

COV-19 WE C U SWISSY

As more drastic measures are put in place around the world slow down the spread, scientists are attempting to find a treatment.

About 35 companies and academic institutions are racing to create a vaccine, and at least four already have candidates they have been testing in animals.

The first of these – produced by Boston-based biotech firm Moderna – will enter human trials imminently. https://www.statnews.com/2016/09/13/moderna-therapeutics-biotech-mrna/

Ego, ambition, and turmoil: Inside one of biotech's most secretive startups

By DAMIAN GARDE @damiangarde / SEPTEMBER 13, 2016



Stéphane Bancel spent most of his career in sales and operations before becoming CEO of biotech startup Moderna Therapeutics.

ARAM BOGHOSIAN FOR STAT

AMBRIDGE, Mass. — At first glance, Moderna Therapeutics looks like the most enviable biotech startup in the world. It has smashed fundraising records and teamed up with pharmaceutical giants as it pursues a radical plan to revolutionize medicine by transforming human cells into drug factories.

But the reality is more complicated.

A STAT investigation found that the company's caustic work environment has for years driven away top talent and that behind its obsession with secrecy, there are signs Moderna has run into roadblocks with its most ambitious projects.

https://www.businessinsider.com/biotech-moderna-prices-initial-public-offering-2018-12?op=1&r=US&IR=T https://archive.is/wip/UDuXr

Moderna Therapeutics is expected to start trading Friday, after pricing Thursday at \$23 a share. The company is selling roughly 27 million shares, valuing the company at about \$7.5 billion. In total, the company is raising \$620 million in the offering, making it the biggest initial public offering in biotech history.

Moderna is developing medical treatments based on messenger RNA, and the company is still in the early days of human trials for its treatments, which include cancer treatments as well as a vaccine for cytomegalovirus, or CMV.

In early November, Moderna filed with the US Securities and Exchange Commission to go public, and it will trade under the ticker MRNA.

https://www.investors.com/news/technology/moderna-ipo-biotech/ https://archive.is/wip/CiNCW

https://www.linkedin.com/in/juan-andres-65129b12/ https://archive.is/akBwb



Juan Andres

Chief Technical Operations and Quality Officer at Moderna Therapeutics



Novartis

7 yrs 5 mos

Global Head Technical Operations (Manufacturing and Supply Chain)

Jan 2013 – Jun 2017 · 4 yrs 6 mos

Basel Area, Switzerland

Responsibilities include all aspects of manufacturing and supply chain for the Pharma Division (25000+ people):

- All manufacturing sites
- -Third party management
- Support functions

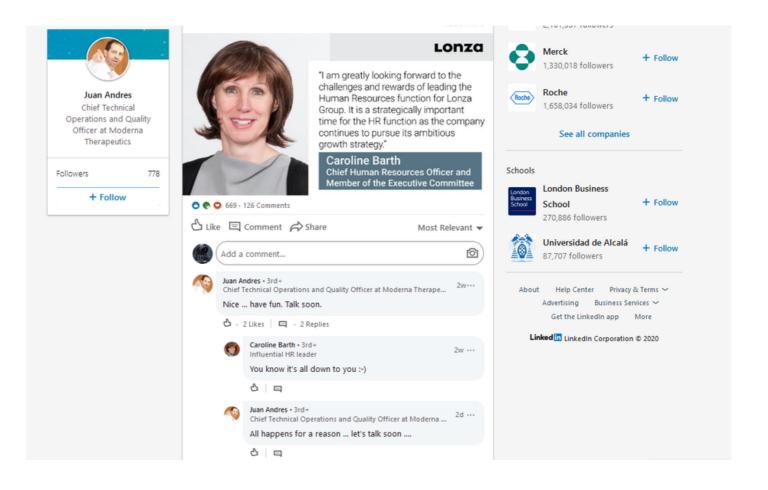
Technologies:

- Small molecules Drug Substance
- Drug Product
- Biologics including technical development.

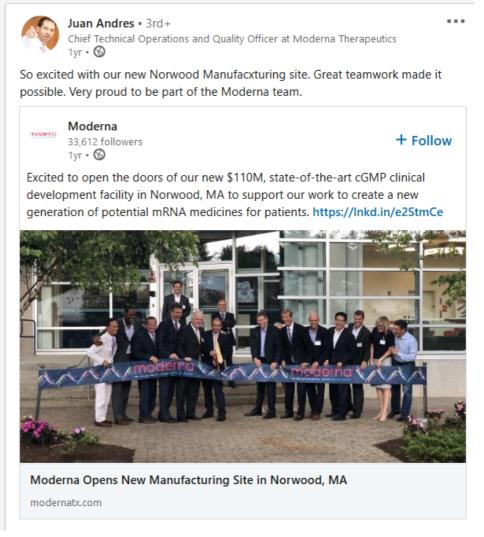
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Group Novartis Quality Head

Feb 2010 - Jan 2013 · 3 yrs







Controversial Startup Moderna Just Filed for the Biggest Biotech IPO Ever

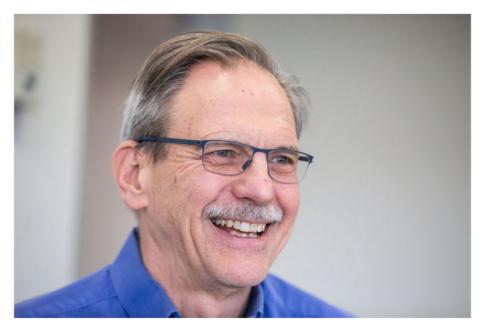
https://www.bloomberg.com/news/articles/2018-12-12/a-harvard-professor-made-400-million-in-moderna-s-biotech-ipo

https://archive.is/Wi4l8

Moderna's Biotech IPO

Timothy Springer invested \$5 million in the startup's early days. His windfall is one in a series of savvy investments.

By Rebecca Spalding
December 12, 2018, 4:50 PM UTC



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Timothy Springer smiles during an interview in Boston, on Dec. 6. Photographer: Scott Eisen/Bloomberg

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On the Sunday before <u>Moderna Inc.</u> launched one of the biggest initial public offerings in biotechnology history, one of its earliest investors was giving a lecture about rocks.

https://aws.amazon.com/solutions/case-studies/moderna-therapeutics/ https://archive.is/yCxQu

https://www.cnbc.com/2018/12/10/cramer-dont-judge-biotech-moderna-on-its-stocks-post-ipo-drop.html https://archive.is/0USWQ

Don't judge early-stage biotech Moderna on its stock's post-IPO drop: Cramer

PUBLISHED MON. DEC 10 2018

INVESTORS SHOULDN'T DRAW CONCLUSIONS ABOUT BIOTECHNOLOGY COMPANY <u>MODERNA</u> SOLELY ON THE STOCK'S WORRISOME ACTION AFTER ITS INITIAL PUBLIC OFFERING, CNBC'S <u>JIM</u> CRAMER SAID MONDAY.

MODERNA IS IN THE EARLY STAGES OF CREATING MEDICINE USING MESSENGER RNA, WHICH TRANSPORTS GENETIC INFORMATION FROM DNA TO A BODY'S CELLS SO THEY CAN PRODUCE THE PROPER PROTEINS TO EXPRESS THOSE GENES. MODERNA'S IDEA IS TO ENGINEER MESSENGER RNA IN PATIENTS WITH GENETIC DISEASES TO TELL THEIR CELLS TO PRODUCE DIFFERENT, POTENTIALLY LIFE-CHANGING PROTEINS.

IN A STROKE OF UNFORTUNATE TIMING, THE COMPANY <u>WENT PUBLIC</u> ON FRIDAY DURING A <u>BRUTAL DAY</u> FOR THE MAJOR AVERAGES. MODERNA'S STOCK FELL NEARLY 20 PERCENT AS A RESULT OF THE WIDESPREAD WEAKNESS.

BUT IF INVESTORS VIEW THE STOCK "PURELY AS SPECULATION, MODERNA HAS A FEW MAJOR THINGS GOING FOR IT," CRAMER SAID. "IT'S RECESSION-PROOF AT A TIME WHEN MANY INVESTORS ARE NOW WORRIED ABOUT A SLOWDOWN. IT'S GOT AN EXCITING CONCEPT; YOU CAN ARGUE THAT MESSENGER-RNA-BASED MEDICINE COULD REVOLUTIONIZE HEALTH CARE. AND THE STOCK HAS PULLED BACK DRAMATICALLY IN THE SHORT TIME SINCE IT'S BEEN PUBLIC."

SO WHILE IT MIGHT NOT BE THE RIGHT PLAY FOR PEOPLE INVESTING FOR RETIREMENT, INVESTORS WITH SOME CASH TO SPARE MIGHT FIND MODERNA TO BE AN INTERESTING BET IF THEY BELIEVE IN THE STORY, THE "MAD MONEY" HOST SAID. WHAT SETS MODERNA APART? WHILE OTHER COMPANIES INCLUDING IONIS PHARMACEUTICALS ARE WORKING ON SIMILAR TREATMENTS, MODERNA'S FOCUS ON DELIVERY AND MANUFACTURING TECHNOLOGIES PUTS IT IN A CLASS ABOVE ITS RIVALS, CRAMER ARGUED.

IN SHORT, MODERNA HAS DEVELOPED TECHNOLOGY THAT MAKES IT EASIER FOR ITS MESSENGER RNA TO REACH THE CORRECT PLACE IN A PATIENT'S BODY WITHOUT RUNNING INTO THE IMMUNE SYSTEM, WHICH CAN DEGRADE THE NEW RNA. MODERNA IS ALSO WORKING ON MANUFACTURING TECH THAT WILL ALLOW IT TO MASS-PRODUCE ITS TREATMENTS ONCE IT GETS FEDERAL APPROVAL, THOUGH THAT IS STILL YEARS AWAY.

THE COMPANY HAS STRUCK HIGH-PROFILE PARTNERSHIPS <u>WITH BIOTECH GIANTS MERCK</u> AND <u>ASTRAZENECA</u>, WHICH IS ALSO MODERNA'S FOURTH-LARGEST SHAREHOLDER. THOSE DEALS, WHICH MANIFEST THEMSELVES IN THE FORM OF "MILESTONE PAYMENTS" AS MODERNA'S DRUGS REACH VARIOUS THRESHOLDS OF SUCCESS, SPEAK TO THE LEGITIMACY OF THE COMPANY'S MISSION, CRAMER SAID.

"THE INDUSTRY CLEARLY BELIEVES THE TECHNOLOGY IS WORTH BETTING ON," HE SAID. "THESE COMPANIES UNDERSTAND THE POTENTIAL OF MESSENGER-RNA-BASED MEDICINE."

CRAMER ACKNOWLEDGED WHY INVESTORS MIGHT BE WARY OF BUYING SHARES IN MODERNA: THE COMPANY HAS NO EARNINGS OR SALES YET AND SPENDS FORTUNES ON ITS 21 DEVELOPMENT PROGRAMS, 10 OF WHICH ARE IN THE EARLY STAGES OF CLINICAL TRIALS.

BUT THE CORPORATE INVESTMENTS HAVE ALLOWED THE COMPANY TO MAINTAIN A CLEAN BALANCE SHEET, WHICH NOW BOASTS \$1.8 BILLION IN CASH TO SPARE THANKS TO THE IPO, HE SAID.

"EARLY-STAGE BIOTECHS LIKE THIS ONE DON'T TRADE ON THE NUMBERS, THEY TRADE ON BELIEF," THE "MAD MONEY" HOST EXPLAINED. "IN ABOUT A MONTH, MODERNA'S QUIET PERIOD ENDS, AND THE ANALYSTS WILL START ROLLING OUT THEIR COVERAGE. IF THEY TELL A BULLISH STORY, AND I THINK THEY PROBABLY WILL, THIS STOCK CAN RALLY."

SO EVEN THOUGH MODERNA'S STOCK HAS LOST NEARLY \$1.5
BILLION IN VALUE SINCE ITS IPO, INVESTORS WOULD BE BETTER
OFF JUDGING THE BIOTECH ON WHETHER THEY THINK ITS
TREATMENTS CAN SUCCEED THAN ON THE STOCK'S
CIRCUMSTANTIAL ACTION. CRAMER SAID.

"THESE SPECULATIVE BIOTECHS ARE A LOT LIKE [THE YANKEES'] GIANCARLO STANTON — WHEN HE STEPS UP TO THE PLATE, HE'S LIKELY TO EITHER STRIKE OUT OR HIT A HOME RUN," HE JOKED. "IF YOU'RE TRYING TO SAVE FOR RETIREMENT, MODERNA IS NOT THE STOCK FOR YOU. HOWEVER, IF YOU WANT TO TAKE A CHANCE WITH YOUR SPECULATIVE 'MAD MONEY' PORTFOLIO, YOU HAVE GOT MY BLESSING TO BUY THIS ONE. I KNOW IT CAN PROBABLY STILL GO LOWER, BUT YOU'RE GETTING A PRETTY DARN GOOD ENTRY POINT."

WATCH: CRAMER INTRODUCES MODERNA, NEWEST BIOTECH SPEC

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29 Jan 2013

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https://webcache.googleusercontent.com/search?q=cache:https://www.modernatx.com/pipelinehttps://archive.is/jahR3

Moderna's mRNA-1273 Novel coronavirus (SARS-

CoV-2) vaccine CEPI

funded

Moderna Announces Funding Award from CEPI to Accelerate Development of Messenger RNA (mRNA) Vaccine Against Novel Coronavirus

January 23, 2020 at 9:15 AM EST

PDF Version

Collaboration includes the National Institutes of Health (NIH) and leverages flexibility of Moderna's mRNA vaccine technology

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jan. 23, 2020-- Moderna, Inc., (Nasdaq: MRNA) a clinical stage biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines to create a new generation of transformative medicines for patients, and the Coalition for Epidemic Preparedness Innovations (CEPI), today announced a new collaboration to develop an mRNA vaccine against the novel coronavirus (2019-nCoV).

https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-funding-award-cepi-accelerate-development
https://archive.is/FpsDe

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Under the terms of the agreement, Moderna will manufacture an mRNA vaccine against 2019-nCoV, which will be funded by CEPI. The Vaccine Research Center (VRC) of the National Institute of Allergy and Infectious Diseases (NIAID), part of NIH, collaborated with Moderna to design the vaccine. NIAID will conduct IND-enabling studies and a Phase 1 clinical study in the U.S.

Over the past four years Moderna has had six positive Phase 1 clinical readouts in its prophylactic vaccines modality and moved two additional programs into development. Moderna's technology platform, fully integrated manufacturing site and development experience, combined with a multi-year relationship with the NIH, including exploring ways to respond to public health threats, allows for the rapid identification and advancement of a vaccine candidate against 2019-nCoV.

"Moderna's commitment to global public health is aligned with CEPI's vision of creating a world in which epidemics are no longer a threat to humanity," said Richard Hatchett, M.D., CEO of CEPI. "We are pleased with the pace of our combined response to the emerging threat of the novel coronavirus. Through our partnership with Moderna and the NIH, we hope to speed the development of a vaccine against the coronavirus and help to alleviate the burden of disease."

"We believe our mRNA vaccine technology offers potential advantages in the speed of development and production scalability, which positions Moderna to potentially develop a vaccine against coronavirus, 2019-nCoV," said Stéphane Bancel, CEO of Moderna. "Advances in global public or the control of the contr

The Coalition for Epidemic Preparedness Innovations (CEPI) launched today at the World Economic Forum in Davos, Switzerland, with \$460 million in funding

http://www.cidrap.umn.edu/news-perspective/2017/01/new-460-million-effort-takes-aim-mers-lassa-nipah https://archive.is/AtJ66 https://cepi.net/

New \$460 million effort takes aim at MERS, Lassa, Nipah

Filed Under: Lassa; Nipah; MERS-CoV; Public Health Stephanie Soucheray | News Reporter | CIDRAP News | Jan 19, 2017

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The Coalition for Epidemic Preparedness Innovations (CEPI) launched today at the World Economic Forum in Davos, Switzerland, with \$460 million in funding and an initial focus on developing vaccines against MERS, Lassa, and Nipah virus.

CEPI, a strategic vaccine development partnership, was created in the wake of the 2013-2016 Ebola outbreak as a way to rapidly develop vaccines for emerging infectious diseases.



"What CEPI is doing is providing a proof-of-concept approach to making world better prepared for new infectious

agents," said Michael Osterholm, PhD, MPH, director of the Center for Infectious Disease Research and Policy at the University of Minnesota, publisher of CIDRAP News. Osterholm served on the planning committees that helped CEPI develop its initial vaccine targets. "I very much applaud this activity and how it reconsiders how we license and deploy these vaccines."

Billing itself as the world's insurance policy against new infectious diseases, CEPI will be based in Oslo, with offices in the United Kingdom, India, and the United States. The governments of Germany, Japan and Norway, plus the Bill & Melinda Gates Foundation and the Wellcome Trust have funded CEPI with an initial \$460 million, and the organization plans to raise \$1 billion within 5 years.

Two vaccine candidates per target

According to a press release from the Wellcome Trust, CEPI will shorten the time it takes to develop new vaccines by, "capitalizing on exciting developments in adaptable vaccine technology and investing in facilities that could respond quickly to previously unknown pathogens."

Coalition for Epidemic Preparedness Innovations



The Coalition for Epidemic Preparedness Innovations is a foundation that takes donations from public, private, philanthropic, and civil society organisations, to finance independent research projects to develop vaccines against emerging infectious disease. CEPI is focused on the World Health Organisation's "blueprint priority diseases", which includes: the Middle East respiratory syndrome-related coronavirus, the Severe acute respiratory syndrome coronavirus 2, the Nipah virus, the Lassa fever virus, and the Rift Valley fever virus, as well as the Chikungunya virus and the hypothetical, unknown pathogen "Disease X". CEPI investment also requires "equitable access" to the vaccines during outbreaks. CEPI was conceived in 2015 and formally launched in 2017 at the World Economic Forum in Davos, Switzerland. Wikipedia

Abbreviation: CEPI

Motto: New vaccines for a safer world

Founders: The Wellcome Trust, Bill and Melinda Gates

Foundation.

Founded at: Davos, Switzerland.

Purpose: Fund vaccine development

Headquarters: Oslo, Norway

Locations: London, UK, Washington D.C, U.S.

Chief executive: Richard J. Hatchett

Key people: Jane Halton (Chair)

virusncov.com COVID-19 Coronavirus - Update

https://virusncov.com/

Coronavirus Cases:

935,581

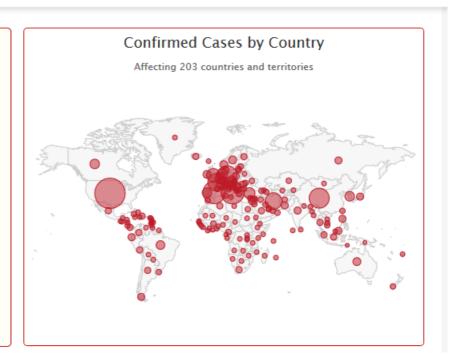
of which 35,478 in severe condition

Deaths: Recovered:

47,223194,276

The coronavirus COVID-19 is affecting 203 countries and territories

Source: WHO update.



http://www.cidrap.umn.edu/infectious-disease-topics/covid-19 https://archive.is/jTSgx

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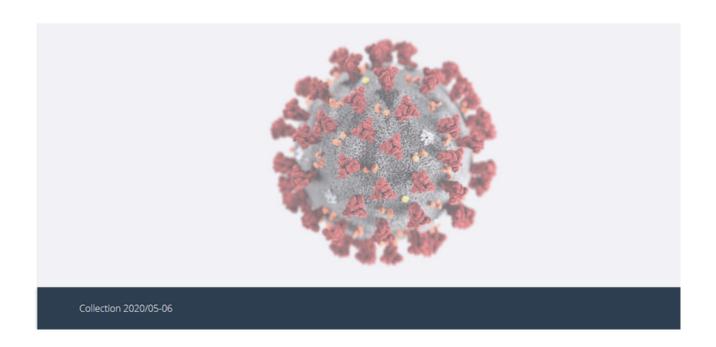
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VIEWPOINT

2019-Novel Coronavirus (2019-nCoV): estimating the case fatality rate – a word of caution

DOI: https://doi.org/10.4414/smw.2020.20203

Publication Date: 07.02.2020 Swiss Med Wkly. 2020;150:w20203



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| Estimating and predicting the extent and lethality of the 2019-Novel Coronavirus (20 nCoV) outbreak, originating in Wuhan/China is obviously challenging, reflected by ma controversial statements and reports. Unsurpassed to date, an ever-increasing flow information, immediately available and accessible online, has allowed the description | | cted by many asing flow of | COV | ics and chameleons o ID-19 ted article) | f | | | | |
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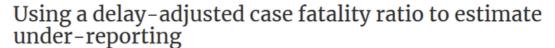
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About

Status: in-progress | First online: 22-03-2020 | Last update: 01-04-2020

Authors: Timothy W Russell*, Joel Hellewell¹, Sam Abbott¹, Christopher I Jarvis, Kevin van Zandvoort, CMMID nCov working group, Stefan Flasche, Rosalind Eggo, W John Edmunds & Adam J Kucharski.

* corresponding author 1 contributed equally

This study has not yet been peer reviewed.

Aim

To estimate the percentage of symptomatic COVID-19 cases reported in different countries using case fatality ratio estimates based on data from the ECDC, correcting for delays between confirmation-and-death.

Methods Summary

- In real-time, dividing deaths-to-date by cases-to-date leads to a biased estimate of the case fatality ratio (CFR), because this calculation does not account for delays from confirmation of a case to death, and under-reporting of cases.
- . Using the distribution of the delay from hospitalisation-to-death for cases that are fatal, we can estimate how many cases so far are expected to have known outcomes (i.e. death or recovery), and hence adjust the naive estimates of CFR to account for these delays.

+++

Trump has claimed hydroxychloroquine showed "tremendous promise" in regards to treating the COVID-19 strain of coronavirus.

saying: "It is known as a malaria drug, and it's been around for a long time and it's very powerful. "But the nice part is, it's been around for a long time, so we know that if things don't go as planned, it's not going to kill anybody."

hydroxychloroquine

Chloroquine is a potent inhibitor of SARS coronavirus infection and spread

Martin J Vincent, Eric Bergeron, Suzanne Benjannet, Bobbie R Erickson, Pierre E Rollin, Thomas G Ksiazek, Nabil G Seidah & Stuart T Nichol □

Virology Journal 2, Article number: 69 (2005) | Cite this article
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Abstract

Background

Severe acute respiratory syndrome (SARS) is caused by a newly discovered coronavirus (SARS-CoV). No effective prophylactic or post-exposure therapy is currently available.

Results

We report, however, that chloroquine has strong antiviral effects on SARS-CoV infection of primate cells. These inhibitory effects are observed when the cells are treated with the drug either before or after exposure to the virus, suggesting both prophylactic and therapeutic advantage. In addition to the well-known functions of chloroquine such as elevations of endosomal pH, the drug appears to interfere with terminal glycosylation of the cellular receptor, angiotensin-converting enzyme 2. This may negatively influence the virus-receptor binding and abrogate the infection, with further ramifications by the elevation of vesicular pH, resulting in the inhibition of infection and spread of SARS CoV at clinically admissible concentrations.

Research | Open Access | Published: 22 August 2005

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About this article

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The first of these – produced by Boston-based biotech firm Moderna – will enter human trials imminently.

In the USA, President Donald Trump has claimed hydroxychloroquine showed "tremendous promise" in regards to treating the COVID-19 strain of coronavirus.

Mr Trump talked about the drug at a White House press conference on Thursday, saying: "It is known as a malaria drug, and it's been around for a long time and it's very powerful.

"But the nice part is, it's been around for a long time, so we know that if things don't go as planned, it's not going to kill anybody."

SEPT 2016 biotech's most secretive startups

statnews.com/2016/09/13/mod...

Dec 2018 Record Biotech IPO

Moderna Therapeutics Sets Record for Biggest Biotech IPO

Published: Dec 07, 2018 By Mark Terry

according to a July corporate update.

The long-awaited and massively hyped initial public offering (IPO) of <u>Moderna Therapeutics</u> <u>hit</u> the market yesterday. The company sold approximately 26.3 million shares priced at \$23 a share. This exceeded the revised goal of \$600 million by about \$4.3 million. Shares are trading on the Nasdaq under the "MRNA" ticker symbol. The raise values the company at about \$7.5 billion.

raised \$324 million at a \$2.2 billion market cap. Other top biotech IPOs included **Axovant Sciences**, which raised \$315 million in 2015, giving it a \$1.5 billion initial market cap, and **Galapagos NV**, which raised \$275 million in an IPO in 2015, with an initial market cap of \$1.7 billion. And a year before them, in 2014, **Juno Therapeutics** raised \$264 million in its IPO, with a \$2.2 billion market cap. **Celgene** acquired Juno earlier this year for \$9 billion. Last week Moderna refiled with the **Securities and Exchange Commission (SEC)**, raising its goal for its initial public offering from \$500 million to \$600 million. The company, which has no products on the market, is fantastic at raising money, but some analysts wonder if the company is overvalued. Since its founding in 2010, Moderna has raised more than \$2.6 billion in equity financing. As of September 30, it had cash, cash equivalents, and investments of \$1.2 billion.

The company focuses on messenger RNA (mRNA) therapeutics. mRNA's role is to transport genetic information from DNA to the ribosome, offering up the amino acid sequence of the eventual proteins the DNA is coding for. Moderna's tech platform is designed to engineer mRNA to deliver whatever protein codes they want the cells to produce, in effect, turning the cells themselves into vaccine or drug-manufacturing factories. Moderna has a development pipeline of 21 programs. Ten are in the clinic and another three have open Investigational New Drug (INDs) submissions. Nine of those in the clinic are in Phase I and one is in Phase II,

Although there is some skepticism as to whether Moderna can live up to expectations, it is unusual in the size of its pipeline. Most biotechs either have no products in the clinic when they launch an IPO, or they have one or two in early-stage trials and the funding is largely designed to help advance them into the clinic or more expensive late-stage trials.

Moderna's chief financial officer, **Lorence Kim**, told *Xconomy* earlier this year, "We're saying we can draw a picture that articulates an outsized return over time, and that outsized return comes from not one drug singly advancing by itself to approval, but instead by a technology that is pushed forward over time. The key thing for investors to wrap their arms around is: can we offer that sort of upside? We believe we can."

Not unusual in biotech IPOs, Moderna is probably years away from having a product on the market. Meanwhile, it has pretty high overhead with 680 staffers and a highly-compensated executive suite. **Stephen Hoge**, Moderna president, in 2017 received \$19 million in options and a \$4.4 million cash bonus. Kim received \$5.5 million in stock and a \$1 million cash bonus. And company chief executive officer **Stephane Bancel** received \$4.6 million in options and a \$1.5 million cash bonus. Those three accounted for a combined \$40 million in cash and stock last year.

And in its latest SEC filings, it indicated it burned through almost \$360 million in operating expenses in the first nine months of this year. It also stated it had accumulated a deficit of \$865.2 million.

Bancel owned 10 percent of the company ahead of the IPO. He's the second-largest shareholder, behind **Flagship Pioneering**, which owned 19.5 percent prior to the IPO. **AstraZeneca** was the third-largest investor, with a pre-IPO stake of 8.4 percent.

The company has been secretive over its history, which it could be because it was privately owned. Now that it has gone public, it will face far more intense scrutiny. As most analysts note, and the company stated in its IPO filings, it's not clear if mRNA drug processes works or are safe. In addition, regulatory agencies such as the **U.S. Food** and **Drug Administration (FDA)** haven't evaluated these types of medicines, which makes the regulatory pathway uncertain.

biospace.com/article/modern

2020 #Funding Award from

#CEPI #GATES }

bloomberg.com/press-releases...

Moderna Announces Funding Award from CEPI to Accelerate Development of Messenger RNA (mRNA) Vaccine Against Novel Coronavirus

January 23, 2020, 2:15 PM UTC

Moderna Announces Funding Award from CEPI to Accelerate Development of Messenger RNA (mRNA) Vaccine Against Novel Coronavirus Collaboration includes the National Institutes of Health (NIH) and leverages flexibility of Moderna's mRNA vaccine technology Business Wire CAMBRIDGE, Mass. -- January 23, 2020 Moderna, Inc., (Nasdaq: MRNA) a clinical stage biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines to create a new generation of transformative medicines for patients, and the Coalition for Epidemic Preparedness Innovations (CEPI), today announced a new collaboration to develop an mRNA vaccine against the

novel coronavirus (2019-nCoV). Under the terms of the agreement, Moderna will manufacture an mRNA vaccine against 2019-nCoV, which will be funded by CEPI. The Vaccine Research Center (VRC) of the National Institute of Allergy and Infectious Diseases (NIAID), part of NIH, collaborated with Moderna to design the vaccine. NIAID will conduct IND-enabling studies and a Phase 1 clinical study in the U.S. Over the past four years Moderna has had six positive Phase 1 clinical readouts in its prophylactic vaccines modality and moved two additional programs into development. Moderna's technology platform, fully integrated manufacturing site and development experience, combined with a multi-year relationship with the NIH, including exploring ways to respond to public health threats, allows for the rapid identification and advancement of a vaccine candidate against 2019-nCoV. "Moderna's commitment to global public health is aligned with CEPI's vision of creating a world in which epidemics are no longer a threat to humanity," said Richard Hatchett, M.D., CEO of CEPI. "We are pleased with the pace of our combined response to the emerging threat of the novel coronavirus. Through our partnership with Moderna and the NIH, we hope to speed the development of a vaccine against the coronavirus and help to alleviate the burden of disease." "We believe our mRNA vaccine technology offers potential advantages in the speed of development and production scalability, which positions Moderna to potentially develop a vaccine against coronavirus, 2019-nCoV," said Stéphane Bancel, CEO of Moderna. "Advances in global public health require the collective effort of publicprivate partnerships – no organization can act alone. We are honored to be supporting NIH and CEPI in their mission to identify a potential vaccine to prevent infection. It is impressive that CEPI was able to commit to this grant in a matter of days. We are thankful for the financial support from CEPI and the multi-year scientific collaboration we have with the NIH." About Coronavirus Coronaviruses are a family of viruses that can lead to respiratory illness, including Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV). Coronaviruses are transmitted between animals and people and can evolve into strains not previously identified in humans. On January 7, 2020, a novel coronavirus (2019-nCoV) was identified as the cause of pneumonia cases in Wuhan City, Hubei Province of China, and additional cases have been found in a growing number of countries. 1,2 About Moderna's Prophylactic Vaccines Modality Moderna scientists designed the Company's prophylactic vaccines modality to prevent or control infectious diseases. This modality now includes five programs, all of which are vaccines against viruses. More than 1,000 participants have been enrolled in Moderna's infectious disease vaccine clinical studies under health authorities in the U.S., Europe and Australia. The potential advantages of an mRNA approach to prophylactic vaccines include the ability to mimic natural infection to stimulate a more potent immune response, combining multiple mRNAs into a single vaccine, rapid discovery to respond to emerging pandemic threats and manufacturing agility derived from the platform nature of mRNA vaccine design and production. Moderna currently has five development candidates for potential commercial uses in this modality, including: respiratory syncytial virus (RSV) vaccine (mRNA-1777 and mRNA-1172 or V172 with Merck), cytomegalovirus (CMV) vaccine (mRNA-1647), human metapneumovirus and parainfluenza virus type 3 (hMPV/PIV3) vaccine (mRNA-1653) and Zika vaccine (mRNA-1893) with the Biomedical Advanced Research and Development Authority (BARDA). Three development candidates in this modality are available for potential global health uses including: influenza H10N8 vaccine (mRNA-1440), influenza H7N9 vaccine (mRNA-1851) and chikungunya vaccine (mRNA-1388), which was developed with the Defense Advanced Research Projects Agency (DARPA). To date, Moderna has demonstrated positive Phase 1 data readouts for six prophylactic vaccines (H10N8, H7N9, RSV, chikungunya virus, hMPV/PIV3 and CMV). Moderna's CMV vaccine is currently in a Phase 2 dose-selection study. Moderna's investigational Zika vaccine (mRNA-1893), currently in a Phase 1 study, was granted FDA Fast Track designation. Moderna has built a fully integrated, highly digitalized manufacturing plant in Norwood, MA which enables the promise of the technology platform.

April 2020 \$483 mil USGOV

https://today.line.me/id/pc/article/Moderna+gets+further+472+million+US+award+for+coronavirus+vaccine+development-l809YB... J

Moderna gets further \$472 million US award for coronavirus vaccine development

thejakartapost.com The Jakarta Post

Diterbitkan: 12.54, 27/07/2020

A woman cleans the entrance doors to Moderna headquarters in Cambridge, Massachusetts on May 18, 2020. Moderna Inc said on Sunday it has received an additional \$472 million from the US government's Biomedical Advanced Research and Development Authority (BARDA) to support development of its novel coronavirus vaccine.

Moderna Inc said on Sunday it has received an additional \$472 million from the US government's Biomedical Advanced Research and Development Authority (BARDA) to support development of its novel coronavirus vaccine.

The US-based drug maker said the additional funding will support its late-stage clinical development including the expanded Phase 3 study of Moderna's vaccine candidate.

In April, Moderna had received \$483 million from the US federal agency that funds disease-fighting technology, when the experimental vaccine was in an early-stage trial conducted by the US National Institutes of Health. "Encouraged by the Phase 1 data, we believe that our mRNA vaccine may aid in addressing the COVID-19 pandemic and preventing future outbreaks," Chief Executive Officer Stéphane Bancel said in a press release. BARDA's total funding for the experimental vaccine of Moderna, the first in the United States to begin human trials of a coronavirus vaccine, is now about \$955 million.

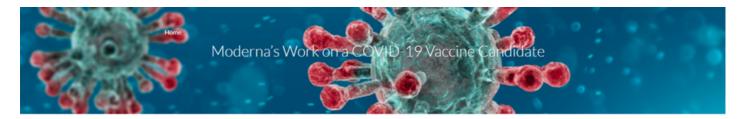
The vaccine uses synthetic messenger RNA (mRNA) to inoculate against the coronavirus. Such treatments help the body immunize against a virus and can potentially be developed and manufactured more quickly than traditional vaccines.

A Phase 3 study, conducted in collaboration with the National Institute of Allergy and Infectious Diseases, will begin on July 27 and involve about 30,000 participants, according to the company.

Moderna said it remains on track to be able to deliver about 500 million doses per year, and possibly up to 1 billion doses per year, beginning in 2021.

The announcement about further funding came two days after the drug developer said its formula used in developing the vaccine was not covered under patents owned by Arbutus Biopharma

Pfizer Inc, Novavax Inc, Britian's AstraZeneca Plc are other few drug makers that received funding from BARDA for coronavirus vaccine development.

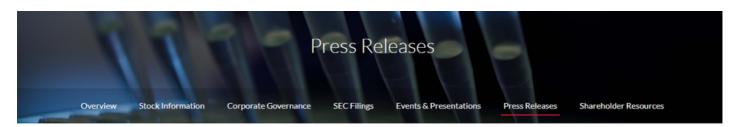


Time is of the essence to provide a vaccine against this pandemic virus.



Moderna is proud to be among the many groups working to respond to this continuing global health emergency. This page summarizes key milestones in our work to advance mRNA-1273, our vaccine candidate against the novel coronavirus.





Moderna Receives FDA Fast Track Designation for mRNA Vaccine (mRNA-1273) Against Novel Coronavirus

May 12, 2020 at 8:00 AM EDT

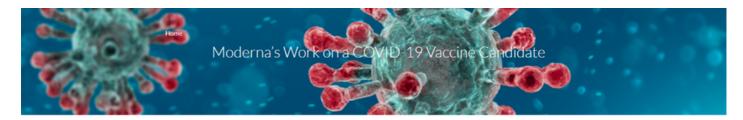
Finalizing protocol for Phase 3 study of mRNA-1273, expected to begin in early summer of 2020

4thModerna mRNA program to receive Fast Track designation

CAMBRIDGE, Mass,--(BUSINESS WIRE)--May 12, 2020-- Moderna, Inc., (Nasdaq: MRNA) a clinical stage biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines to create a new generation of transformative medicines for patients, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for the Company's mRNA vaccine candidate (mRNA-1273) against the novel coronavirus (SARS-CoV-2).

"Fast Track designation underscores the urgent need for a vaccine against the novel coronavirus," said Tal Zaks, M.D., Ph.D., Chief Medical Officer at Moderna. "As we await the full set of clinical data from the NIAID-led Phase 1 study, we are actively preparing for our Phase 2 and Phase 3 clinical studies to continue learning about the potential of mRNA-1273 to protect against SARS-CoV-2."

Fast Track is designed to facilitate the development and expedite the review of therapies and vaccines for serious conditions and fill an unmet medical need. Programs with Fast Track designation may benefit from early and frequent communication with the FDA, in addition to a rolling submission of the marketing application. The Company previously received Fast Track designation for its investigational Zika vaccine (mRNA-1893) and its methylmalonic



Time is of the essence to provide a vaccine against this pandemic virus.



Moderna is proud to be among the many groups working to respond to this continuing global health emergency. This page summarizes key milestones in our work to advance mRNA-1273, our vaccine candidate against the novel coronavirus.



SO WTF

Several more studies have confirmed the effectiveness

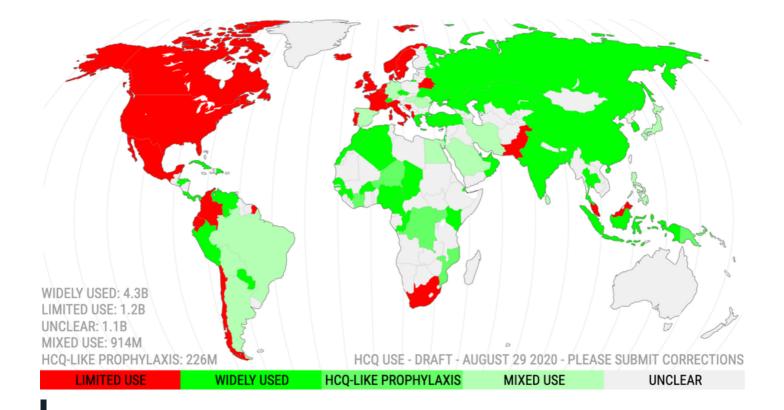
#HCQ

https://c19study.com

PrEP100%PEP100%Early100%Late60%All72%

82 studies (47 peer reviewed)

Global HCQ studies.PrEP, PEP, and early treatment studies show efficacy, while late treatment shows mixed results.



Note: In Vitro, Ex Vivo, Meta, Theory, Safety, Review, News, and Retracted items are not included in the percentages and study count. There is a total of 140 items. Recently added studies: IHU Marseille et al., Fiolet et al. Positive/negative effects vary in degree and certainty, please read the papers or descriptions thereof for more details. Every study has some limitations when considered in isolation (for example confounding factors; suboptimal treatment regimens; dosing regimens that may be too low, too high, or insufficiently account for the long half-life of HCQ; large treatment delays; small sample sizes; lack of focus on severity; reliance on Internet surveys; and patient characteristics very different from the most at-risk population).

| 8/26 | Meta | Early, IHU Marseille (Preprint) (meta analysis - not Meta-analysis on chloroquine derivatives and COVID-19 mortality Updated meta analysis of 26 studies showing CQ/HCQ OR 0.60 [0.50 - 0.73], p<0.0001 from clinical studies (~269,771 potential lives saved with g |
|------|----------|--|
| 8/26 | Meta | Late Fiolet et al., Clinical Microbiology and Infecti Effect of hydroxychloroquine with or without azithromycin on the mortality of COVID-19 Meta analysis of late stage studies (and one early treatment study with only 2 deaths), showing HCQ RR 0.83 [0.65-1.06], before exclusions RR 0.8 |
| 8/25 | Positive | Early Ip et al., medRxiv, doi:10.1101/2020.08.20.2 Hydroxychloroquine in the treatment of outpatients with mildly symptomatic COVID-19: Retrospective 1,274 outpatients, 47% reduction in hospitalization with HCQ with propensity matching, HCQ OR 0.53 [0.29-0.95]. Sensitivity analyse |
| 8/25 | Positive | Late Castelnuovo et al., European J. Internal Med Use of hydroxychloroquine in hospitalised COVID-19 patients is associated with reduced Retrospective 3,451 hospitalized patients showing a 30% reduction in mortality with HCQ after propensity adjustment, HR 0.70 [0.59 - 0.84] (~ |
| 8/24 | Positive | Late Catteau et al., Int. J. Antimicrobial Agents, d Low-dose Hydroxychloroquine Therapy and Mortality in Hospitalized Patients with COVI Retrospective 8,075 hospitalized patients, 4,542 low-dose HCQ, 3,533 control. 35% lower mortality for HCQ (17.7% vs. 27.1%), adjusted HR 0.68 [0 |
| 8/21 | Positive | Early Ly et al., Preprint, 2020 (Preprint) Pattern of SARS-CoV-2 infection among dependant elderly residents living in retirement Retrospective analysis of retirement homes, HCQ+AZ >= 3 days mortality OR 0.39, p=0.026 (~364,191 potential lives saved with global HCQ). 169 |
| 8/21 | Safety | N/A Lane et al., The Lancet Rheumatology, doi:1 Risk of hydroxychloroquine alone and in combination with azithromycin in the treatment Retrospective study of RA patients using HCQ vs. sulfasalazine (another DMARD). HCQ treatment showed no increased risk in the short term (up |
| 8/21 | Positive | Late Gonzalez et al., medRxiv, doi:10.1101/2020 The Prognostic Value of Eosinophil Recovery in COVID-19: A Multicentre, Retrospective Retrospective study focused on eosinophil recovery with 9,644 hospitalized patients in Spain, showing lower mortality for HCQ (14.7% vs 29.2%, p |
| 8/20 | Positive | Late Dubernet et al., J. Global Antimicrobial Resi A comprehensive strategy for the early treatment of COVID-19 with azithromycin/hydrox Retrospective analysis of 36 hospitalized patients showing HCQ/AZ associated with lower ICU admission, p=0.008. Median age 66, no mortality |
| 8/20 | Safety | Early Prodromos, C., New Microbes and New Infe Hydroxychloroquine is protective to the heart, not Harmful: A systematic review Review concluding that HCQ/AZ does not cause Torsade de Pointes or related deaths, HCQ decreases cardiac events, and HCQ should not be res |
| 8/17 | Safety | Early Mohana et al., medRxiv, doi:10.1101/2020.0 Hydroxychloroquine Safety Outcome within Approved Therapeutic Protocol for COVID-1 Safety study of 2,733 patients in Saudi Arabia showing HCQ in mild to moderate cases in an outpatient setting, within the protocol recommendati |

Surgisphere: governments and WHO changed Covid-19 policy based on suspect data from tiny US company

Surgisphere, whose employees appear to include a sci-fi writer and adult content model, provided database behind Lancet and New England Journal of Medicine hydroxychloroquine studies



▲ A tiny US company, Surgisphere, is behind flawed data which led to governments and the world health organisation changing health policy Photograph: Anthony Brown/Alamy Stock Photo

The World Health Organization and a number of national governments have changed their Covid-19 policies and treatments on the basis of flawed data from a little-known US healthcare analytics company, also calling into

On 22 May the Lancet published a blockbuster peer-reviewed study which found the antimalarial drug hydroxychloroquine, which has been promoted by <u>Donald Trump</u>, was associated with a higher mortality rate in Covid-19 patients and increased heart problems.

Trump, much to the dismay of the scientific community, had <u>publicly touted hydroxychloroquine</u> as a "wonder drug" despite no evidence of its efficacy for treating Covid-19.

The Lancet study, which listed Desai as one of the co-authors, claimed to have analysed Surgisphere data collected from nearly 96,000 patients with Covid-19, admitted to 671 hospitals from their database of 1,200 hospitals around the world, who received hydroxychloroguine alone or in combination with antibiotics.

The negative findings made global news and prompted the WHO to halt the hydroxychloroquine arm of its global trials.

But only days later Guardian Australia <u>revealed glaring errors in the Australian data</u> included in the study. The study said researchers gained access to data through Surgisphere from five hospitals, recording 600 Australian Covid-19 patients and 73 Australian deaths as of 21 April.

But data from Johns Hopkins University shows only 67 deaths from Covid-19 had been recorded in Australia by 21 April. The number did not rise to 73 until 23 April. Desai said one Asian hospital had accidentally been included in the Australian data, leading to an overestimate of cases there. The Lancet published a small retraction related to the Australian findings after the Guardian's story, its only amendment to the study so far.

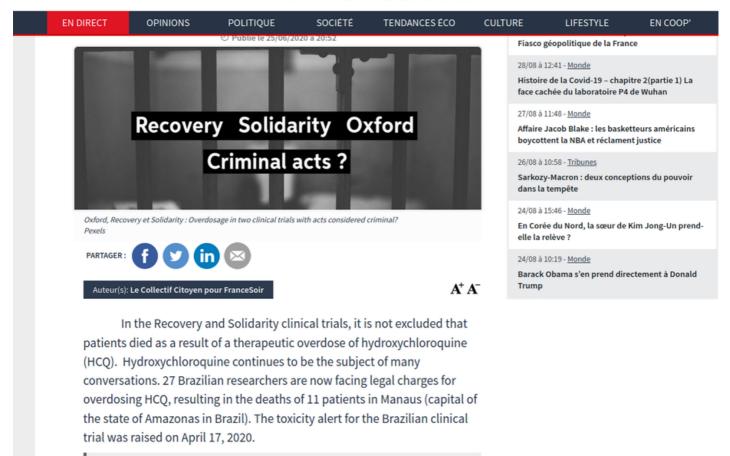
The Guardian has since contacted five hospitals in Melbourne and two in Sydney, whose cooperation would have been essential for the Australian patient numbers in the database to be reached. All denied any role in such a database, and said they had never heard of Surgisphere. Desai did not respond to requests to comment on their statements.

Another study using the Surgisphere database, again co-authored by Desai, found the anti-parasite drug ivermectin reduced death rates in severely ill Covid-19 patients. It was published online in the Social Science Research Network e-library, before peer-review or publication in a medical journal, and <u>prompted the Peruvian government to add ivermectin to its national Covid-19 therapeutic guidelines</u>.

The New England Journal of Medicine <u>also published a peer-reviewed Desai study based on Surgisphere data</u>, which included data from Covid-19 patients from 169 hospitals in 11 countries in Asia, Europe and North America. It found common heart medications known as angiotensin-converting—enzyme inhibitors and angiotensin-receptor blockers were not associated with a higher risk of harm in Covid-19 patients.

BOTH NOW RETRACTED YET FDA HAVING REVERSED ITS DECISION ALLOWING ITS USE OFF LABEL FOR COV19 HAS NOT REVERSED IT DECISION





In the Recovery and Solidarity clinical trials, it is not excluded that patients died as a result of a therapeutic overdose of hydroxychloroquine (HCQ). Hydroxychloroquine continues to be the subject of many conversations. 27 Brazilian researchers are now facing legal charges for overdosing HCQ, resulting in the deaths of 11 patients in Manaus (capital of the state of Amazonas in Brazil). The toxicity alert for the Brazilian clinical trial was raised on April 17, 2020.

A synthetic COVID virus highly pathogenic for humans created by the Wuhan Institute of Virology and the USA.

Published on 06/08/2020 at 10:34 - Updated on 07/29/2020 at 11:21

Wuham Pixabay

Author (s): Valère Lounnas for FranceSoir A A

TRIBUNE ANALYSIS- This is not yet another fake news but an indisputable reality described in an article freely available on the internet, published in 2015 in Nature Medicine. A completely extraordinary scientific text which describes the manufacture of a viable chimeric synthetic COVID virus

and highly pathogenic for humans on the pretext of studying the pandemic potential of coronaviruses of animal origin of which bats are a natural reservoir.

Editor's note: this article represents an analysis of coronaviruses in general which are not to be confused with Covid-19 which is a subset of it. According to an article in Nature, SARS-Cov2 would **probably** be associated as a Nature article says with the bat. (updated July 20, 2020)

The scientists responsible for this research are **Ralph S. Baric**, professor and director of the microbiology laboratory at Chapel Hill University (North Carolina) and **Shi Zheng Li**, doctor in microbiology graduated from the Faculty of Sciences of Montpellier, now at head of the biosafety and special pathogens laboratory at the famous Wuhan Institute of Virology.

In retrospect, this article takes on a premonitory character which questions the situation in which the entire planet was plunged in 2020.

After an introduction which mentions the global chaos which would result from a pandemic caused by a coronavirus of bats which would have crossed the species barrier to infect humans, we discover the detailed description of the manufacture of an artificial virus with a pathogenic character as marked as that of the 2002-2003 epidemic. This chimeric virus was a synthetic hybrid, constructed from the 2002-2003 mouse-adapted human acute respiratory syndrome (SARS) virus (SARS-MA15). In a second step, the surface protein S (spicule) of the virus adapted to mice was substituted by the spike protein SHC014 originating froma bat virus identified at the Wuhan institute. The presence of the SHC014 protein in a bat coronavirus that binds to ACE2 cell penetration receptors found in many mammals is the great discovery of Shi Zheng Li published in Nature in 2013. The question was whether the SHC014 protein could activate human ACE2 directly without adaptation, since it had **five mutations** in regions essential for its binding to the ACE2 receptor compared to the S protein of SARS-Cov from 2002-2003. The chimeric virus produced, dubbed SHC014-MA15, was perfectly viable and replicated in human upper respiratory cell cultures at the same concentration levels as seen in patients of the deadly 2002-2003 epidemic. In contrast, laboratory mice infected with the hybrid SHC014-MA15 virus developed a noticeable pathogenic effect with weight loss but little mortality while those infected with the adapted SARS-MA15 virus died within 4 days.

Remarkably, the SHC014 protein conferred on the hybrid virus SHC014-MA15 a very pronounced infectious character and specific to the cells of the human upper respiratory tract without the need for adaptation mutations.

The surface protein SHC014 of the eponymous bat virus is therefore likely, **once artificially integrated into other viruses, to enhance their pathogenesis to a potentially fatal level.**comparable to that of the 2003 epidemic. This kind of research which consists in increasing the biological capacities of an organism by genetic manipulation obtained by microbiology is now banned from institutional research in the USA. Note that in his statements to the press a French virologist expert denied that such manipulations could have taken place in Wuhan or elsewhere. However, what about research in secret military laboratories? On reading this article, we understand better why the Americans and Chinese accuse each other of having been at the origin of the SARS-Cov2 (COVID-19) pandemic

We also better understand **the fears that the authorities have about the feasibility of a vaccine**, the perhaps limited duration of acquired immunity, but also the possibility of life-saving cross-immunity between coronaviruses. All these questions are dealt with in depth by the authors through a series of experiments carried out on their laboratory mice.

Valère Lounnas is a former scientific researcher at the European Molecular Biology Laboratory (EMBL) in Heidelberg. His specialty was **the theoretical study of proteins** and their function. He then worked in the pharmaceutical industry in computer-aided drug design (CMAO) before becoming a medical writer.

We are making available to interested readers the rigorous literal translation of this article published in 2015 in Nature Medecine.

Translation of the Nature Medecine article: <u>Download the PDF version</u>

FILE [A synthetic COVID virus highly pathogenic for humans created by the Wuhan Institute of Virology and the USA]

•••

Construction of SARS-like chimeric viruses.

Both wild-type and chimeric viruses were derived from either SARS-CoV Urbani or the corresponding mouse-adapted (SARS-CoV MA15) infectious clone (ic) as previously described 27. Plasmids containing spike sequences for SHC014 were extracted by restriction digest and ligated into the E and F plasmid of the MA15 infectious clone. The clone was designed and purchased from Bio Basic as six contiguous cDNAs using published sequences flanked by unique class II restriction endonuclease sites (BgII). Thereafter, plasmids containing wild-type, chimeric SARS-CoV and SHC014-CoV genome fragments were amplified, excised, ligated and purified. *In vitro* transcription reactions were then preformed to synthesize full-length genomic RNA, which was transfected into Vero E6 cells as previously described 2. The medium from transfected cells was harvested and served as seed stocks for subsequent experiments. Chimeric and full-length viruses were confirmed by sequence analysis before use in these studies. Synthetic construction of chimeric mutant and full-length SHC014-CoV was approved by the University of North Carolina Institutional Biosafety Committee and the Dual Use Research of Concern committee.

https://www.nature.com/articles/nm.3985

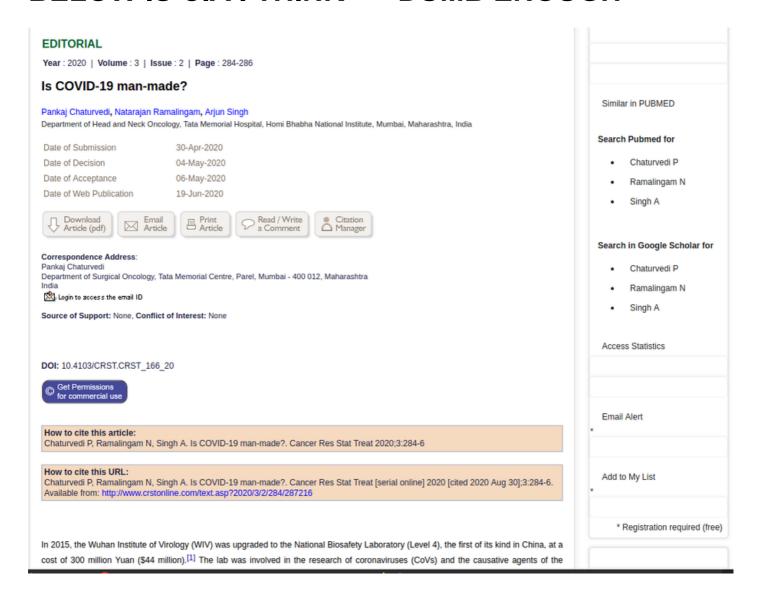
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BELOW IS CIA I THINK - -- DUMB ENOUGH



WOULD ANY ONE OTHER THAN AN AMERICAN USE CNN AS A SOURCE

8. Available from: https://www.nationalreview.com/2020/04/corona virus-china-trail-leading-back-to-Wuhan-labs/. [Last accessed 2020 May 24]. †

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0-19 man-made?

http://www.crstonline.com/article.asp?issn=

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http://www.crstonline.com/article.asp?issn=2590-3233;year=2020;volume=3;issue=2;spage=284;epage=286;aulast=Chaturvedi

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Notice



Hydroxychloroquine, a less toxic derivative of chloroquine, is effective in inhibiting SARS-CoV-2 infection in vitro

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The outbreak of coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2/2019-nCoV) poses a serious threat to global public health and local economies. As of March 3, 2020, over 80,000 cases have been confirmed in China, including 2946 deaths as well as over 10,566 confirmed cases in 72 other countries. Such huge numbers of infected and dead people call for an urgent demand of effective, available, and affordable drugs to control and diminish the epidemic.

We have recently reported that two drugs, remdesivir (GS-5734) and chloroquine (CQ) phosphate, efficiently inhibited SARS-CoV-2 infection in vitro¹. Remdesivir is a nucleoside analog prodrug developed by Gilead Sciences (USA). A recent case report showed that treatment with remdesivir improved the clinical condition of the first patient infected by SARS-CoV-2 in the United States², and a phase III clinical trial of remdesivir against SARS-CoV-2 was launched in Wuhan on February 4, 2020. However, as an experimental drug, remdesivir is not expected to be largely available for treating a very large number of patients in a timely manner. Therefore, of the two potential drugs, CQ appears to be the drug of choice for large-scale use due to its availability, proven safety record, and a relatively low cost. In light of the preliminary clinical data, CQ has been added to the list of trial drugs in the Guidelines for the Diagnosis and Treatment of COVID-19 (sixth edition) published by National Health Commission of the People's Republic of China.

CQ (N4-(7-Chloro-4-quinolinyl)-N1,N1-diethyl-1,4-pentanediamine) has long been used to treat malaria and amebiasis. However, *Plasmodium falciparum* developed widespread resistance

Sections Figures References

Acknowledgements

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Ethics declarations

Additional information

Supplementary information

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<u> http://english.whiov.cas.cn/</u>

















status







country, province

Statistics by Statistics by disease code test

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test

Statistics by source of funds or

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Statistics by recruiting research

objects

registration intervention

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Clinical trial(transparency articles unit

to 22:19 on August 28, 2020 Beijing time)

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·New coronavirus pneumonia clinical research index (updated ·Transparency and sharing of clinical trial raw data: philosophical propositions about medical research ethics and its significance to clinical trials

Clinical Trial Registration Platform

·A milestone event of clinical trial transparency

·Statement of the International Medical Journal Editors Committee on the registration of clinical trials

China Clinical Trial Registry Policy

More information

·Special instructions on the rejection of the supplementary registration application for the clinical trial "Evaluation of the management platform (ResMan) safety and effectiveness of the HIV immune gene CCR5 embryo gene editing"

·Announcement on the establishment of the Hong Kong Center ·Announcement on the registration of acupuncture clinical of China Clinical Trial Registration Center

·Announcement on uploading statistical analysis results of clinical trials

Announcement on the free use of the clinical trial public

·Announcement on the sharing of original clinical trial data

trials in the acupuncture clinical trial registration center ·Registration Notice

·Statement of the Secretary-General of the International Medical Journal Editors Committee on the clinical trial electronic management platform

· Purpose of China Clinical Trial Registry

China Registered Clinical Trial Ethics Review Committee

More information

·The Chinese version of the 2008 Declaration of Helsinki (Declaration of Helsinki)

·Informed Consent Form pdf ·Ethical review application form

| Sumula number studies | of Begistration Number | Registration date | Researcher unit | Researcher Unit (English) | Registration topic | Registration title (English) | Expected date of inclusion of participants | |
|-----------------------------|------------------------|----------------------|--|--|---|--|--|---|
| | 1 ChiCTR2000029308 | 1/23/2020 | Wuhan Jinyintan Hospital (Wuhan Infectious Disease Hospital) | Wuhan Jinyintan Hospital (Wuhan Infectious Diseases Hospital) | treatment of hospitalized patients with novel coronavirus | A randomized, open-label, blank-controlled trial for the efficacy and safety of lopinavir-ritonavir and interferon-alpha 2b in hospitalization patients with novel coronavirus pneumonia (COVID-19) | 1/10/2020 | |
| | 2 ChiCTR2000029381 | 1/27/2020 | The First Affiliated Hospital of Guangzhou Medical University | The First Affiliated Hospital of Guangzhou Medical University | | A prospective comparative study for Xue-Bi-Jing injection in the treatment of novel coronavirus pneumonia (COVID-19) | 1/24/2020 | ı |
| | 3 ChiCTR2000029386 | 1/28/2020 | Chongqing Public Health Medical Treatment Center | Chongqing Public Health Medical Center | A randomized controlled study of glucocorticoids in the treatment of severe new coronavirus pneumonia (COVID-19) | Adjunctive Corticosteroid Therapy for Patients with Severe Novel Coronavirus Pneumonia (COVID-19): a Randomized Controlled Trial | 1/29/2020 | l |
| | 4 ChiCTR2000029387 | 1/28/2020 | Chongqing Public Health Medical Treatment Center | Chongqing Public Health Medical Center | A randomized controlled study of treatment strategies for mild to | Comparison of efficacy and safety of three antiviral regimens is patients with mild to moderate novel coronavirus pneumonia (COVID-19): a randomized controlled trial | 1/25/2020 | l |
| | 5 ChiCTR2000029400 | 1/29/2020 | China Academy of Chinese Medical Sciences | | Pneumonia (COVID-19) with Traditional Chinese Medicine | Clinical Controlled Trial for Traditional Chinese Medicine in the treatment of Novel Coronavirus Pneumonia (COVID-19) | 1/29/2020 | ı |
| | 6 ChiCTR2000029418 | 1/30/2020 | Dongzhimen Hospital, Beijing University of Chinese Medicine | | | Chinese Herbal medicine for Severe nevel coronavirus pneumonia (COVID-19): a Randomized Controlled Trial | 2/3/2020 | l |
| | 7 ChiCTR2000029430 | 2/1/2020 | Tianjin University of Traditional Chinese Medicine/Bubei Hospital of Integrated Traditional Chinese and Western Medicine | | | Study for the TCM syndrome characteristics of novel coronavirus pneumonia (COVID-19) | 2/3/2020 | l |
| | 8 ChiCTR2000029431 | 2/1/2020 | Zhongshan Hospital Affiliated to Dalian University | Affiliated Zhongshan Hospital of Dalian University | Clinical study of anti-coronavirus pneumonia (COVID-19) treatment with macrophages as targets | Clinical study for the remedy of M1 macrophages target in the treatment of novel coronavirus pneumonia (COVID-19) | 1/29/2020 | ı |
| | 9 ChiCTR2000029432 | 2/1/2020 | The First Affiliated Hospital of Guangzhou University of Chinese Medicine | The First Afflicated Hospital of Guangzhou University of Chinese Medicine | Large-dose Tanreging injection in the treatment of new coronavirus | A Real World Study for the Efficacy and Safety of Large Dose Tanreqing Injection in the Treatment of Patients with Novel Coronavirus Pneumonia (COVID-19) | 2/1/2020 | l |
| | 10 ChiCTR2000029433 | 2/1/2020 | Hebei Yiling Hospital/Wohan University People's Hospital | Hebei Yiling Hospital, Renmin Hospital of Wuhan University | Capsules/granules in the treatment of suspected cases of novel | A randomized, open-label, blank-controlled trial for Lian-Hua Qing-Wen Capsule/Granule in the treatment of suspected novel coronavirus pneumonia (COVID-19) | 2/1/2020 | l |
| | 11 ChiCTR2000029434 | 2/1/2020 | Hebei Yiling Hospital/Wuhan University People's Hospital | | capsules/granules in the treatment of new coronavirus pneumonia | A randomized, open-label, blank-controlled trial for Lian-Hua Qing-Wen Capsule/Granule in the treatment of novel coronavirus pneumonia (COVID-19) | 2/1/2020 | l |
| | 12 ChiCTR2000029435 | 2/1/2020 | Wuhan First Hospital | | A Randomized Controlled Trial of Traditional Chinese Medicine for the Presenting of Newel Companions Presentation (COVTD-10) | Randomized controlled trial for traditional Chinese medicine in the prevention of novel coronavirus pneumonia (COVID-19) in high risk population | 2/1/2020 | l |
| | 13 ChiCTR2000029436 | 2/1/2020 | The First Affiliated Hospital of Henan University of Traditional Chinese Medicine | The First Hospital of He'nan University of Chinese Medicine | medicine treatment plan for novel coronavirus pneumonia | A single arm study for evaluation of integrated traditional Chinese and western medicine in the treatment of novel coronavirus pneumonia (COVID-19) | 2/1/2020 | l |
| | 14 ChiCTR2000029437 | 2/1/2020 | Hubei Hospital of Integrated Traditional Chinese and Western Medicine/Tianjin University of Traditional Chinese Medicine | Hubei Provincial Integrated Hospital of traditional Chinese and Western Medicine | Single-cohort study on the treatment of novel coronavirus pneumonia (COVID-19) with integrated traditional Chinese and | A single arm study for combination of traditional Chinese and Western Medicine in the treatment of novel coronavirus pneumonia (COVID-19) | 2/3/2020 | |
| | 15 ChiCTR2000029438 | 2/1/2020 | Tianjin University of Traditional Chinese Medicine/Beijing Hospital of Traditional Chinese Medicine | Beijing hospital of Traditional Chinese medicine; Hubei integrated traditional Chinese and Western Medicine Hospital | Clinical trial of combined traditional Chinese and Western medicine | A randomized controlled trial of integrated TCM and Western Medicine in the treatment of severe 2019-nCoV pneumonia (novel coronavirus pneumonia, NCP) | 2/4/2020 | |
| | | | Tianjin University of Traditional Chinese | | | | | П |

WHAT WAS THAT ABOUT NOT OPEN

| 275 ChiCTR2000030293 | 2/27/2020 Shanghai Public Health Clinical Center | Shanghai Public Health Clinical Center | Clinical Observation and Research Plan for Patients with Novel Coronavirus Pneumonia (COVID-19) patients 3/1/20 | 020 |
|----------------------|--|--|--|------|
| 276 ChiCTR2000030300 | 2/28/2020 Nanjing Second Hospital | Nanjing Second Hospital | Withfrawal of umbilical cord messeschymal stem cells (hucMSCs) Umbilical cord messeschymal stem cells (hucMSCs) in the treatment of high-risk patients with new coronavirus presumonia (COVID-19) patients presumonia (COVID-19) patients | 020 |
| 277 ChiCTR2000030304 | 2/28/2020 The Third Affiliated Third Hospital of Sun Yat- sen University | The Third Affiliated Hospital of Sun Yat-sen University | Study on the protective factors of psychological resilience of Protective factors of mental resilience in first-line nurses with clinical first-line nurses of new coronavirus pneumonia (COVID-19) novel coronavirus pneumonia (COVID-19) | 020 |
| 278 ChiCTR2000030305 | $2/28/2020^{\hbox{\scriptsize The Fourth Affiliated Hospital of Zhejiang}}_{\hbox{\scriptsize University School of Medicine}}$ | The Fourth Affiliated Hospital of Zhejiang University School of Medicine | Multi-omics research and emergency plan optimization of spleen irreporating and dampens-removing combined with anti-virsal treatment of new occuratives parameters (2001–201) (CVID-19) (CVID-19) | 020 |
| 279 ChiCTR2000030306 | 2/28/2020 Shenzhen University Luohu Hospital Group Medical Center | Luohu hospital group medical center of Shenzhen University | Withdraw the asymptomatic insidious new coronavirus pneumonia Cancelled Mechanism of novel coronavirus pneumonia (COVID-19) virus indicating immune escape mechanism and vaccine (COVID-19) virus with sidest latest immune system induced by development through newloop protein envelope protein and vaccine development of the envelopment of the envelopmen | 020 |
| 280 ChiCTR2000030312 | 2/28/2020 The First People's Hospital of Jiangxia District Wuhan | First People's Hospital of Jiangxi District | An open, single-arm, single-center clinical study evaluating the deflectiveness and safety of anti-SAMS-CoV2 train inactivated glasma in the treatment of patients with new coronavirus infection convalencery plasma in the treatment of power of the coronavirus infection processing of the coronavirus process | .020 |
| 281 ChiCTR2000030314 | 2/28/2020 Xiangyang Central Hospital, Affiliated Hospital of Hubei University of Arts and Science | l Xiangyang Central Hospital, Affiliated Hospital of Hubei Unive of Arts and Sciences | sity Application of Maxing Shigan Decoction and Shengjiang Powder in Children with Novel Coronavirus Pneumonia (COVID-19) coronavirus pneumonia (COVID-19) 27820 | 020 |
| 282 ChiCTR2000030315 | 2/28/2020 Affiliated Hospital of Changchun University of Traditional Chinese Medicine | Affiliated Hospital of Changchun University of traditional Chin Medicine | (COVID-19) (COVID-19) | 020 |
| 283 ChiCTR2000030317 | 2/28/2020 West China Hospital of Sichuan University | West China Hospital, Sichuan University | Clinical study of a new type of "gastroscope isolation mask" during preventing and controlling the novel coronavirus pneumonia (COVID-19) epidemic (COVID-19) Epidemic period 3/1/20 | 020 |
| 284 ChiCTR2000030322 | 2/28/2020 Xinyang Central Hospital | Xinyang Central Hospital | Identification and clinical treatment of critical and severe patients Identification and Clinical Treatment of Severe novel | 020 |
| 285 ChiCTR2000030324 | 2/28/2020 Xiangyang Central Hospital, Affiliated Hospital of Hubei University of Arts and Science | l Xiangyang Central Hospital, Affiliated Hospital of Hubei Unive of Arts and Sciences | sity Application of "Zang-Fu Acupuncture" TCM Tuina in Children with Traditional Chinese Medicine Zang-Fu Point-pressing massage Novel Coronavirus Pneumonia (COVID-19) for children with novel coronavirus pneumonia (COVID-19) | 020 |
| 286 ChiCTR2000030325 | 2/28/2020 Xiangyang Central Hospital, Affiliated Hospita | Xiangyang Central Hospital, Affiliated Hospital of Hubei | Investigation of mental health of first-line medical and nursing care A survey for mental health of first-line medical providers and to action of crisis intervention model for novel coronavirus 2/28/20 | 020 |
| | of Hubei University of Arts and Science The Second Affiliated Hospital of Anhui | of Arts and Sciences | onia (COVID-19) in Xiangyang is of clinical characteristics of novel coronavirus | |
| 287 ChiCTR2000030327 | Archiversity Medical University | The Second Affiliated hospital of Anhui Medical Universi | onia (COVID-19) 1/21/20 | 020 |
| 288 ChiCTR2000030328 | Union Hospital, Tongji Medical College, 2/28/2020 Huazhong University of Science and Technology | Union Hospital, Tongji Medical College, Huazhong Unive | ginal text a application of inhaled acetylcysteine solution in the surgary of entral Hospital, Affiliated Hospital of Hubel University of ent of sovel coronavirus pneumenia (COVID-19) | 020 |
| 289 ChiCTR2000030329 | 2/28/2020 The Second Affiliated Hospital of Xi'an Medica | The Second Affiliated Hounital of Yi'an Medical University | s and Sciences 4 trial for umbilical cord blood CIK and NK cells in the ent of mild and general patients infected with novel 3/5/20 | 1020 |
| 107 030 114101000000 | College | | ntribute a better translation virus pneumonia (COVID-19) | |
| 290 ChiCTR2000030330 | The First Affiliated Hospital of University of 2/28/2020 Science and Technology of China (Anhui Provincial Hospital) | The First Affiliated Hospital of University of science and of China (Anhui Provincial Hospital) | I research of 6-minute walk training on motor function 2/28/26 of motor function of new coronavirus pneumonia (UUVIII-19) of movel coronavirus pneumonia (COVIII-19) | .020 |
| 291 ChiCTR2000030331 | 2/29/2020 The First Affiliated Hospital of University of Science and Technology of China | The First Affiliated Hospital of University of science and techn of China (Anhui Provincial Hospital) | ogy New coronavirus pneumonia (COVID-19) case follow-up cohort Construction of a Bio information platform for novel coronavirus pneumonia (COVID-19) patients follow-up in Anhui | 020 |
| 292 ChiCTR2000030333 | 2/29/2020 Huazhong University of Science Tongji Hospital, Tongji Medical College | Tongji Hospital of Tongji Medical College; Huazhong Science a Technology University | d A randomized, open, blank controlled study on the efficacy and A randomized, open-label controlled trial for the efficacy and safety of pirfesidone in the treatment of severe and critical patients safety of Pirfesidone in patients with severe and critical novel with Wishan novel coronavirus infection (COVID-19) coronavirus presuments (COVID-19) | 020 |
| 293 ChiCTR2000030334 | 2/29/2020 School of Life Sciences, Xianlin Campus, Nanjing University/Nanjing Second Hospital | College of Life Sciences, Xianlin Campus, Nanjing University/Nanjing Second Hospital | Research on Novel Coronavirus MicroRNA (COVID-19) as a Marker microRNA as a marker for early diagnosis of novel coronavirus for Early Diagnosis of Infection (COVID-19) 2/19/20 | 020 |
| 294 ChiCTR2000030363 | 2/29/2020 Huazhong University of Science Tongji Hospital, Tongji Medical College | Tongji Hospital, Tongji Medical College, Huazhong University Science and Technology | of novel coronavirus infection in children (COVID-19) epidemiology, clinical features and treatment outcome 2/23/20 | 020 |
| 295 ChiCTR2000030381 | | First people's hospital of Jiangxi district, Wuhan | Withfrawal of a randomized, open, controlled, single-center clinical A randomized, open-label, controlled and single-center trial to study evaluating the effectiveness and safety of ant SASE CoVV2 incitorated views inactivated plasma in the treatment of patients with new coronavirus infection pneumonia (COVID-19) and the coronavirus infection pneumonia (COVID-19) patient construction and association of non-contact doctor-national construction and supplications of non-contact doctor-national constructions are constructed as a construction of non-contact doctor-national constructions are constructed as a construction of non-contact doctor-national constructions are constructed as a construction of non-contact doctor-national constructions are constructed as a construction of non-conta | 020 |

Case 2:20-cv-01277-JJT Document 1 Filed 06/29/20

file name -- ican-v-fda

| | FACTS |
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| 22 | I. Background |
| 23 24 | 9. The first vaccine for COVID-19 to begin trials in the United States is mRNA-1273.3 |
| 24 25 | This experimental vaccine is being developed by NIAID, the NIH institute directed by Dr. Fauci, |
| 26 | |
| 27 | |
| 28 | 3 See https://www.nih.gov/news-events/news-releases/nih-clinical-trial-investigational-vaccine-covid-19-begins. |
| | |
| | 3 |
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| | Case 2:20-cv-01277-JJT Document 1 Filed 06/29/20 Page 4 of 12 |
| | |
| 1 | along with a biotechnology company, Moderna Inc.4 |
| 2 | 10. The first vaccine for COVID-19 to begin trials in the United States is mRNA-1273.5 |
| 3 | This experimental vaccine is being developed by NIAID, the NIH institute directed by Dr. Fauci, |
| 4 | along with a biotechnology company, Moderna Inc.6 |
| 5 | 11. NIAID used taxpayer dollars to sponsor, assume responsibility for, and perform the |
| 6 | first clinical trial for the mRNA-1273 vaccine.7 Likewise, NIAID's parent department, the |
| 8 | |
| 9 | Department of Health and Human Services ("HHS"), awarded \$483 million to accelerate |
| 10 | development of mRNA-1273, including to "fund the development of mRNA-1273 to FDA |
| | licensure and manufacturing process scale-up to enable large-scale production in 2020 [before |

licensure is granted]."8

went over an important hurdle in the development of vaccines.").

| 13 | 12. HHS has also granted those developing and those who will sell this product broad |
|----|---|
| 14 | immunity from liability for injuries.9 |
| 15 | 13. Furthermore, a number of NIAID employees are listed as inventors on two patents |
| 16 | relating to the development of mRNA-1273. 10 The first is patent application number 62/412,703 |
| 17 | titled Prefusion Coronavirus Spike Proteins and Their Use 11 and the second is patent application |
| 18 | threa Frejusion Coronavirus Spike Froieins and Their Ose 11 and the second is patent application |
| 19 | 4 See https://www.nih.gov/news-events/news-releases/nih-clinical-trial-investigational-vaccine- |
| 20 | covid-19-begins. |
| 21 | 5 See https://www.nih.gov/news-events/news-releases/nih-clinical-trial-investigational-vaccine- covid-19-begins. |
| 22 | 6 See https://www.nih.gov/news-events/news-releases/nih-clinical-trial-investigational-vaccine- covid-19-begins. |
| 23 | 7See https://clinicaltrials.gov/ct2/show/NCT04283461; https://projectreporter.nih.gov/project_info_history.cfm?aid=10110093&icde=49376321; |
| 24 | https://projectreporter.nih.gov/project_info_description.cfm?aid=9872016&icde=49376321. |
| 25 | 8 https://www.modernatx.com/modernas-work-potential-vaccine-against-covid-19; https://investors.modernatx.com/node/8671/pdf. |
| 26 | 9 See https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx. 10 See https://science.sciencemag.org/content/early/2020/02/19/science.abb2507/tab-pdf?version |
| 27 | ed=true (see "Competing interests" on page 4). |
| 28 | 11 See http://appft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&p=1&u=%2 Fnetahtml%2FPTO%2Fsearch-adv.html&r=1&f=G&l=50&d=PG01&S1=344,774&OS=344 |
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