

# **Astellas' Efforts Against the Spread of the Coronavirus Disease (COVID-19)**

*November 19, 2021*

With the continuing spread of COVID-19, we are, as part of our mission as a pharmaceutical company, taking various actions and measures to contribute to securing the safety of patients and alleviating strain on healthcare resources. The following are our activities and status to date in areas including the stable supply of products, contribution to the R&D of drugs, and assistance to regions where infection is spreading.

## **Continuation of business and maintaining a stable supply of products**

We are currently advising our employees to combine working at an office and working from home in accordance with the situation in each country and region to secure the safety of our employees and to prevent the further spread of the disease. While taking measures to prevent the spread of the disease, we are continuing to gather and provide necessary information to medical institutions in regions around the world consistent with the rules of each respective institution with regards to sales activities.

While placing the highest priority on the safety of our employees, in order to continue our social mission of ensuring a stable supply of drugs, quality control, managing safety, and providing information, our essential business continues to be carried out with strict measures taken to prevent infections.

As for the supply of products, in particular, there are currently no issues caused by COVID-19, as we have been able to manage risks around procuring raw materials and distributing finished products by closely cooperating with suppliers and manufacturers taking into account business continuity and at stable supply.

## **For ensuring patient safety and alleviating strain on healthcare resources**

In an effort to help ensure patient safety and alleviate strain on healthcare resources as the COVID-19 pandemic continues, Astellas is continuing to implement the following actions to our clinical trial operations.

- In countries and regions with continuing spread of COVID-19, we temporarily suspended start-up activities and new enrollment for interventional clinical studies. But all clinical trial related activities have resumed in all regions, following the benefit-risk assessment of each study.
- Consistent with the issued guidance from regulatory bodies of each country, we assessed protocols and implementing measures to reduce the burden on healthcare systems while

ensuring that the maintenance of patient safety.

- Furthermore, in order to prioritize patient safety, we also provided measures, when applicable, such as remotely monitoring the safety of a patient via phone, conducting necessary medical exams at medical institutions close to a patient's home outside of the trial site, and/or sending investigational drug to a patient's home, in case a patient could not visit the trial site designated in the protocol.
- In counties and regions where the COVID-19 pandemic continues and our clinical trials are ongoing, trial activities are being modified based on local condition and restriction for patients and study sites to flexibly respond to changes related to the ongoing pandemic.
- Accommodations for remote patient participation and remote monitoring activities, continue, as outlined in the clinical protocol, or as necessitated by local restriction.
- We will be frequently reassessing this approach, which applies to all interventional clinical trials led by us and our group companies. However, a different approach may be implemented for some clinical trials led by our collaboration partners.

We remain focused on ensuring patient safety, while maintaining regulatory compliance and data integrity across clinical development programs.

### **Contributing to the R&D of drugs**

We have taken appropriate actions, such as provide drugs, by cooperating with bodies concerned in response to requests by the government.

In Japan, we have provided compounds in response to a request from the Ministry of Health, Labour and Welfare and National Institute of Infectious Diseases to cooperate in the "Basic Screening Plan for Drugs for Coronavirus Disease."

In addition, we are conducting collaborative research with The Japanese Association for Infectious Diseases for the purpose of exploring the risk factors relevant to severe COVID-19 in Japanese. We hope that the results of this collaborative research will be leveraged in the diagnosis, treatment, and prevention of COVID-19 in the future.

We also responded to requests from the European Federation of Pharmaceutical Industries Associations (EFPIA) and the Innovative Medicines Initiative (IMI) to cooperate in the "Activities Aimed at Developing Drugs for the Novel Virus" and providing consultation on countermeasures.

Astellas Pharma Europe Ltd. is a member of the CARE (Corona Accelerated R&D in Europe) Consortium, the largest initiative in Europe addressing the challenges of COVID-19. CARE is funded by IMI, a public-private partnership aiming to speed up the development of better and safer medicines for patients. The goal of the CARE consortium is to deliver treatments for the current COVID outbreak as well as future coronavirus outbreaks.

Furthermore, as part of our membership of the non-profit organization, TransCelerate BioPharma Inc.<sup>1</sup>, Astellas is participating in the COVID-19 Task Force, alongside 20 other biopharmaceutical member companies, to share industry best practices in managing the continuity of clinical trial operations during the global COVID-19 pandemic while ensuring patient safety and maintaining study integrity.

We continuously respond to requests from various governments to provide compounds for the research phase. While placing the highest priority on safety, we will at the same time continue to contribute in our efforts to swiftly evaluate various possibilities in research and development of drugs for COVID-19.

### **Activities in each country and region**

Astellas has awarded approximately 48 financial supports to NGOs, government and medical institutions in 30 countries to buy personal protective equipment (PPE) for those fighting COVID-19. The following are our supports in each country and region.

- Astellas Pharma China, Inc. donated one million yuan to the Red Cross Society of China for purchasing protective clothing, masks, disinfecting solutions, and other equipment for healthcare professionals serving at hospitals in Wuhan, China, and procuring medical treatment equipment in FY2019. In addition, we have donated approximately 300,000 yuan worth of personal protective equipment to the same society, which has been distributed to hospitals in Wuhan City.
- At a national level in the United States, Astellas Pharma US, Inc. provided financial support worth \$700,000 to help humanitarian organizations working to support communities affected by COVID-19 in FY2020. This includes Astellas' corporate donations to Americares, the American Red Cross, and Direct Relief to help their emergency efforts. Additionally, Astellas awarded funding to five non-profit healthcare organizations to support patients and care partners during the pandemic. The company also coordinated opportunities to mobilize equipment, personal protective equipment (PPE) donations, blood donations in alignment with the Centers for Disease Control and Prevention guidance, employee contributions, and volunteerism to meet the critical demand for time and resources where needs were most pressing. Locally at the Astellas- US headquarters in Illinois, Astellas partnered with multiple state organizations, as a Founding Partner to the Governor's Illinois COVID-19 Response Fund and the Illinois Biotechnology Innovation Organization (iBIO) COVID-19 PPE Relief Fund. Furthermore, as part of the company's ongoing commitment to ensuring that patients have access to our products, we have implemented changes to our patient assistance programs in the US offered through Astellas Pharma Support Solutions<sup>SM</sup>, which offers support to patients needing access and reimbursement assistance. The changes were made to make the application and verification process easily accessible for patients who have lost their jobs or insurance

coverage as a result of COVID-19 and increase customer service capacity in light of the influx of patients requiring assistance.

- Astellas Pharma Inc. donated worth 5 million yen to Astellas Foundation for Research on Metabolic Disorders<sup>2</sup> as a grant for COVID-19 related research in Japan in FY2020.
- In Italy, our group company, Astellas Pharma S.p.A., made a donation worth 174,800 euros for the necessary supply of goods to public medical institutions and NPOs in FY2020.
- In Spain, our group company, Astellas Pharma S.A., made a donation worth 200,000 euros to the country's health ministry for the necessary supply of goods to medical institutions in FY2020.
- In India, our group company, Astellas Pharma India Private Limited, and Astellas Pharma Inc. have made a donation worth around 4,900,000 Indian Rupee to an NPO for the necessary supply of goods to COVID-19 affected areas in India in FY2021.

Other than above, the following activities have been implemented through the Astellas foundations.

- Astellas Foundation for Research on Metabolic Disorders financially supported COVID-19 related research in the research funding applications in FY2020. Further, the foundation provided to researchers who was economically affected by COVID-19 participating in studying abroad program supported by the foundation
- In 2020, the Astellas Global Health Foundation provided a combined \$2 million in new and redirected emergency relief focused on improved healthcare infrastructure, COVID-19 training and education impacting more than 725,000 lives in Kenya, Dominican Republic, South Sudan, Democratic Republic of the Congo (DRC), Ghana, Ethiopia and Nigeria. The funding addressed the urgent needs of partners seeking to prevent the immediate spread and combat the long-term effects of COVID-19 in particularly vulnerable and hard-to-reach communities. In 2021, the Astellas Global Health Foundation has provided \$750,000 in new COVID-19 preparedness, recovery and relief funding in Honduras and Nepal. Newly committed funding focuses on health system strengthening through vaccine education and support activities.

Furthermore, to assist healthcare systems coping with increasing demands by government or non-profit organizations presented by the escalation of COVID-19 around the world, Astellas will authorize a maximum of 4 weeks of paid leave (in accordance with each country's provision) to employees who are medically qualified and wish to contribute by participating in volunteer activities within their community.

Astellas, upon accurately ascertaining situations that change from day to day, will continue to work in cooperation with relevant authorities and organizations of each country by quickly gathering information and promptly taking necessary measures.

(1) TransCelerate BioPharma, headquartered in Philadelphia, U.S., is dedicated to improving the health of people around the world by simplifying and accelerating the R&D of innovative new therapies and enables companies, like Astellas,

with the opportunity to share key learnings and engage in the pharmaceutical and biopharmaceutical community.

- (2) Astellas Foundation for Research on Metabolic Disorders is a foundation established in 1969 with the purpose of contributing to the development of public health and medical care and the advancement of therapeutic drugs. The foundation provides research and studying abroad support. Astellas supports this activity.
- (3) Astellas Global Health Foundation (AGHF) merges three former philanthropic entities in November 2018 – the Astellas USA Foundation (AUSF), the Astellas European Foundation (AEF), and the Astellas Asia-Oceania Foundation (AAOF) – into one organization. AGHF is dedicating to improving access to health in underserved global communities.