

Cellular medicine Clinical trial next year

Novumcella Inc. for intractable disease

Cholesterol drug combination

Start-up Novumcella Inc. (Minato-ku, Tokyo-based president Yasuyuki Kusuhara), who is engaged in R & D on regenerative medicine, will start clinical trials of "cellular medicine" that treats disease by administering cells to the body next year in Japan.

Aims for approval at the end of 2021 in a new hybrid method that utilizes blood cholesterol-lowering drug "statin".

It is used to treat the disease called "systemic scleroderma" where the skin becomes thick.

One of the designated intractable diseases in the country, the number of patients is about 20,000 in the country.

Not only skin but also various organs and blood vessels cause dysfunction. Inflammation caused by any auto-immune abnormality is considered to be the main cause. Treatment with steroids, immunosuppressants, etc. has limited efficacy. Side effects are also problems.

Novumcella Inc. begins clinical trials with a new treatment that combines stem cells capable of differentiating into various organs and statins that lower cholesterol. It is a technology invented by Dr. Masaaki Ii of Osaka Medical College, license out to Novumcella Inc.

The new technology uses autologous mesenchymal stem cells extracted from the adipose tissue of patients. When stem cells are cultured, biodegradable polymer particles containing Statin, which is a drug for lowering blood cholesterol, are mixed. The particles are then taken up by the stem cells.

Mesenchymal stem cells have the property of aggregating at the site of inflammation and gradually release statin-containing polymers at the lesion site of the patient.

Statins are known to have an effect of suppressing inflammation.

In addition, mesenchymal stem cells themselves are known to secrete various substances to suppress inflammation, and it is an attempt to suppress inflammation with a double effect.

Dr. Ii has confirmed the effect with a mouse, and plans to conduct an examination for research purpose at Osaka Medical College in the autumn of 2019. In parallel, Novumcella Inc. plans to provide the necessary treatment for new drug applications. A clinical trial will be conducted in the early and mid-term from 2020, and approval will be submitted in the first half of 2021.

In addition to being classified as a regenerative medicine product, the policy is to apply for treatment for rare diseases (orphan drugs), and by taking advantage of the country's early approval system, approval is expected by the end of 2021.

The cost of manufacturing is several hundred thousand yen per one, and the drug price expected by the company is one million yen.

It may be administered several times a year, but it is still cheaper than the current approval of JCR Pharma's "Temcell", which costs 14 million per dose.

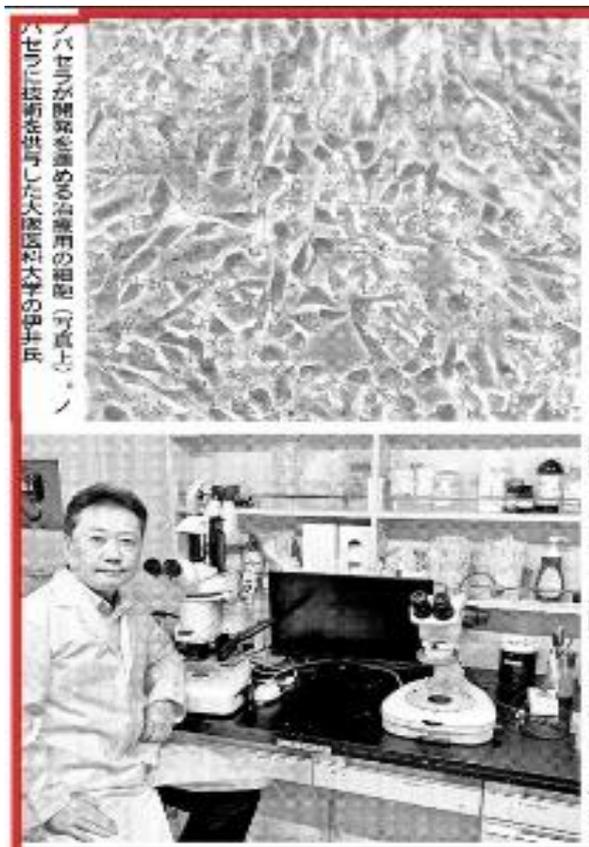
Experiments in mice suggest that it is effective not only for systemic scleroderma but also for other

diseases such as ulcerative colitis, vascular dementia and osteoarthritis of the knee.

Expanding adaptation is also in sight.

Mr. Kusuhara, who has experience with pharmaceutical companies, established Novumcella Inc. in August 2016.

In addition to the development of cellular medicines, we also carry out development support operations centered on bioproducts and analysis of medical big data.



Therapeutic cells for development by Novumcella Inc.

Dr. Ii of Osaka Medical College who provided technology to Novumcella Inc.

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