Ver.1.0

Info Sheet for Technical description

No. 0009 - 2

Organization

* Mandatoty fields

Name of Organization*	Orizuru Therapeutics, Inc.	
Address, City, States, Zip, Country*	2-26-1 Muraoka-higashi, Fujisawa-shi, Kanagawa, 251-8555 Japan	
URL	https://orizuru-therapeutics.com/en/	
Brief Descriptions of Organization* (Approx. 100 words)	This company is a spinout from Takeda Pharmaceuticals and Kyoto University, focusing on the development of induced pluripotent stem cell (iPSC) technology-based regenerative medicine. It has two lead assets in development for the treatment of severe chronic heart failure and brittle type I diabetes mellitus. The IND-enabling studies are ongoing and clinical trials will start soon. The lead assets are OZTx-556: iPSC-derived cardiomyocytes, and OZTx-410: iPSC-derived pancreatic islet cells. Our 3D bioreactor and original differentiation methods using small molecule compounds gives us competitive advantages in pharma industry-level of quality and scalability.	
Contact address	Name*	Michiko Isobe
	Department* / Position	Business Development/BD Specialist
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What kind of technology do you want to offer? *

- ☑ **A.** Clinical Development Pipelines → Please see **Sheet【A】**
- ☐ **B.** Regenerative Medicine-related Consumables / Instruments / Materials / CDMO Servicies etc. → Please see **Sheet【B】**
- ☐ **C.** Platform Technologies(*) that are not included in the above (Group B) → Please see **Sheet【C】**

  * Peripheral technologies that contribute to a significant improvement in productivity throughout the value chain of pharmaceuticals, from research and development to manufacturing and ultimately market launch.

If you agree to the following, please check "Yes" below. *

The technologies introduced in this 'Info Sheet' are in the public domain, as they have been published in research papers or have related patent applications.

- ☑ Yes

Do you have any collaborations/partnerships with pharmaceutical companies?

- ☐ Yes
- ☑ No

If you have already received funding from VCs or other sources, up to which stage has the investment round progressed?

- ☐ Angel / Seed (including AMED/JST grants)
- ☑ Series A
- ☐ Series B
- ☐ Series C
- ☐ Series D or further advenced stages

Do you agree to leave your presentation materials at FIRM hands and entrust us to make use of them for the purpose of promoting your partnering opportunities? *

Options*	Comments
☑ Yes	
☐ No	

Filled in by*	Michiko Isobe
Date*	20-Sep-23

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Sheet【A】 Clinical Development Pipelines

Info Sheet for Technical overview

No. 0009 - **2**

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Title*

OZTx-410, iPS cell-derived pancreatic islet cell (iPIC) sheet for brittle type 1 diabetes

Development Phase*

☐	Basic Research	☐	Drug Discovery	☑	Pre-Clinical
☐	Clinical Trial (Phase I)	☐	Clinical Trial (Phase II)	☐	Clinical Trial (Phase III)
☐	Review	☐	Others		

Diesease Area*

☐	Cancer	☐	Central nervous system	☐	Ophthalmology
☐	Musculoskeletal	☑	Endocrine / Metabolism	☐	Cardiovascular
☐	Urogenital	☐	Digestive organ	☐	Blood
☐	Infection	☐	Dermatology	☐	Immunity
☐	Otolaryngology	☐	Respiratory	☐	Others

Description*

iPIC was created using a unique purification method (~98% purity) that removes undesirable cells resulting exclusively in endocrine lineage-cells with 60% β-cells and 40% others (α-cells, etc.). OZTx-410, an iPIC sheet, showed efficacy with the onset of normoglycemia within 40 days post-implantation in diabetes mellitus mice with long-term engraftment and physiological insulin release after subcutaneous implantation. Similar results were shown in pig models. Long term durability of implant was confirmed with immunohistochemical analysis of grafts 6 months post-implantation showing islet-like structures which contain glucagon resulting in dynamic regulation of insulin secretion through paracrine interactions between β-cells and α-cells. Safety was shown past 1 year with neither teratoma nor hypoglycemia episodes. Furthermore, we have more than 10 billion iPIC generated using a liter-scale bioreactor for the massive and uniform-size islets (100-200 μm diameter) needed per patient for treatment. In addition, there are more than 60 worldwide patents pending. First in human trial for OZTx-410 will initiate soon and we believe Orizuru Therapeutics will provide a best-in-class product in type 1 diabetes.

Filled in by*	Michiko Isobe
Date*	20-Sep-23