

# MONEX GROUP

## Announcement of Subsidiary's Release

TOKYO, January 28, 2022 – Genex, Inc., a group company of Monex Group, Inc., issued the following press release today.

In April 2021, Monex Group revised its business principle and announced its intent to help realize individual self-fulfillment and optimize each person's lifetime balance sheet. In addition to our core financial businesses, we are entering new fields that enhance well-being.

Genex, Inc. plays an important role in promoting business that embodies our new business principle.

Attachment: Genex, Inc. press release

Genex to begin whole genome information management services for people with rare diseases  
- In a first for a private company, Genex will work with physicians to support diagnoses and clinical trials for mitochondrial and designated intractable diseases -

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FOR IMMEDIATE RELEASE:

## **Genex to Begin Trusted Whole-Genome Information Management Services for People with Rare Diseases, in a First for a Private Company in Japan**

- Being a patient-initiated genomic data custodian, Genex will work with physicians to support diagnoses and clinical trials for mitochondrial disease -

TOKYO, January 28, 2022 – GENEX, Inc. (headquarters: Tokyo; Representative Director and President: YAGI Ken; hereinafter, Genex) is pleased to announce that it is participating in joint research on the pathology and development of treatments for mitochondrial disease\*<sup>1</sup>, a designated Nanbyo (rare intractable diseases), and has begun a model business operation that acquires and manages whole genome information\*<sup>2</sup> on behalf of patients in January 2022.

With permission from the multi-institutional joint research project with Saitama Medical University, Chiba Children's Hospital and Juntendo University, Genex will serve as a custodian of whole genome information using a highly secure system. This is the first time a private company in Japan that is neither a medical nor an academic research institution will store and manage whole genome information on behalf of patients.\* Genex aims to help create a sustainable ecosystem where patients and the public are more involved; affected individuals are empowered to provide information that can contribute to others and the greater society, and in return they receive offers to participate in clinical trials, access to expanded diagnostic and therapeutic options, and benefit from an enhanced quality of life. \*Based on a Genex survey as of January 11, 2022

### **Background**

Patients with rare diseases, such as designated intractable diseases, often spend years getting a definitive diagnosis and treatment protocol. On the other hand, as studies have progressed with detailed genomic information of individual patients, so has the understanding of mechanisms of rare diseases. While whole genome information is a resource that can provide definitive value to both the patient and others who suffer similar conditions, until now, there has been no system to acquire and manage whole genome information directly from patients in Japan.

### **Overview**

Genex began operations to acquire and manage whole genome information for patients suffering from mitochondrial diseases and to support physicians in diagnosis and improving patient recruitment in clinical trials. Prior to this, under the Ethical Guidelines for Human Life Sciences and Medical Research implemented on June 30, 2021, and following a review by the Institutional Review Board, Genex received permission to participate in a multi-institutional joint research project with Saitama Medical University, Chiba Children's Hospital and Juntendo University (principal investigator: Professor Akira Ohtake, Department of Pediatrics and Department of Clinical Genomics, Faculty of Medicine, Saitama Medical University). Genex is ready to obtain an electronic informed consent and a saliva sample from each patient. Whole genome information entrusted to Genex by the patients is securely protected in our Personal Data Bank (PDBank)<sup>TM</sup> \*<sup>3</sup> and safely managed for use in accordance with each individual's consent status.

Genex acquires whole genome information from mitochondrial disease patients 16 and over who have provided or will provide consent. With this information, it issues test reports and conducts other activities to translate its findings into clinical settings. In addition, as part of the joint research project, this whole genome information is being combined with medical records and other information gathered for over 15 years by the research institutions in the hopes to produce new findings and results.

## Future outlook

Genex envisions a future where individuals decide the “with whom” (designated receiving party) and the “when and how” (consent agreement) of their own whole-genome information. As a first step, Genex will collaborate with pharmaceutical companies, patient advocacy groups and other organizations and provide joint research intellectual property and characteristic data sets for drug development and clinical trials. In addition, given the approximately 400 million people suffering from rare or undiagnosed diseases, we hope to expand into other diseases and healthcare fields to scale our operations and become profitable.

Many challenges remain for the rare diseases community. One is the high risks associated with business feasibility and personal information management, leading to a significant disincentive to sponsor industry-initiated clinical trials. In recent years, however, pharmaceutical companies around the world are taking a more strategic approach to rare diseases research and development. With this trend, Genex will spearhead its rare-disease initiative and strive to create a proof of concept of a broader genomic medicine ecosystem.

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## Glossary

1. Mitochondrial disease is a collective name for disorders caused by a decline in mitochondrial activity and is the most common group of hereditary metabolic disorders. With an incidence rate of one out of 5,000 births, mitochondrial disease often causes a variety of serious fatal symptoms, especially for those afflicted in childhood. Some patients develop mitochondrial disease slowly over time after reaching adulthood. Nonetheless, there is no curative treatment and the disease can only be managed by supportive therapy. Much hope is being held for breakthroughs to identify the genetic and environmental factors that lead to the onset of this disease, which affects mitochondrial activity in a wide range of organ systems.

There are approximately 1,500 patients in Japan who are qualified to receive specified medical expenses, as having mitochondrial disease, in the national Nanbyo (rare intractable diseases) healthcare system. However, this number could underestimate the actual prevalence when we consider possible 20,000 undiagnosed cases. Mitochondrial dysfunction may possibly be related with diabetes, Alzheimer’s Disease, Parkinson’s Disease and other afflictions and is biologically associated with aging and cancer. By gathering high-quality information on the characteristics of mitochondrial disease, we hope to help accelerate the development of diagnostic tests and treatment methods, expand indications of existing drugs, and enhance understanding of related disorders with better disease stratification.

2. Whole genome information is obtained from the 3 billion nucleotides of an individual’s complete DNA base sequence. It includes intron, regulatory region, genome structure and other information that cannot be obtained from gene panel testing or exome sequencing. Even highly experienced physicians find it difficult to diagnose mitochondrial disease and other rare diseases based on symptoms and common test results alone. Whole-genome analysis can be used as a powerful and exhaustive search tool. In addition, whole-genome analysis has the potential to provide new information on disease causative genes for potential drug targets.

3. Personal Data Bank (PDBank)<sup>TM</sup> is a service that securely protects and safely manages whole genome information entrusted by individuals for use in accordance with individual consent status. Under a government-backed “Information Bank” (Trusted Personal Data Management Service: TPDMS) certification scheme, it utilizes “paspit for X” based on “paspit” developed by DataSign, Inc. (<https://datasign.jp/>), which has received certification for fulfilling set criteria in the handling of personal information and safety management. Genex has developed a system that safely manages entrusted whole genome information, which potentially can be considered sensitive personal information.

**About GENEX, Inc.:** Established as a start-up in August 2019 to plan and operate genome and healthcare-related data platforms with Monex Group, Inc., Sugi Holdings, Co., Ltd., Kaken Pharmaceutical Co., Ltd., and others as shareholders.

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