardt and his loyalists have demonstrated a willingness to insert themselves into the scientific process in order



A doctor receives the Sinopharm coronavirus vaccine from a paramedic at a vaccination center, in Peshawar, Pakistan, Feb 3. Pakistani authorities have started vaccinating frontline health workers against the coronavirus amid a steady decline in confirmed cases and fatalities. Wednesday's start of the vaccine campaign comes days after Pakistan received half a million doses of the Sinopharm vaccine donated by China. (AP)

to achieve preferred policy outcomes, withhold information from the public, and even mislead Congress," the letter said.

In mid-January, the US Fish and Wildlife Service under then-President **Donald Trump** announced it would remove 3.4 million acres (1.4 million hectares) in Oregon, Washington state and Northern California from federal protections.

The lawmakers called that decision "as bewildering as it is damaging." Fish and Wildlife, which is overseen by the Interior Department, didn't immediately respond to an email seeking comment on the letter.

Environmentalists accused Fish and Wildlife of taking a parting shot at protections designed to help restore the owl in favor of the timber industry. The tiny owl is listed as threatened under the Endangered Species Act and was rejected for an upgrade to endangered status last year by the agency despite losing nearly 4% of its population annually.

Timber groups applauded the decision. Loss of the ability to log in areas protected for the spotted owl has devastated rural communities, experts say.

"While the Biden administration has taken actions to mitigate the effects of this rule, we ask that you quickly review this decision and to determine whether USFWS contradicted or ignored scientific recommendations made by career staff," lawmakers wrote to the inspector general. (AP)