Shin Hatou, M.D., Ph.D., CEO, CELLUSION
“Corneal endothelial regenerative medicine utilizing iPSC derived CECSi cells”

Cellusion is a university based startup company from Keio University School of Medicine.
Cellusion works on Corneal Endothelial Regenerative Medicine with iPSC Derived Endothelial Cells.
There are many unmet medical needs in a Corneal transplantation. There are around 13 million patients waiting for corneal transplants globally. However, only 180,000 operations are conducted per year. Therefore, there is an enormous supply and demand gap among them. Bullous Keratopathy is the most major corneal disease. Over 50% of corneal transplants are for this disease. Although surgical techniques have advanced, surgery is still very difficult with many complications.

[Our solution]
Our solution is cell transplant of corneal endothelial cells from allogenic iPS cells. Corneal Endothelial cells are mass produced from allogenic iPS cells. The cells are just injected into the space between the cornea and lens. With our solution, cell transplant is far easier, and much safer for patients compared to conventional transplants. By our therapy, more patients are treatable globally.
Our cell transplant technique allows clouded cornea to recover and become transparent. We also have developed the mass production process of Corneal Endothelial cells from iPS cells by direct differentiation. We can treat at least 1000 patients per batch. It takes only a month to produce cells from iPS cells. In addition, we can preserve frozen stocks of cells, which enables us to easily distribute cells to hospitals and clinics globally.

[Market structure and size]
Currently, there are 1.2 million new patients each year which translates into approximately $5.8 billion by year. In addition, there remain 9.8 million patients waiting for therapy which translates into roughly $47 billion and market size growth to grow 2% per year.
Several competitors tried to use cultured Corneal Endothelial cells from donor cornea. But cell production size is limited. We however can produce cells, one or two digits more compared to competitors. We are also able to create cryo-preserved Corneal Endothelial cells from iPS cells. We are the pioneers of iPS cell based Bullous Keratopathy treatment and are going to start first in human clinical study next year.

[Future plans]
Opportunities which we expect here are joining our Series B financing, or building licensing. Or co developing partnerships, please contact our website.

[Q & A]
Q.
When you said you are going to the clinical trial, you say that this year or next year? This is the first question. And the second thing is I remember that you're using iPS cells but because of your corneal application, you don't have to worry about the HLA or immune response type of things. Maybe if you can explain it.
A.
First question, we are preparing for a first in human clinical study with Keio University in Keio University Hospital next year. And some audience may know that the our project just have approved by Japanese MHLW(厚生労働省）. And the first clinical study will start in next year. In addition, we are preparing for the sponsored clinical trial in Japan and we would like to start the

clinical trial from 2023. At the same time, we are preparing for clinical trial in the US and we would like to start it from 2024.
Next, and the second question. In the conventional corneal transplantation, we don't match the HLA or blood types because there are no blood vessels in the cornea. So, the risk of immunological rejection is very low compared to other transplantations, such as kidney transplantation or liver transplantation. And after corneal transplantation, just topical steroids are used to treat the immunological rejection. In our next project, just the topical steroids are used to prevent the immunological rejection after the transplantation.

Q.
I have two questions. First one is “how much is a cost of production for one patient?” Do overestimate and the second question is, you refer clinical trial next year and is this clinical trial or clinical research?

Presenter: The first question, we have now calculated the manufacturing cost. The COG is about the 5%. And the sales price of our product could be about the 600,000 YEN for a patient, as you know, conventional Corneal Transplant treatment costs about 600,000 YEN for a patient and our sales price could be equivalent to conventional corneal transplant therapy.
And next question, next year is a doctor initiating clinical study in Keio university hospital.