Informed Consent Form for Treatment with RONAPREVE for Intravenous Infusion Set 300/RONAPREVE for Intravenous Infusion Set 1332

Prepared July 2021

*This material is an English version of the material prepared based on the Risk Management Plan.

1. About RONAPREVE

1) RONAPREVE and special approval

In July 2021, RONAPREVE received special approval as a treatment for SARS-Cov-2 infection (novel coronavirus infection [below, COVID-19]).

When emergency use is necessary to prevent the spread of a disease that may have a significant impact on the lives and health of the public in Japan, the special approval system allows the Minister of Health, Labour and Welfare to approve a drug after hearing expert opinions if it is already used to treat the disease outside Japan, even if the drug does not meet the normal requirements for approval.

At the time of approval, only preliminary clinical study results were evaluated. So information will continue to be collected and efficacy and safety will be reassessed after data have been collected.

Please receive a thorough explanation of RONAPREVE from your doctor before starting RONAPREVE treatment.

2) Effects and efficacy of RONAPREVE

RONAPREVE uses a combination of 2 types of antibodies* that bind to SARS-CoV-2. By binding 2 types of antibodies to SARS-CoV-2 and inhibiting the growth of the virus, this drug treatment prevents symptoms from becoming severe.

A clinical study (COV 2067) was conducted outside Japan to confirm efficacy and safety in patients with mild to moderate I COVID-19 (in which administration of oxygen is not needed). The preliminary results of this non-Japanese study showed that RONAPREVE reduced the risk of hospitalization or death due to COVID-19 by 70% compared with placebo.

* Antibodies: Molecules that bind specifically to an antigen (marker) on a particular foreign substance and stimulate the removal of that foreign substance from the body

3) Method of treatment with RONAPREVE

RONAPREVE is administered as a single intravenous drip infusion. RONAPREVE is used for patients at risk of severe COVID-19 who do not need supplemental oxygen while RONAPREVE is being administered.

4) Items to confirm before receiving RONAPREVE treatment

Before starting treatment, tell your doctor if any of the following apply to you.

- Patients who have developed serious allergic symptoms such as itchiness or rash after using a drug
- Patients who are pregnant, who might be pregnant, or who are breastfeeding

- Patients using any other drugs (also tell your doctor about any over-the-counter drugs or foods you are using)

5) Expected adverse reactions

Although available information on adverse reactions is limited, the following clinically significant adverse reactions have been observed. If you notice anything unusual during RONAPREVE administration, please consult your doctor, nurse, or pharmacist. Adverse reactions may also appear after administration is complete, so please consult your doctor, nurse, or pharmacist in that case too. Tell your doctor, nurse, or pharmacist if you have any concerns because symptoms or illnesses that have not been previously reported may occur.

5-1) Hypersensitivities including anaphylaxis

- General itchiness, hives, itchy throat, lightheaded feeling, palpitations, difficult breathing, cold sweats, dizziness, facial paleness, cold hands or feet, etc.
- Anaphylaxis is a sudden allergic reaction that occurs throughout the body. It can cause a sudden decrease in blood pressure, leading to difficulty breathing and loss of consciousness.

5-2) Infusion reactions

- Fever, chills, nausea, irregular heartbeat, chest pain, chest discomfort, weak feeling, unusual and sudden feeling of depression or excitement, headache, hives, general itchiness, muscle pain, dizziness, difficult breathing, bronchial spasm, sore throat

Note: Please refer to the patient handbook “For Patients Receiving RONAPREVE Treatment and Their Families” regarding the information above.

2. There are no penalties even if you do not give consent

After hearing this explanation, even if you decide to not consent to receiving treatment with RONAPREVE, it will not adversely affect your (the patient’s) future treatment. You (the patient) can receive another appropriate treatment that does not include RONAPREVE.

3. Even if you give consent, you can withdraw it before starting treatment

If you (the patient) consent to receiving treatment with RONAPREVE and you change your mind before starting treatment, you can withdraw consent at any time.

Even in this case, it will not adversely affect your (the patient’s) treatment. You (the patient) can receive another appropriate treatment that does not include RONAPREVE.

4. Other necessary matters related to protection of human rights

When you (the patient) receive treatment with RONAPREVE, please tell your doctor, nurse, or pharmacist if you notice anything unusual. Information that you (the patient) provide to your doctor, nurse,

or pharmacist may be shared with the Japanese regulatory authorities or pharmaceutical companies to assess efficacy and safety.

If there is anything that you do not understand about treatment with RONAPREVE, anything that you want to check, or anything that you want to ask about, please do not hesitate to talk with your doctor at any time before or after deciding to consent to treatment.