

24 Mar 2020 |

Coronavirus Update: South Korea's Celltrion Progresses Antibody, Yancopoulos: 'The World Is Counting On Us'

Antibody Therapies Could Ease Huge Burden On Emergency Care

by Scrip Team

Regeneron's head of R&D George Yancopoulos delivers some stirring words about the need to unify against the global threat posed by COVID-19.

Regeneron's Yancopoulos: 'The World Is Counting On Us'

While some politicians have fallen short of delivering stirring messages to bring hope and unify the world against COVID-19, it seems that some biopharma leaders are able to take on this responsibility.

Step forward George Yancopoulos, <u>Regeneron Pharmaceuticals Inc.</u>'s president and chief scientific officer, who spoke yesterday at the Bio-Europe Spring 'virtual conference' alongside many other biopharma leaders working on answers to the pandemic. They included Stéphane Bancel, CEO of <u>Moderna Inc.</u>, which could be the first company to develop a vaccine against the virus.

While Yancopoulos said an active vaccine would probably be the "final answer" to COVID-19, he said patients with the most acute respiratory illness, which is killing patients and overwhelming hospitals in Italy and Iran and beyond, could benefit from more rapidly developed therapies, including Regeneron's own antibody-based therapies. (Also see "*Sanofi And Regeneron Initiate* 400-Patient Coronavirus Trial With Kevzara" - Scrip, 16 Mar, 2020.)

But most of all, Yancopoulos said, a unified and creative approach to working across boundaries will help the world beat the pandemic.

"This crisis is a great opportunity to show that we can



REGENERON'S GEORGE YANCOPOULOS

all come together, all sides of humanity, to show that we really are one," he said. "We can rise above [it]; we can beat this. It's great to have all these opportunities to collaborate with all members of ecosystem, those on the academic side, on the medical institution side.

"I can call anybody in the industry, I can call up the head of R&D at Pfizer, Michael Dolstein. And his first question is: 'What can we do to help?' People calling us up and say: 'Hey, your antibodies which were used in Ebola... looks like they may be the first nearest term thing [to work] here - can we help?' Manufacturers say can we give you capacity...everybody's just pulling together and saying what can we do."

He said his company was in an ongoing discussion with Moderna about using its RNA platform to deliver Regeneron antibodies to some patients, reflecting what he said was a creative and united mindset across the sector. He also praised the US Food and Drug Administration, which he said had been collaborating closely with Regeneron, and matching its employees' around-the-clock working hours to speed progress against the pandemic.

"Like I said, it's a great opportunity to show that as an industry we're really the good guys and we can really make a difference, we can maybe save the world. In fact, I think the world is counting on us."

He concluded: "I think it's a time to step up and show that we're going to help each other out, whether it's going to visit an elderly person, going to deliver masks to somebody, you know, doing the right thing. So I hope [we can do this] within the industry, regulators, anywhere in our ecosystem, just in terms of humanity helping humanity. I think this is time for us to show we're all in it together."

South Korea's Celltrion Progresses Antibody Therapy and Diagnostic

South Korea has been an outlier among nations in curbing the spread of the coronavirus, a success attributed to its swift action on restricting movement and using mass testing to identify and isolate cases. Now one of its leading biosimilar companies is joining efforts to develop therapies and diagnostics.

<u>Celltrion Inc.</u> has completed early development of a possible antibody therapeutic against the coronavirus, identifying a library of antibodies sourced from the blood of recovered patients in



the country that might neutralize the virus.

These are being screened now, with local and global trials planned for the third quarter after expedited discussions with authorities over validated study designs.

Ki-Sung Kwon, the company's head of R&D, said the aim was to find an optimized antibody by the end of July that block the spike (S) glycoprotein the virus uses to enter human cells. Chairman Jungjin Seo predicted Celltrion might be able to supply any resulting product to about one million people per month, but that it will determine capacity after considering general inventory levels and shipments. At present, it has inventories of more than a year for its products but is in discussions with a potential contract manufacturer.

Celltrion aims to export excess supplies after treating South Korean patients, and the government has to discuss and co-operate over supplies with other countries, Seo noted.

The company also aims to launch a 15-20 minute, rapid antibody-based self-testing kit for the SARS-CoV-2 antigen in the summer, focusing again on the gene that encodes the S protein. There are plans to make this available in Europe through Celltrion Healthcare and for approvals in the US and elsewhere. At present, an antibody-based test is used and a separate RT-PCR test is required.

Junshi and IMCAS Join Forces To Develop Antibody Therapy

Shanghai Junshi Biosciences Co., Ltd. is to collaborate with the Institute of Microbiology of the Chinese Academy of Sciences (IMCAS) to develop novel coronavirus-neutralizing antibodies (NAbs).

The partners say NAbs also potentially facilitate virus clearance and can be readily mass-produced.

The companies have obtained multiple strains of NAbs capable of blocking viral cell invasion in laboratory assays and conducted preclinical studies, with a view to filing INDs with domestic and overseas regulatory agencies.

Junshi was established in 2012 and listed in Hong Kong in late 2018, and already has an R&D pipeline of 20 drug candidates including in cancer and

Inside The COVID-19 Pipeline

By Bridget Silverman

20 Mar 2020

Updated daily as additional research gets underway, this pipeline tracker follows the global effort to find drugs that could help treat



metabolic diseases.

Cellenkos Files Cell Therapy Study For Covid-19 ARDS

Houston, TX-based Cellenkos Inc. a subsidiary of Hong Kong-listed *Golden Meditech Holdings Ltd.* is developing a cell therapy for acute respiratory distress

COVID-19 and the symptoms it causes, and accelerate a vaccine that could help limit the spread of the pandemic.

Read the full article here

syndrome (ARDS) associated with COVID-19. The company has submitted a clinical development proposal to the Biomedical Advanced Research and Development Authority (BARDA) to start a Phase I/II clinical trial with CK0802. Cellenkos hopes to leverage its clinical experience with CK0802 for other inflammatory disorders, including amyotrophic lateral sclerosis.

KN0802 is a novel allogenic cell therapy, consisting of TREG cells derived from clinical-grade umbilical cord blood units, developed from Cellenkos' proprietary manufacturing platform, that overcomes immune dysfunction by resolving chronic inflammation

Cellenkos currently holds two INDs from US FDA for inflammatory bone marrow failure and for Guillain-Barré syndrome.