

Roche announces collaboration with Atea Pharmaceuticals to develop a potential oral treatment for COVID-19 patients

- **Roche and Atea partner to jointly develop AT-527, an orally administered direct-acting antiviral (DAA) currently in Phase 2 clinical trials**
- **AT-527 has the potential to be the first novel oral antiviral to treat COVID-19 patients outside the hospital setting as well as in the hospital and may also be used in post-exposure prophylactic settings**
- **Oral, small-molecule DAAs for COVID-19 patients allow for large-scale manufacturing and facilitate broad patient access**
- **If approved, Atea will distribute AT-527 in the United States and Roche will be responsible for global manufacturing and distribution outside the United States**

Basel, 22 October 2020 - Roche (SIX: RO, ROG; OTCQX: RHHBY) and Atea Pharmaceuticals, Inc. announced today that they are joining forces in the fight against COVID-19 to develop, manufacture and distribute AT-527, Atea's investigational oral direct-acting antiviral, to people around the globe. AT-527 acts by blocking the viral RNA polymerase enzyme needed for viral replication, and is currently being studied in a Phase 2 clinical trial for hospitalised patients with moderate COVID-19. A Phase 3 clinical trial, expected to start in Q1 2021, will explore the potential use in patients outside of the hospital setting. In addition, AT-527 may be developed for post-exposure prophylactic settings.

AT-527, while being a potential oral treatment option for hospitalised patients, also holds the potential to be the first oral treatment option for COVID-19 patients that are not hospitalised. Additionally, the manufacturing process of small-molecule DAAs allows the ability to produce large quantities of a much needed treatment. If successful, AT-527 could help treat patients early, reduce the progression of the infection, and contribute to decreasing the overall burden on health systems.

The collaboration aims to accelerate the clinical development and manufacturing of AT-527, to investigate its safety and efficacy, and to provide this potential treatment option to patients around the world as quickly as possible. If AT-527 proves safe and effective in clinical trials and regulatory approvals are granted, Atea will be responsible for distributing this treatment option in the U.S, with the option to request Genentech's support, and Roche will be responsible for distribution outside the United States.

"The ongoing complexities of COVID-19 require multiple lines of defence. By joining forces with Atea, we hope to offer an additional treatment option for hospitalised and non-hospitalised COVID-19 patients, and to ease the burden on hospitals during a global pandemic." said Bill Anderson, Chief Executive Officer of Roche Pharmaceuticals. "In jointly developing and manufacturing AT-527 at scale, we seek to make this treatment option available to as many people around the world as we possibly can."

“Roche shares our passion for delivering innovative new medicines to address great unmet medical needs. The COVID-19 pandemic has highlighted the urgent need for a novel, oral antiviral to treat this highly infectious and often deadly virus,” said Jean-Pierre Sommadossi, Ph.D., Chief Executive Officer and Founder of Atea Pharmaceuticals. “AT-527 is expected to be ideally suited to combat COVID-19 as it inhibits viral replication by interfering with viral RNA polymerase, a key component in the replication machinery of RNA viruses. Importantly, the manufacturing process for our small molecule direct-acting antiviral allows us to produce AT-527 quickly and at scale.”

About AT-527

AT-527 is an investigational, oral, purine nucleotide prodrug, which has demonstrated in vitro and in vivo antiviral activity against several enveloped single-stranded RNA viruses, including human flaviviruses and coronaviruses. This highly selective purine nucleotide prodrug was designed to uniquely inhibit viral RNA dependent RNA polymerase, an enzyme that is essential for the replication of RNA viruses. Antiviral activity and safety of AT-527 has been demonstrated in Phase 2 clinical studies of hepatitis C patients, and in preclinical in-vitro assays with SARS-CoV2 virus. AT-527 is not yet licensed or approved for any indication in the United States or any other country.

About Roche’s response to the COVID-19 pandemic

As a leading healthcare company we are doing all we can to support countries in minimising the impact of COVID-19. We have developed a growing number of diagnostic solutions that help to detect and diagnose the infection in patients, as well as providing digital support to healthcare systems, and we continue to identify, develop and support potential therapies which can play a role in treating the disease.

We understand the impact of COVID-19 goes beyond those who contract it, which is why we are working with healthcare providers, laboratories, authorities and organisations to help make sure that patients continue to receive the tests, treatment and care they need during these challenging times. As we learn from the pandemic, we are partnering with governments and others to make healthcare stronger and more sustainable in the future.

Our diagnostics solutions:

Reliable, high-quality testing is essential to help healthcare systems overcome this pandemic. Our portfolio includes:

- a high-volume molecular test to detect SARS-CoV-2, the virus that causes COVID-19, (FDA Emergency Use Authorisation (EUA) and available in countries accepting the CE Mark)
- a SARS-CoV-2 laboratory-based antibody test, aimed at detecting the presence of antibodies in the blood targeting the nucleocapsid (FDA EUA and CE Mark)
- an IL-6 test to assist in identifying severe inflammatory response in patients with confirmed COVID-19 (FDA EUA and CE Mark)
- Roche v-TAC, which could help simplify the screening, diagnosis and monitoring of patients with respiratory compromise in the current COVID-19 pandemic

- a SARS-CoV-2 rapid antibody test to help determine at the point of care whether a person has been exposed to the virus (CE Mark)
- a rapid antigen test to support in the detection of SARS-CoV-2 at the point of care within 15 minutes (CE Mark)
- a high-volume molecular test to simultaneously detect and differentiate between SARS-CoV-2 and influenza A/B, as the symptoms are similar for both (FDA EUA and CE Mark)
- a second SARS-CoV-2 antibody test, aimed at measuring the spike protein to support vaccination development and complement our existing portfolio
- a point-of-care molecular PCR test that simultaneously detects and differentiates between SARS-CoV-2 and influenza A/B infections to support urgent triage and diagnosis (FDA EUA and CE Mark)

Our research into therapies:

Roche is committed to improving the treatment of COVID-19. We are actively involved in understanding the potential of our existing portfolio and are exploring the potential of our investigational molecules.

In August, we announced a partnership with Regeneron to develop, manufacture, and increase global supply of their investigational antibody combination for COVID-19 if it proves safe and effective in clinical trials and regulatory approvals are granted.

At the beginning of the pandemic, on 19 March, we announced the initiation of COVACTA - a global Phase III randomised, double-blind, placebo-controlled clinical trial to evaluate the safety and efficacy of intravenous Actemra®/RoActemra® (tocilizumab) plus standard of care in hospitalised adult patients with severe COVID-19 pneumonia compared to placebo plus standard of care. On 29 July we announced that COVACTA did not meet its primary endpoint of improved clinical status in patients with COVID-19 associated pneumonia or the key secondary endpoint of reduced mortality.

Separately, we have studied Actemra®/RoActemra® in the EMPACTA study in COVID-19 associated hospitalised pneumonia in patients that are often underrepresented in clinical trials. On 18 September we announced that the phase III EMPACTA study showed Actemra®/RoActemra® plus standard of care reduced the likelihood of progression to mechanical ventilation or death in hospitalised patients with COVID-19 associated pneumonia compared to placebo plus standard of care. However, there was no statistical difference in mortality between patients who received Actemra®/RoActemra® or placebo.

Actemra®/RoActemra® is also being studied in combination with the investigational antiviral remdesivir in hospitalised patients with severe COVID-19 pneumonia in the REMDACTA trial in partnership with Gilead, announced 28 May. Actemra®/RoActemra® is not approved by any health authority for use in COVID-19 pneumonia. Roche has further initiated an internal early research programme focused on the development of medicines for COVID-19 and is engaged in multiple research collaborations.

In these exceptional times, Roche stands together with governments, healthcare providers and all those working to overcome the pandemic.

About Roche

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims to improve patient access to medical innovations by working with all relevant stakeholders. More than thirty medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and cancer medicines. Moreover, for the eleventh consecutive year, Roche has been recognised as one of the most sustainable companies in the Pharmaceuticals Industry by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2019 employed about 98,000 people worldwide. In 2019, Roche invested CHF 11.7 billion in R&D and posted sales of CHF 61.5 billion. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit www.roche.com.

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