NEWS RELEASE

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National University Corporation
Gifu University

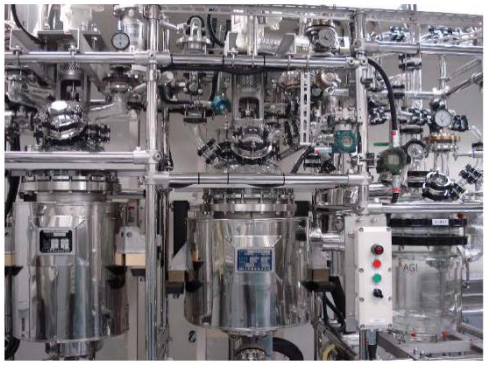
Members of the Press

A facility to manufacture investigational drugs that meets international standards was established for the first time at the university. It enables the development of an investigational drug to inhibit the rare intractable disease Creutzfeldt-Jakob disease, and purification of investigational drugs for people for the first time.

National University Corporation Gifu University (location: Yanagido, Gifu City, Gifu prefecture, JAPAN, President: Dr. Hisataka Moriwaki) reports that we established a facility to manufacture intravenous drip medications for the first time in Japan on February 10, 2015. This facility enables us to manufacture investigational drugs to inhibit progression of Creutzfeldt-Jakob disease (*1, hereafter CJD) within the university and to perform clinical trials for people. In addition, we also report that we held a symposium “A challenge to neurodegenerative diseases with the development of innovative medical research – To establish a system for prion disease clinical trials” in February 14, 2015.

*1 CJD: A rare intractable disease with observed symptoms such as progressive dementia, visual disturbance, confusion, dizziness, and apathy etc. The patients die 3 to 12 months after its onset. Treatment methods have not been established to date. (See below in detail)

■ Regarding a facility to manufacture intravenous drip medications



To manufacture investigational drugs, an aseptic condition is essential and it needs to meet international standards. The manufacturing environment in our facility fulfills these standards and this is the first case in the world where a university has introduced it.
The device can manufacture drugs by synthesizing many kinds of organic compounds in a high temperature and pressure environment and portion packaging can be performed within the facility under aseptic conditions.
Although manufacturing of investigational drugs will be consigned to a pharmaceutical company for the time being, we are planning to apply for a manufacturing license for pharmaceutical products in the future.

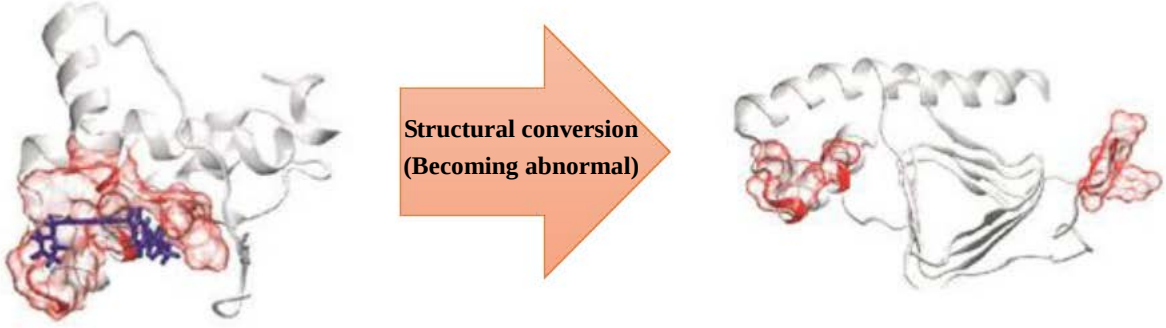
■ About CJD

CJD’s symptoms are progressive dementia, visual disturbance, confusion, dizziness, and apathy etc. and the majority of CJD patients die 3 to 12 months after its onset.
The cause of this disease is a protein called “prion” that exists in brain neurons. The prion adopts an abnormal conformation, obtains toxic properties, and kills neurons after getting damaged. Effective treatment methods have not been established to date.
CJD occurs at a rate of one case per million in the population and the number of cases are not many. Therefore this is a difficult field for private enterprise to start research and development of therapeutic agents due to management problems. Gifu University intends to lead this field as a national university.

■ About investigational drugs for CJD

A lead compound which is effective for prion diseases was developed by professor Kuwata of the United Graduate School of Drug Discovery and Medical Information Science at our university in 2007. The cause of diseases related to prions is thought to be that a prion protein is converted into an abnormal structure. A medical chaperone, a compound which stabilizes the normal prion protein structure (left figure) and inhibits conversion into the abnormal structure (right figure), was newly developed as a therapeutic agent in the graduate school.

Prion protein structure



[Normal structure] **[Abnormal structure]**

The red area in the left figure shows a part of the normal prion. When a prion takes on an abnormal structure as indicated in the right figure, the red area is separated into two parts. A medical chaperone, which is indicated with a purple color, stabilizes the normal structure and inhibits conversion into the abnormal structure by fitting into a cavity on the surface of the normal structure and working as a joint.

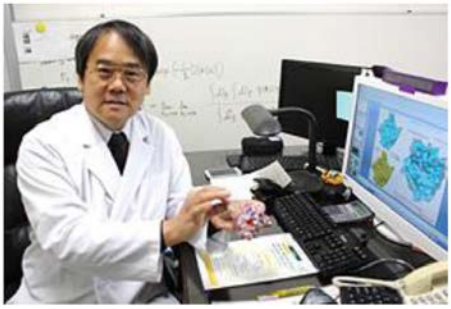
■ Regarding future research

We are thinking that developing CJD therapeutic drugs at our university will be useful for the development of drugs for Alzheimer's disease, which is also a dementia and has a larger number of cases than CJD. Symptoms of Alzheimer's disease progress slowly over a long period, and effects of a drug tend to be difficult to be observed. On the other hand, CJD’s symptoms are distinctive and progress quickly, and the effects of a drug tend to be easier to be observed. Therefore, developing CJD therapeutic drugs has a potential to progress drug research for other dementias including Alzheimer's disease. We plan to implement a clinical trial for CJD in 2 years.

■ Response at the symposium

We held a symposium “A challenge to neurodegenerative diseases with the development of innovative medical research – To establish a system for prion disease clinical trials” in Nagoya in February 14, 2015. A total of 73 people, including patients’ families, researchers, doctors, people related to pharmaceutical companies, and the press (newspaper and TV etc.) attended this symposium. The discussion was so lively that we forgot about the time, and the symposium ended with great success. We could collect information not only related to clinical trials but also related to various problems surrounding prions. The contents are planned to be published as a lecture text. After the symposium, we have received several inquiries related to a clinical trial from patients’ families.

■ A profile of Dr. Kazuo Kuwata



1982	Graduated from Gifu University School of Medicine
1984	Assistant professor, Gifu University School of Medicine
1989	Concurrent instructor, Gifu University Hospital
1993-2002	Associate professor, Gifu University School of Medicine
1999-2000	Associate professor (concurrent appointment), the Institute for Protein Research, Osaka University
2004-2010	Professor and director, Center for Emerging Infectious Diseases, Gifu University
2007- Present	Professor, Biomedical Informatics and Medical Information Sciences Division, The United Graduate School of Drug Discovery and Medical Information Science, Gifu University
2007- Present	Professor (concurrent appointment), Department of Developmental Genetics, Division of Molecular and Structure, The Graduate School of Medicine, Gifu University
2011- Present	Professor (concurrent appointment), Zoonotic Disease Research Division, Research Center for Wild-life Management, Faculty of Applied Biological Sciences, Gifu University
2012- Present	Professor (concurrent appointment), Life Science Research, The Organization for Research and Community Development, Gifu University

■ Summary for educational institution

Name: National University Corporation Gifu University Representative: President Hisataka Moriwaki
Address: 1-1 Yanagido, Gifu City, Gifu Prefecture, Japan
URL: http://www.gifu-u.ac.jp

■ Inquiries regarding this release

■ Regarding inquiries, interviews and requests for materials about this release, please contact the following: ■

The agency acting PR for Gifu University: CuA united Inc. The person in charge: Inoue
Tel: 052-332-1334, Fax: 052-308-3804 / Email: info@cua-united.com / URL: http://www.cua-united.com/