Corporation obtaining approval, the name of its representative, and the address of its main office

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Approved Type 1 Use Regulation

Names of types of living modified organisms	Conditionally Replicative Adenovirus Type 5, of which E1 region was modified to express E1A gene under the control of survivin promotor and express E1B19K gene under the control of CMV promotor.（Surv.m-CRA-1 ）
Content of Type 1 Use of living modified organisms	Use for the purpose of human gene therapy, storage, transportation, disposal, and other acts attendant with these.
Method of Type 1 Use of living modified organisms	1 Diluent Preparation (1) Enclose the undiluted solution of Surv.m-CRA-1 in a sealed container, and store in a lockable freezer with temperature monitoring function, located in the therapeutic facility. (2) Melt and prepare the frozen undiluted solution of Surv.m-CRA-1 within a safety cabinet. (3)When transporting the solution of original Surv.m-CRA-1 diluted at the prescribed concentration (called “diluted solution” hereinafter) through any open area, it shall be enclosed in a double-sealed container. (4)Transport the diluted solution to a treatment room clearly divided from the other areas (simply called “treatment room” hereinafter) immediately after preparation, and fill it into a device consist of a dedicated injection needle, syringe and tube (that is called “injection set” hereafter). 2 Administration to a Patient (1) Use the injection set and inject the diluted solution into a solid tumor by visual observation, through an endoscope, under CT guidance or ultrasonic guidance. After injection, remove the needle carefully to minimize the leakage and aerosolization of the diluted solution. (2) When the solution is injected from the injection site or through digestive tracts, spread a sterilized unwoven fabric doubly around the mouth. 3 Patient Management After Administration (1) After administering the diluted solution to the patient, disinfect his/her wounded part and cover it with gauze. For virus release prevention, make sure to have the patient dressed with a mask and a gown, and transport him/her from the treatment room to an

	individual room for which containment measures for the environment may be taken (to be simply called “individual room” hereinafter). (2) As containment measures for the individual room, no positive pressure shall be applied, its entrance door shall be closed all the time, and any person who enters the room shall wear a gown, mask and gloves. (3) The patient shall be managed in an individual room for 2 weeks after administration. However, this management will be released if Surv.m-CRA-1 contained in the patient’s sputum (only when he/she experiences respiratory symptoms and produces sputum; the same applies hereafter), saliva, urine, and fecal waste (only when the solution was administered through digestive tracts by using an endoscope), exhibited a negative result in several tests performed on the next day of administration or later. (4) When the patient needs to go out of the individual room to any open area temporarily for reasons such as taking a test, have him/her to minimize the chance of blood sampling or excretion and obligate him/her to wear a mask and a gown. (5) After the patient was released from the individual room management, if Surv.m-CRA-1 was detected in the patient’s sputum, saliva, urine, and fecal waste (only when the administration was through digestive tracts by using an endoscope), discuss if it is necessary to bring him/her back under the individual room supervision. If it is decided to be necessary, take the same steps as the above (3) and (4). 4 Infectious Waste Management (1) For the patient’s excrement (blood, body fluid, urine, fecal waste and tumor tissues; the same applies hereinafter) which was excreted in the individual room during the management period, give inspections as necessary, apply virus inactivation treatment, and dispose according to the Rules regarding the medical waste management, provided by medical facilities, based on the Waste Disposal and Public Cleansing Act (Act No. 137 of 1970), which is called “Medical Waste Management Rules” hereinafter. (2) For tools such as the injection set, which were used invasively on the patient, as well as tools, cloths and gauze that were in contact with the patient’s excrement, apply virus inactivation treatment first, and dispose according to the Medical Waste Management Rules if they are disposable, or cleanse thoroughly if they are recyclable such as needle guide device. (3) For the undiluted or diluted solution of Surv.m-CRA-1, apply virus inactivation first, and dispose according to the Medical Waste Management Rules. (4) When the virus inactivation is conducted in other areas, use a double-sealed container for transportation. (5) After administering the diluted solution to the patient, make sure to disinfect the treatment room floor. (6) Make sure to disinfect the individual room floor if some excrement has dropped on the floor during the management period, and after the individual room management is completed.