Medical News

Multiple Coronavirus Vaccines are Ready to be Rolled Out Soon

The whole world pharma industry is working at an unprecedented pace to bring out an effective and safe vaccine against SARS-Cov2 as soon as possible.

Status of the Vaccines

Company	Type	Doses (days)	Route	Trials	Status
Sinovac	Inactivated	2 (0,14)	IM	Phase 3	
SinoPharma	Inactivated	2 (0,21)	IM	Phase 3	
Bharat Biotech	Inactivated	2 (0,28)	IM	Phase 3	
Oxford/AstraZeneca	Viral Vector (Non-replicating)	2 (0,28)	IM	Phase 3	Complete
CanSino	Viral Vector (Non-replicating)	1 dose!	IM	Phase 3	
Gamaleya-Sputnik	Viral Vector (Non-replicating)	2 (0,21)	IM	Phase 3	Complete
Janssen (J & J)	Viral Vector (Non-replicating)	2 (0,21)	IM	Phase 3	
Novavax	Protein Sub-Unit	2 (0,21)	IM	Phase 3	
Moderna	LNP-mRNA	2 (0,28)	IM	Phase 3	Complete
BioNTech / Pfizer	3LNP-mRNAs	2 (0,28)	IM	Phase 3	Complete
Wantai - Xiamen	Viral Vector (Replicating)	1 dose!	Intra-Nasal	Phase 2	
Inovio	DNA Vaccine	2 (0.28)	Intra Dermal	Phase 2	

The main players in this race include Pfizer-BioNTech, Moderna and Oxford-AstraZeneca. The first 2 groups are working on a novel approach based on mRNA. It would require two injections approximately 4 weeks apart. Both Pfizer-BioNTech, Moderna have announced approximately 95% efficacy in their press releases. These results are still awaiting publication in peer reviewed journals. The main problem with these vaccines is their storage and transportation at -70 C and -5C respectively.

The third vaccine is by Oxford-Astra Zeneca group. They have developed a DNA based vaccine after injecting the spike producing gene of coronavirus to a harmless chimpanzee adenovirus. They have completed their trials in the UK and Brazil and the one in USA is also near completion. According to the press release, their vaccine is effective in 70% of the cases. This might sound less impressive compared to the mRNA-based vaccines, but comparison may not be fair. The criteria used for prevention in the mRNA-based vaccines was different than that used in DNA based vaccine. The efficacy may be equivalent. Ultimately the later vaccine may turn out be more useful globally due to much less cost (approximately 1/4th of the mRNA vaccine) and the fact that this vaccine can be stored in ordinary refrigerators.

UK Licenses Vaccine Against COVID-19

The Medicines and Healthcare products Regulatory Authority (MHRA) in the United Kingdom have authorized the Pfizer/BioNTech vaccine for emergency use. The U.K. has already purchased 40 million doses of the vaccine, and the first 10 million doses should arrive this month.

Chairman and chief executive officer of Pfizer, Albert Bourla, says, “Today's emergency use authorization in the U.K. marks a historic moment in the fight against COVID-19. This authorization is a goal we have been working toward since we first declared that science will win, and we applaud the MHRA for their ability to conduct a careful assessment and take timely action to help protect the people of the U.K.”

Pfizer and BioNTech combined believe that they can produce and supply 50 million vaccine doses throughout 2020 and up to 1.3 billion by the end of 2021.

Although the vaccine needs to be kept at -94°F (-70°C), the pharmaceutical companies explain that it can be stored in a standard fridge at 35–46°F (2–8°C) for 5 days.

The first doses are likely to be given to residents and healthcare workers in U.K. care homes. Next, the vaccine will be provided to people over 80 and National Health Service (NHS) staff.

The FDA Move Toward Vaccine Approval

On Tuesday, Food and Drug Administration (FDA) Commissioner Stephen Hahn said it was possible that the FDA would approve Pfizer's experimental vaccine before the end of the year. However, in the ABC News interview, he explained that “it's hard to predict. We need everything to fall into place.”

Next week, Donald Trump, who is keen to leave his mark on the vaccine process, will be meeting with industry and government leaders to discuss the vaccine. In a statement, White House spokesman Brian Morgenstern said:

“President Trump's Operation Warp Speed

continues rapidly advancing toward a safe and effective coronavirus vaccine five times faster than any other vaccine in history."

Moderna Apply for Approval for mRNA Vaccine Candidate in the US and Europe

Today, Moderna announced the completion of their phase 3 clinical trial primary efficacy analysis. The vaccine candidate is 94.1% effective against COVID-19 and 100% effective against severe COVID-19. The company will percent of adults in the U.S. Left untreated, the condition could lead to serious health problems like heart attack and stroke. Though typically managed with statins, some individuals experience unacceptable muscle pain with statins. Bempedoic acid provides an alternative approach to lowering of LDL-cholesterol while avoiding these side effects.

PARP Inhibitors for Maintenance Therapy in Ovarian Cancer

PARP, or poly-ADP ribose polymerase, inhibitors block repair of damaged DNA in tumor cells which increases cell death, especially in tumors with deficient repair mechanisms. One of the most recent important advances ovarian cancer treatment, PARP inhibitors have improved progression-free survival and are now being approved for first-line maintenance therapy in advanced stage disease. Several additional large-scale trials are underway with PARP inhibitors set to make great strides in improving outcomes in cancer therapy.

Drugs for Heart Failure with Preserved Ejection Fraction

Heart failure with preserved ejection fraction (HFpEF) – also known as diastolic heart failure – is the condition in which the ventricular heart muscles contract normally, but do not relax as they should. With preserved ejection fraction, the heart is unable to properly fill with blood – leaving less available to be pumped out to the body. Currently, recommendations for this treatment are directed at accompanying conditions and mere symptom relief. But SGLT2 inhibitors, a class of medications used in the treatment of type 2 diabetes, is now being explored in HFpEF – alluding to a potential new treatment option.

Twincretin 'Impressive': Topline Data from Phase 3 Trial in Diabetes

Updated with comments December 10, 2020 // Tirzepatide, a novel subcutaneously injected drug that acts via two related but separate pathways of glucose control, produced strikingly positive effects in top-line results from the phase 3, placebo-controlled study SURPASS-1 in 478 adults with type 2 diabetes, according to a December 9 press release from the manufacturer, Lilly.

The tirzepatide molecule exerts agonist effects at both the glucose-dependent insulinotropic polypeptide (GIP) receptor and the glucagon-like peptide-1 (GLP-1) receptor, and has been called a "twincretin" for its activity encompassing two different incretins. Phase 2 trial results caused excitement, with one physician calling the data "unbelievable" when reported in 2018.

SURPASS-1 enrolled patients who were very early in the course of their disease, had on average relatively mild elevation in glucose levels, and few metabolic comorbidities. They took one of three doses of the agent (5, 10, or 15 mg) as monotherapy or placebo for 40 weeks.

Julio Rosenstock, MD, said in the Lilly statement: "The study took a bold approach in assessing A1c targets. Not only did nearly 90% of all participants taking tirzepatide meet the standard A1c goal of less than 7%, more than half taking the highest dose also achieved an A1c less than 5.7%, the level seen in people without diabetes."

Rosenstock is principal investigator of SURPASS-1 and director of the Dallas Diabetes Research Center in Texas.

The discontinuation rate in the high-dose group was 21.5% compared with less than 10% in the two lower-dose cohorts. Lilly said most of the dropouts "were due to the pandemic and family or work reasons." The dropout rate in the placebo group was 14.8%.

These data were not included in the efficacy analysis, however, which "muddied" the analysis somewhat, one pharma analyst told BioPharma Dive.

Commenting on the new trial data, Ildiko Lingvay, MD, told *Medscape Medical News*: "I am very impressed with these results," which are "unprecedented for any glucose-lowering medication that has ever been tested."

Lingvay, of the Department of Internal Medicine/Endocrinology, and medical director,

Office of Clinical Trials Management at UT Southwestern Medical Center, Dallas, was not involved in the study.

She added that the weight loss seen with tirzepatide "is equally impressive with greater than 10% of body weight loss above placebo achieved within 40 weeks of treatment and without any directed weight loss efforts."

If the agent is eventually approved, "I am enthusiastic about the prospect of having another very powerful tool to address both diabetes and apply today for emergency use approval in the United States.

In addition, it will also apply to the European Medicines Agency for conditional marketing authorization.

In a press release, Moderna highlighted that 196 people enrolled in their 30,000-participant trial have now had COVID-19. Of them, 11 were in the group that had received the vaccine.

There were 30 cases of severe COVID-19, all in the placebo group. One person in this group died.

The 196 cases of COVID-19 in the study occurred among diverse participants, including older adults and those from minority ethnic groups.

The company stressed that they will submit the results of the study to a peer reviewed journal.

Cleveland Clinic Unveils Top 10 Medical Innovations for 2020

A panel of top doctors and researchers presents the medical advancements with the power to transform healthcare in the next year

Dual-Acting Osteoporosis Drug

Osteoporosis is a condition in which bones become weak and brittle, effectively increasing their risk of breaking. With osteoporosis, the loss of bone occurs silently and progressively – often without symptoms until the first fracture. Providing more bone-strengthening power, the recent FDA approval of a new dual-acting drug (romosozumab) is giving patients with osteoporosis more control in preventing additional fractures.

Expanded Use of Minimally Invasive Mitral Valve Surgery

The mitral valve allows blood flow from the heart's left atrium to the left ventricle. But in about 1 in 10 individuals over the age of 75, the mitral valve is defective causing the action of regurgitation. Expanding the approval of a minimally invasive valve repair device to a population of patients who have failed to get symptom relief from other therapies provides an important new treatment option.

Inaugural Treatment for Transthyretin Amyloid Cardiomyopathy

A disheartening cardiovascular disorder, ATTR-CM is a progressive, underdiagnosed, potentially fatal disease in which amyloid protein fibrils deposit in, and stiffen, the walls of the heart's left ventricle. But a new agent to prevent misfolding of the deposited protein is showing a significantly reduced risk of death. Following Fast-Track and Breakthrough designations in 2017 and 2018, 2019 marked the FDA approval of tafamidis, the first-ever medication for treatment of this increasingly recognized condition

.4. Therapy for Peanut Allergies

It's a terrifying reality for 2.5 percent of parents – the possibility that at any moment, their child might be unable to breathe due to an allergic reaction. Though emergency epinephrine has reduced the severity and risk of accidental exposure, these innovations are not enough to quell the ever-present anxiety. But development of a new oral immunotherapy medication to gradually build tolerance to peanut exposure holds the opportunity to lend protection against attack.

Closed-Loop Spinal Cord Stimulation

Chronic pain is a terribly frustrating condition, and a large reason for prescription of opioid medication. Spinal cord stimulation is a popular treatment for chronic pain through which an implantable device provides electrical stimulus to the spinal cord. But unsatisfactory outcomes due to subtherapeutic or overstimulation events are common. Closed-loop stimulation is allowing for better communication between the device and the spinal cord providing more optimal stimulation and relief of pain.

Biologics in Orthopaedic Repair

After orthopaedic surgery, the body can take anywhere from months to years to recover. But biologics – cells, blood components, growth factors, and other natural substances – have the power to replace or harness the body's own power and promote healing. These elements are finding their way into orthopaedic care, allowing for the

possibility of expedited improved outcomes.

Antibiotic Envelope for Cardiac Implantable Device Infection Prevention

Worldwide, roughly 1.5 million patients receive an implantable cardiac electronic device every year. In these patients, infection remains a major, potentially life-threatening complication. Antibiotic-embedded envelopes are now made to encase these cardiac devices, effectively preventing infection.

Bempedoic Acid for Cholesterol Lowering in Statin Intolerant Patients

High cholesterol is a major concern for nearly 40very powerful tool to address both diabetes and obesity," she added. The full results of SURPASS-1 will be presented at the American Diabetes Association 81st Scientific Sessions and published in a peer-reviewed journal in 2021.

PSIM News

Flagship conference of PSIM was held from 13th to 15th March 2020 in Lahore with the theme "Evidence Innovation and Leadership for Physicians". Conference attracted more than 1000 participants from across the country.

National and international esteemed faculty from all disciplines of medicines shared updated knowledge and delivered talks. 12 preconference workshops, Poster presentation competition and first Convocation of PSIM was also part of the program. Pride of Pakistan, World famous Scientist Dr. Atta ur Rehman was the chief guest of the convocation where eligible physicians were awarded Associate fellowship and Fellowship of PSIM. Inaugural ceremony of the conference was honoured by Presence of Prof Khawaja Sadiq Hussain along with principals, vice chancellors of medical universities and senior physicians of the country. Prof. Aftab Mohsin was the Chairman Organizing Committee.

A three days certified online course A-Z of Hypertension was successfully conducted by PSIM, Prof Aziz Ur Rehman SVP PSIM as course director from 14th to 16th August 2020 .Course was attended by more than 300 participants .Course was designed to meet the educational needs of physicians in primary care, family practice, cardiology, internal medicine, nephrology and endocrinology and included 12 eminent speakers from all over Pakistan. On the successful completion of course and wonderful response from members, PSIM is starting 3 months certified international hypertension course in May 2021.

Midsummer meeting of PSIM was held in Muzaffarabad in collaboration with Azad Jammu & Kashmir Medical College from 3rd to 5th September 2020. Meeting included pre-conference workshops, state of the art lectures, public awareness seminar and grand round. Renowned faculty from all over Pakistan imparted knowledge to physicians, residents and students. Conference was very well attended by more than 300 delegates from around Pakistan.

KPK Chapter PSIM held a launch ceremony with CME activity at Khyber Medical University on 26th Sept 2020.Activity was attended by physicians from Peshawar Swat Mardan, Swabi , Sawat and Abbotabad. Prof Amir Ghafoor VP KPK PSIM was the chief organizer of the event.

Updates on Diabetes, 6-Month Online International Diabetes Course, organized by National Diabetes Chapter, Pakistan Society of Internal Medicine was initiated on 27th Sep 2020. This course has completed its 11 modules out of 24 modules with 500 registered participants successfully. This course has many renowned National speakers & panelists. International Speakers from around 9 countries worldwide are also the part of the faculty in this course. This Online course is the initiative from Pakistan Society of Internal Medicine, under the patronage of Course Director, Prof. M. Zaman Shaikh and it will end on 14th Mar 2021.

Balochistan Chapter PSIM was formally launched in Quetta on 26th Oct 2020 with a CME activity followed by Inaugural Ceremony. Governor Balochistan was the chief guest of the event. Prof Abdul Baqi was nominated VP Baloschistan PSIM.

PSIM celebrated World Diabetes Day on 14th November 2020 by holding six different interactive workshops on different aspects of

Diabetes. Prof. Sajid Abaidullah VP Punjab was the incharge of this event in Punjab while in Sindh Prof. Zaman Sheikh (Diabetes Chair PSIM) and Prof. Bikha Ram Devrajani (VP Sindh) arranged symposia in Karachi and Hyderabad respectively. PSIMRA (Pakistan Society of Internal Medicine Research Award) for young physicians, clinicians and researchers was announced to promote the culture of innovation and research in the field of medicine. These awards are a step to foster research ecosystem in the field of medicine. HealthRAB and Pharm Evo are collaborating partners of PSIM in these awards. Abstract submissions are open.