

AiPharma signs production and distribution deal for China and the Russian Federation with FUJIFILM for Avigan®

Agreement will boost global production, distribution of Avigan

Ireland, Dublin, Jun 14, 2021 ([Issuewire.com](https://www.issuewire.com)) - AiPharma signs production and distribution deal for China and the Russian Federation with FUJIFILM for its influenza antiviral drug Avigan® for COVID-19

AiPharma, a Biotechnology company headquartered in Ireland announced that it has signed an exclusive manufacturing and distribution deal for China and the Russian Federation with

FUJIFILM Toyama Chemical Co., Ltd. for its influenza antiviral drug "Avigan®" (generic name: favipiravir) for treating patients with COVID-19 and potentially other future indications.

FUJIFILM has established strategic partnerships with domestic and overseas companies for various manufacturing processes to source raw materials and pharmaceutical substances to further scale capabilities to meet the growing demand for the COVID-19 treatment.

The agreement will cover manufacturing and distribution for China and Russia, which are home to 1.5 billion of the world's 7.8 billion people.

Avigan, approved in Japan as an influenza antiviral drug, selectively inhibits viral RNA polymerase necessary for influenza virus replication. Due to this mechanism of action, Avigan may have an anti-viral effect on the SARS-CoV-2 coronavirus, because, like influenza viruses, coronaviruses are single-stranded RNA viruses that also depend on viral RNA polymerase.

FUJIFILM will be able to allocate additional capacity for the production of the pharmaceutical intermediates used to manufacture Avigan and has established strategic partnerships with domestic and international companies to source raw materials and pharmaceutical substances.

"It is our goal to making Avigan available to as many people around the world as possible," said Mary O'Brien, Director of AiPharma. "We are building distribution networks to support and scale our global objective. AiPharma is in discussion with a number of contract manufacturing companies in Ireland to produce Avigan for the Russian market, we expect to complete these negotiations in the coming weeks and to initiate the technology transfer process."

"We believe this partnership creating access to Russia and China will further strengthen the position of Avigan is one of the most promising broad-spectrum anti-viral for COVID-19, Influenza, and for all the further potential indications. We expect ramping up production to serve these two large markets immediately" Junji Okada, President FUJIFIL Toyama Chemical Co., Ltd

One of AiPharma's portfolio companies is Global Response Aid, a joint venture with Agility (KSE/DFM: AGLTY), who, together with an appointed CMO, has the exclusive worldwide license outside Japan, China, and Russia with FUJIFILM Corporation (TYO/4901:FUJIY) for the development, production, and distribution of Avigan. Avigan is already approved in several countries as a treatment for COVID-19. Including India,

Indonesia, Malaysia, and Thailand. In a seven-month period, more than 11 million tablets of Avigan

were purchased in secondary markets generating revenues of over USD 33 million. In a separate deal with

Fujifilm, the Japanese government has also stockpiled over 65 million tablets. As recently announced by Global Response Aid, a Phase 3 US-Canada clinical trial of Avigan, after a positive interim analysis, will continue evaluating its efficacy for outpatient treatment of subjects with mild to moderate cases of COVID-19 and will publish results by Q3.

AiPharma and GRA are working to further strengthen the clinical development of the drug by initiating a series of planned clinical studies on reducing hospitalization rates of high-risk populations and post-exposure prophylaxis usage of Avigan to prevent the spread of COVID-19.

About AiPharma

AiPharma is a biopharmaceutical company focused on discovering, developing, and commercializing oral therapies to address the unmet medical needs of patients with life-threatening viral diseases. Leveraging the Company's deep understanding of antiviral drug development, nucleotide chemistry, biology, biochemistry, and virology, AiPharma has built a nucleotide prodrug platform to develop novel product candidates to treat single-stranded ribonucleic acid, or ssRNA, viruses, which are a prevalent cause of severe viral diseases. Currently, AiPharma is focused on the clinical and commercial development of orally available, potent, and selective nucleotide prodrugs for difficult-to-treat, life-threatening viral infections, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, dengue virus, hepatitis C virus (HCV) and respiratory syncytial virus (RSV). AiPharma also holds exclusive commercial rights for Avigan in Russia and China.

For more information, please visit www.aipharmalab.com

About Global Response Aid

AiPharma, innovative pharma research, development, and commercialization company, and Agility (KSE/DFM: AGLTY), a leading logistics company, established Global Response Aid to address the market challenges created by the COVID-19 pandemic and other threats to public health. GRA delivers innovative, effective healthcare solutions through a range of pharmaceutical products and technology platforms. It works closely with governments, regulatory authorities, hospitals, clinics, healthcare providers, life sciences companies, NGOs, and public institutions to develop strategies that allow them to tackle public health challenges.

For more information, please visit www.globalresponseaid.com

About Avigan® (favipiravir)

Avigan® (favipiravir) / Reeqonus (For the Americas' market) is a broad-spectrum antiviral in oral tablet form developed by FUJIFILM Toyama Chemical Co., Ltd. (FFTC) and approved in Japan as a treatment and stockpile countermeasure for pandemic influenza. Following promising clinical studies, Russia, Thailand, Indonesia, India, and Malaysia approved favipiravir-based antiviral medications for the emergency treatment of COVID-19.

Additional clinical trials for favipiravir in COVID-19 are ongoing in the United States, China, and the United Kingdom. Unlike most other interventions that researchers are evaluating in the COVID-19 indication, favipiravir has already been thoroughly studied in human trials outside of North America and has a known safety profile, with over 3,000 subjects receiving at least one dose of the drug in controlled clinical trials, and more than 30,000 people having received Avigan in Observational Studies. The safety profile has been further confirmed by the hundreds of thousands of patients that have received favipiravir during the COVID-19 pandemics in the authorized countries. Favipiravir's oral tablet form may also provide advantages in the community setting over other COVID-19 interventions, which often require injection or intravenous administration.

About FUJIFILM

FUJIFILM Toyama Chemical Co., Ltd. conducts the research, development, manufacture, and sales of radiopharmaceuticals and small molecule pharmaceutical products. Under close cooperation with FUJIFILM Corporation, it aims to develop innovative diagnostic and therapeutic radiopharmaceuticals, as well as therapeutic drugs having unique mechanisms of action in the fields of "oncology," "central nervous system diseases," and "infectious diseases" where significant unmet medical needs still exist. It also works to develop new medicines utilizing drug delivery system (DDS) technologies, designed to deliver the required amount of a drug in a timely manner to the specific body area. By exploring synergy with in vitro diagnostic devices and reagents owned by FUJIFILM group companies, the company will expand its offering of comprehensive solutions from diagnosis to treatment. FUJIFILM Toyama Chemical Co., Ltd. has expanded its business areas to medical IoT solutions including a system to support pharmacists' drug dispensing auditing work, and a transportation device that enables strict temperature control suited for blood products, cells, and tissue used for regenerative medicine. Through the development and supply of high-quality, high added-value new drugs and products that support the clinical settings, FUJIFILM Toyama Chemical Co., Ltd. strives to solve various social challenges and contribute to improving medicine and enhancing the quality of life. For more information, please visit <http://fftc.fujifilm.co.jp/en/>

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