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CHUGAI

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Chugai in-licenses New Oral Drug Candidate for COVID-19 from Roche

- Chugai obtained exclusive development and marketing rights in Japan from Roche for AT-527 as an oral therapy for COVID-19
- A phase II clinical study of AT-527 is currently ongoing in COVID-19 patients

TOKYO, February 19, 2021 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that it concluded a license agreement with Roche (SIX: RO, ROG; OTCQX: RHHBY) for the development and marketing in Japan for AT-527, a new oral drug candidate for COVID-19.

AT-527 was created by Atea Pharmaceuticals (Nasdaq: AVIR) in the U.S. as a direct-acting antiviral drug to inhibit viral RNA polymerase, an enzyme that is essential for the replication of RNA viruses. It is being investigated as a potential oral treatment for COVID-19. Roche and Atea have partnered to jointly develop AT-527. 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. Under the license agreement between Roche and Chugai, Chugai obtained exclusive development and marketing rights in Japan for AT-527.

Globally, phase II clinical studies are currently ongoing in patients with moderate COVID-19 requiring hospitalization and patients with mild to moderate COVID-19 who are not hospitalized. A phase III clinical study is expected to start in the first half of 2021 to evaluate the efficacy and safety of AT-527 for patients with mild or moderate COVID-19 outside of the hospital settings.

“The COVID-19 pandemic shows no signs of slowing with the spread of COVID-19 variants, and new therapeutic options are still required. We have a strong sense of mission to develop AT-527 in collaborative efforts with Roche and Atea, to contribute to a wide range of patient care from mild to moderate,” said Chugai’s President and COO, Dr. Osamu Okuda. “We are committed to make efforts for regulatory application in Japan to deliver AT-527 as a convenient oral antiviral drug to patients as soon as possible.”

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 II 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 any country.

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