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PRESS RELEASE

Metagen Therapeutics and JSR, Alliance to Establish Microbiome Medicine Investigational Drug Manufacturing Facility

**~ Scheduled to be operational by end of 2025 for start of clinical trials
in Japan and overseas~**

Metagen Therapeutics, Inc. (Headquarter: Tsuruoka City, Yamagata Prefecture; President and CEO: Taku Nakahara), a company that promotes medical and drug discovery based on gut microbiota research, and JSR Corporation (Headquarter: Minato-ku, Tokyo; Representative Director and CEO: Eric Johnson), a leading materials company, have signed an agreement to establish an investigational drug manufacturing facility for microbiome drugs.

Research and development of microbiome medicines that utilize gut microbiota have been conducted around the world in recent years, as advances in analytical technology and other areas have led to the scientific elucidation of the relationship between intestinal microbiota and human health and diseases. At Metagen Therapeutics, we are developing "oral FMT drugs" that enable Fecal Microbiota Transplantation (FMT) through oral administration. JSR has also been focusing on microbiome as one of the next generation research topics and are conducting research and development regarding this.

With this alliance, Metagen Therapeutics and JSR will collaborate to establish an investigational manufacturing facility for FMT drugs. The facility will be located in the collaboration laboratory of the JSR Bioscience and Informatics R&D center (JSR BiRD), JSR's next-generation life science core research center in Kawasaki, Kanagawa Prefecture, and is scheduled for completion in March 2025. Once completed, Metagen Therapeutics will begin preparations to manufacture investigational oral FMT drug candidates for the preclinical stage treatment of ulcerative colitis. JSR will support Metagen Therapeutics' manufacturing of this drug, and will also conduct research and studies for the eventual manufacturing of the drug.

Commenting on the alliance, Taku Nakahara, CEO of Metagen Therapeutics, said, "It has become clear that disruption of the gut microbiota is associated not only with ulcerative colitis but also with various other diseases such as cancer and Parkinson's disease, and microbiome drug discovery is expected in various fields in the future. This partnership is a major step towards the start of clinical trials in Japan and overseas for FMT drugs originating in Japan, and we are very pleased to be able to establish an investigational



drug manufacturing facility at JSR BiRD. Since April of this year, Metagen Therapeutics has been recruiting potential gut microbiota donors through J-Kinso Bank, a gut microbiota bank. In April 2025, we plan to open a stool donation facility in Tsuruoka City, Yamagata Prefecture, to receive stool donations from donors and to extract gut microbiota that will be used as raw materials for FMT drugs. We are committed to further accelerate the development of FMT drugs and deliver them to patients as soon as possible.

Hirohisa Koga, Director of JSR BiRD Center, added, "We are very honored to participate in this joint project with Metagen Therapeutics. The development of new therapies using oral FMT drugs has the potential to revolutionize the future of medicine. We are pleased to be able to contribute to the advancement of that medicine through this alliance. We recognize that the establishment of an investigational drug manufacturing facility at JSR BiRD is an important step in the development of oral FMT drugs. We will continue to work closely with Metagen Therapeutics to establish manufacturing technologies and contribute to the development of oral FMT drugs.

About microbiome/microbiota

The human intestinal tract is home to more than 40 trillion^{*1} gut bacteria of about 1,000 species, and the population of bacteria is called microbiome or microbiota.

Fecal microbiota transplantation (FMT)

FMT is a treatment method in which the gut microbiota contained in the stool of a healthy person is transplanted into the intestine of a patient to rebuild the patient's intestinal environment. In January 2023, the Antibiotic Fecal Microbiota Transplantation (A-FMT) for ulcerative colitis was started as an Advanced Medical Care B Program. In August 2024, a clinical trial (specific clinical research) on "combination therapy with immune checkpoint inhibitors and intestinal microbiota transplantation" for gastrointestinal cancer was initiated.

■ Metagen Therapeutics, Inc.

The company has been accelerating its drug discovery and development work on gut microbiome-based therapeutics for various diseases such as cancer, ulcerative colitis, and Parkinson's disease. It aims for social impact through medical care and drug discovery. Metagen Therapeutics, Inc. is a biotech startup founded in 2020 with the mission of "Living up to the hopes of patients through microbiome science" and to create social impact through medical care and drug discovery based on gut microbiome research. Co-founded by a Juntendo University physician and researchers from Keio University and Tokyo Institute of Technology, the company is promoting social implementation of Fecal Microbiota Transplantation (FMT) and FMT-driven reverse translational drug discovery. Currently, the company is focusing on development in the areas of immunological



diseases (inflammatory bowel disease), oncology, and central nervous system diseases.

<https://www.metagentx.com/en/>

■ JSR Corporation

JSR Corporation is developing its business globally on the strength of its technological capabilities, focusing on the digital solutions business, including semiconductor materials, and the life sciences business, while promoting innovation to provide value to leading industries around the world and exploring next-generation businesses to meet society's challenges.

<https://www.jsr.co.jp/>

<https://www.jsrlifesciences.com/ja/>

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Source:

1. Sender, R., Fuchs, S. & Milo, R. Revised Estimates for the Number of Human and Bacteria Cells in the Body. PLoS Biol. 14, e1002533 (2016)