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Novel Therapeutic & Prevention Approaches to the Novel Coronavirus

Announcer:
You're listening to *The Drug Report* on ReachMD, hosted by Linda Bernstein, Pharm.D., Clinical Professor on the Volunteer Faculty of the School of Pharmacy, University of California, San Francisco.

Dr. Bernstein:
Welcome to *The Drug Report* with a special focus on the COVID-19 pandemic.

Researchers all over the world are trying many novel approaches to conquering the Novel Coronavirus, cause of the current deadly pandemic. Let's look at a few of these approaches and what they may mean for today and potential viral mutations going forward.

Celltrion Group, through a partnership with the Korea Centers for Disease Control and Prevention (KCDC), narrowed their top neutralizing antibody candidates to 14 of the most powerful and will begin cell-line development. They hope to roll out mass production of the therapeutic antibody and, together with the KCDC, conduct efficacy and toxicity testing in mice and non-human primates. Ki-Sung Kwon, Head of R&D Unit at Celltrion said, "These antibodies can recognize multiple epitopes, thus increasing the probability of nonspecific antigen binding. We anticipate moving to first-in-human clinical trials in July. We are also on track with the development of a 'super antibody' or 'an antibody cocktail' and the launch of a rapid self-testing diagnostic kit in the summer of this year."

Regeneron is trying two approaches to COVID-19. Based on recent clinical data from studies in China with another IL-6 inhibitor, they believe there is a potential role for *Kevzara® (sarilumab)* in the treatment of severe and critical hospitalized patients with COVID-19. Together with Sanofi, they are conducting controlled clinical trials to evaluate Kevzara in this setting on an investigational basis.The global trial program is now enrolling patients at medical centers in the United States, Italy, Spain, Germany, France, Canada, and Russia.

Regeneron is also looking to develop a novel multi-antibody cocktail that can be administered as prophylaxis before exposure to the SARS-CoV-2 virus or as treatment for those already infected. Hundreds of virus-neutralizing, fully human antibodies have been isolated from the company's mice which have been genetically modified to have a human immune system. Regeneron has also isolated antibodies from humans who have recovered from COVID-19 in order to maximize the pool of potentially potent antibodies. From this large pool of candidates, Regeneron will select the top two antibodies for a 'cocktail' treatment based on potency and binding ability to the SARS-CoV-2 spike protein, as well as other desirable qualities. Using a multi-antibody approach allows for targeting of different parts of the virus and may help protect against multiple viral variants. They used similar technologies to rapidly develop a treatment for Ebola virus infection, which is currently under review by the U.S. Food and Drug Administration.

Eli Lilly, in conjunction with the National Institute of Allergy and Infectious Diseases, is planning to test rheumatoid arthritis drug Olumiant (baricitinib), a Janus kinase (JAK) inhibitor, in patients hospitalized with COVID-19. The study is starting this month in the U.S., and investigators plan expanded testing to Europe and Asia.

Meanwhile, Lilly also unveiled plans to test an investigational monoclonal antibody, LY3127804, in pneumonia patients hospitalized with COVID-19. That trial is starting later this month in the U.S.

Roche has announced that the US Food and Drug Administration (FDA) has formally approved its phase 3 trial of Actemra in severely ill COVID-19 patients who have been hospitalized with pneumonia. Actemra (tocilizumab) – an interleukin-6 inhibitor – has already been approved in China for the treatment of patients infected with the novel coronavirus disease who have developed serious lung damage and also have elevated levels of IL-6 in the blood. Previous research has suggested that elevated IL-6, a biomarker for inflammation and a high-level immune response, is associated with a higher mortality in people with community-acquired pneumonia.

Japanese company Fujifilm has launched a Phase II clinical trial of its influenza drug Avigan (favipiravir) to treat COVID-19 patients in the US. It will also be tested on 80 patients at Hadassah Hospital in Israel. Approved in 2014 in Japan, Avigan specifically targets RNA polymerase required for influenza virus replication. This mechanism is also expected to have an antiviral effect on the novel coronavirus, which is a single-stranded RNA virus similar to influenza and requires viral RNA polymerase. For the new study in the US, around 50 coronavirus patients will be enrolled at Brigham and Women's Hospital, Massachusetts General Hospital, and the University of Massachusetts Medical School. The trial will evaluate the drug's safety and efficacy as a potential COVID-19 therapy.

Finally, Johnson & Johnson announced the selection of a lead COVID-19 vaccine candidate from constructs it has been working on since January 2020 and by rapid scaling of the company's manufacturing capacity they hope to provide a global supply of more than one billion doses of a vaccine. The company expects to initiate human clinical trials of its lead vaccine candidate at the latest by September 2020 and anticipates the first batches of a COVID-19 vaccine could be available for emergency use authorization in early 2021, a pace they state is substantially accelerated in comparison to the typical vaccine development timeframe.

For more information on COVID-19 treatment and prevention studies, see clinicaltrials.gov.

For *The Drug Report*, I'm pharmacist Dr. Linda Bernstein.

Announcer:
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