Press Release

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Daiichi Sankyo Announces Support by the Japan Agency for Medical Research and Development's CiCLE Program for Its Collaborative Research with Saitama Medical University on Fibrodysplasia Ossificans Progressiva, and Commencement of an Industry-Government-Academia Research & Development Collaboration for Development of Therapies Using the Research

Tokyo, Japan, (October 17, 2017) – Daiichi Sankyo Company, Limited (hereafter Daiichi Sankyo) announced today that the research that it is jointly conducting with Saitama Medical University (Main campus: Hidaka-shi, Saitama Prefecture) to create innovative therapies for fibrodysplasia ossificans progressiva (FOP)[*1] has been adopted for support under the Cyclic Innovation for Clinical Empowerment (hereafter CiCLE)[*2] program of the Japan Agency for Medical Research and Development (hereafter AMED). The company also announced that an industry-government-academia R&D collaboration for creating innovative therapies based on this research commenced on October 17, 2017.

FOP is a progressive, serious disease in which bone tissue forms where it is not normally present, such as in muscles, tendons and other soft tissues. The estimated prevalence is 1 case per 2 million population worldwide and is a designated intractable disease in Japan. The cause has been reported to be a mutation in the ALK2 gene, but an effective treatment has yet to be developed.

The candidate FOP therapy that Daiichi Sankyo has discovered in joint research with Saitama Medical University is an antibody against ALK2 (humanized monoclonal antibody), which by specifically inhibiting the abnormally enhanced ALK2 signaling in FOP, should suppress ossification. In the future, with support under the CiCLE program, through the industry-government academia coordination among AMED, Saitama Medical University and Daiichi Sankyo, there will be greater commitment to R&D for the early creation of innovative therapies for FOP.[*1]

***1 Fibrodysplasia ossificans progressiva (FOP)**

FOP is an inherited disease in which bony tissue forms in skeletal muscle, tendons and ligaments and other soft tissues where bone tissue does not normally form (called ectopic ossification). In this disease, ectopic ossification may occur anywhere in the body, including the face, and fusion between ectopic bone tissue and existing bone tissue results in physical deformation and marked impairment of the range of motion of joints. It has been reported that the cause of FOP is a mutation in the ALK2 gene, a BMP signaling receptor gene. Activated by the mutation, ALK2 transmits excessive bone formation signals, which causes ectopic ossification. Up till now, no medication for the suppression of ectopic bone formation in FOP or eliminating already formed ectopic bone has been developed so effective therapies are desired.[*2]

***2 Cyclic Innovation for Clinical Empowerment (CiCLE)**

The purpose of CiCLE, which AMED inaugurated in fiscal 2017, is through industry-academia-government collaboration, bring together Japanese expertise in order to accelerate the practical application of medications, medical devices and medical technologies that accurately meet the needs of the clinical setting as well as promote the creation of an environment strongly conducive to nurturing open innovation and ventures in the medical field. This new program caters to a wide variety of projects ranging from those at the basic research stage to those at the development stage with a view to practical application, which includes clinical studies. Projects are not limited to specific areas.