

Financial Terms for Commercial Use of iPS Cell Stock

As of 2023/12/04

CiRA Foundation

Fee Structure for Commercial Use

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Precautions

1. This paper was made in order to clarify the definition of terms in “Collaborative Research Agreement for Material Transfer (CRA)” and “Ownership Transfer Agreement (OTA)”. We carefully translate the Japanese descriptions into English, but there may be some inaccurate descriptions. If you have any questions, please contact us at ips-stock-shinsa@cira-foundation.or.jp.
2. Users should get the appropriate license from iPS Academia Japan which controls Kyoto Univ.'s patents related to iPS Cells. For further details and inquiries, please directly engage with iPS Academia Japan. The third-party patent information will be provided by the CiRA Foundation during the contract signing process. At their own risk, users may need to refer to and deal with effective patents in their country.
3. If users want to use our research-grade iPS Cell Stock for their research use, we can sign the CRA without the description of iPS Stock System Maintenance Fee. Then, we must modify the contract before users start to use clinical-grade ones for humans.

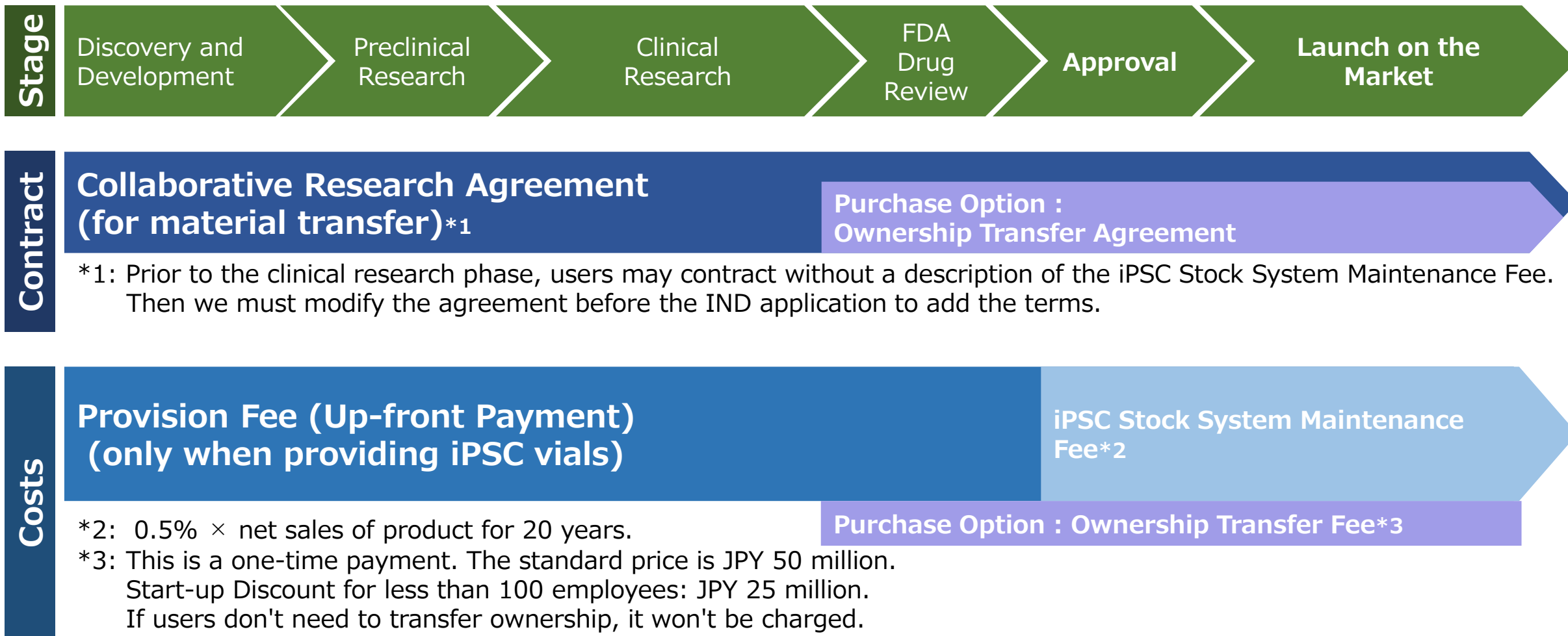
Provision Fee (Up-front Payment per vial)

iPS Cell Stock 		To Non-Profit (ex. university, research institution)	To Profit (ex. private company, start-up)
HLA homozygous			
-Research-grade	:	Free	JPY 50,000/one(1) vial
-Clinical-grade	:	Free	JPY 100,000/one(1) vial
SeV iPS /"KTRH"			
-Only Clinical-grade	:	Free	JPY 100,000/one(1) vial
HLA genome-edited			
-Research-grade	:	Free	JPY 100,000/one(1) vial
-Clinical-grade	:	Free	JPY 200,000/one(1) vial

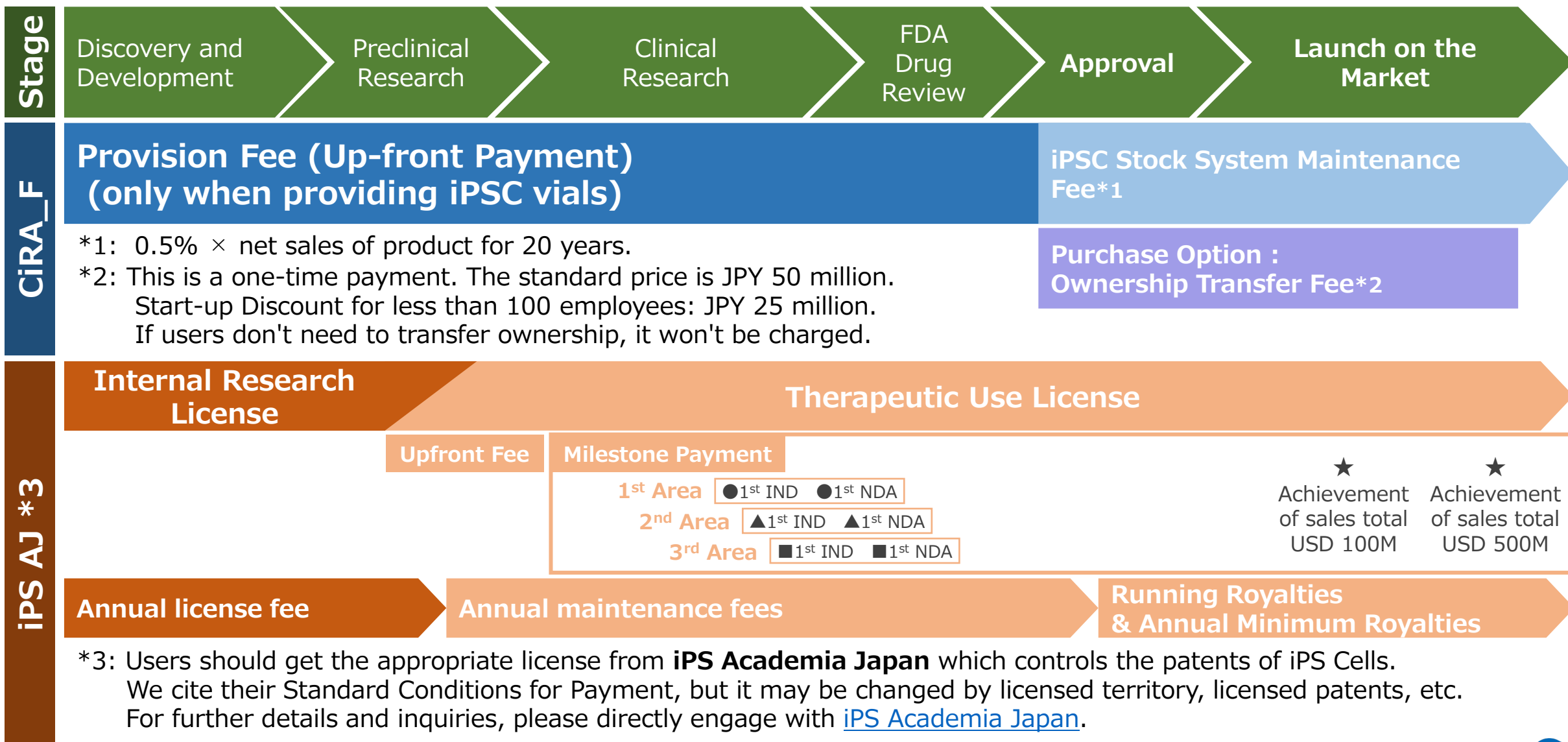
- ✓ In addition to the provision fee above, an applicant of iPSC stock, whether profit or non-profit, is required to arrange for shipping from CiRA Foundation to its research location by its cost.
- ✓ After obtaining market authorization for the product, the applicant will owe iPS Stock System Maintenance Fee (Please see the next slide).
- ✓ We provide only research-grade iPS Cell Stock to new users who first use our iPS Cell Stock in principle. But as for HLA genome-edited lines and KTRH lines, users can use clinical-grade iPS Cell Stock for their non-clinical research.

Overview of Terms and Conditions of CRA

※Collaborative Research Agreement (CRA)



Standard Conditions for Payment



iPSC Stock System Maintenance Fee (iMF)

Art.24 of Collaborative Research Agreement(CRA)

■ What is “iMF”?

When users use iPS cells for regenerative medicine provided for the Collaborative Research to manufacture and/or market the users' products, they shall pay us costs as set forth in items below under the title of an iPSC stock system maintenance fee as a consideration for commercial exploitation.

Users shall become obliged to make payments to us under the conditions below*1 each time when marketing authorization is granted for **a management unit(UNIT)*2** of their products; provided, however, that the maximum number of UNITS shall be limited to three, and for four UNITS or more, the users shall not become obliged to make payment. *(Cited from Art.24 of CRA)*

*1 Payment conditions: 0.5% × net sales of product for 20 years.

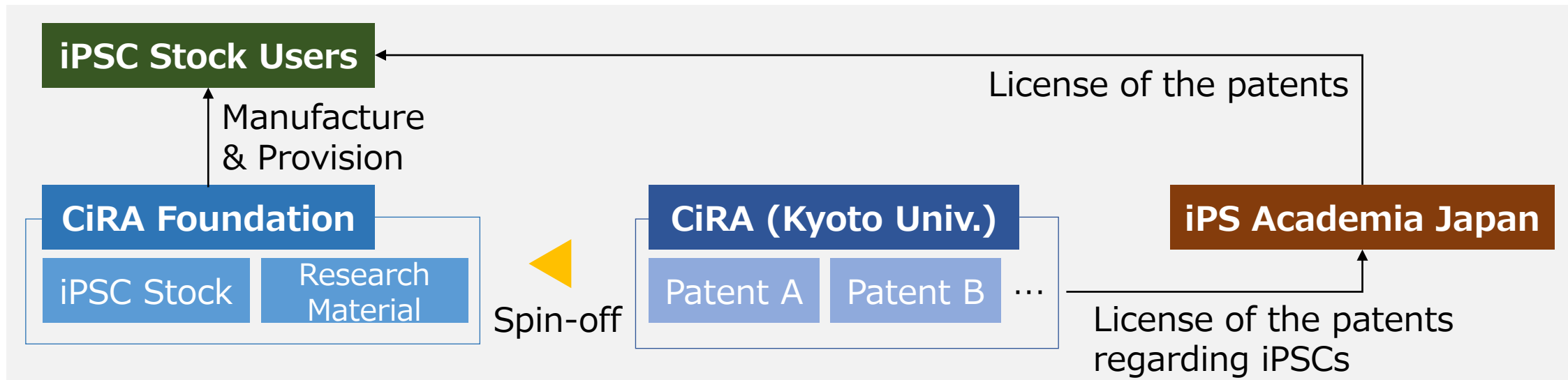
*2 UNIT: a product family with the same clinical value such as selling under the same brand name, including cases when the name for selling is different in collaborative or overseas development

iPSC Stock System Maintenance Fee (iMF)

Art.24 of Collaborative Research Agreement(CRA)

■ Is “iMF” different from the patent license?

YES, it is. iMF is a consideration for commercial exploitation of the iPS Cell Stock. The patents of Kyoto University relevant to the iPS Cells are controlled by iPS Academia Japan. Their license program is indicated on [their website](#). Also, users have to get the appropriate license regarding the third parties' patents from the licensor in their countries.



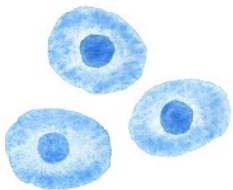
iPSC Stock System Maintenance Fee (iMF)

Art.24 of Collaborative Research Agreement(CRA)

■ If Expected Product Will Not Be Single Product i.e. Multiple Products, What happens?

If other product is originated from the provided iPSC stock, iMF will be imposed based on a concept of “**unit**”, meaning a product family with the same clinical value such as selling under the same brand name.

Until Third Unit
If Fourth Unit ? → For Free



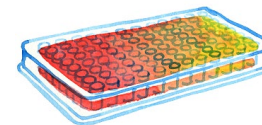
Unit 1st
iMF 0.5%/y



Unit 3rd
iMF 0.5%/y



Unit 2nd
iMF 0.5%/y



Unit 4th
~~iMF 0.5%/y~~
¥
FREE



Interpretation of “UNIT”

■ Occasions when we regard as **different** **UNITs**

1. When users develop another product from iPSC Stock

	1 st Approval	2 nd Approval
Drug Name	TerraCiRA	CiRASkin
Differentiated Cells	T cells	Epidermal Cells
Raw Material	iPSC Stock	iPSC Stock
Manufacturing Method	With A method in A factory	With B method in B factory
Efficacy/Effect	Acute Lymphoblastic Leukemia	Severe Burn

2. When the products are the same, but aim for different clinical positioning

	1 st Approval	2 nd Approval
Drug Name	TerraCiRA	TCelliRA
Differentiated Cells	T cells	T cells
Raw Material	iPSC Stock	iPSC Stock
Manufacturing Method	With A method in A factory	With A method in A factory
Efficacy/Effect	Acute Lymphoblastic Leukemia	Covid-19

Interpretation of “UNIT”

■ Occasions when we regard as the same UNIT

1. When its name is changed due to M&A etc., but it aims for the same clinical positioning

	1 st Approval	2 nd Approval
Drug Name	TerraCiRA	TCelliRA
Differentiated Cells	T cells	T cells
Raw Material	iPSC Stock	iPSC Stock
Manufacturing Method	With A method in A factory	With B method in B factory
Efficacy/Effect	Acute Lymphoblastic Leukemia	Acute Lymphoblastic Leukemia

2. When the new indication is added

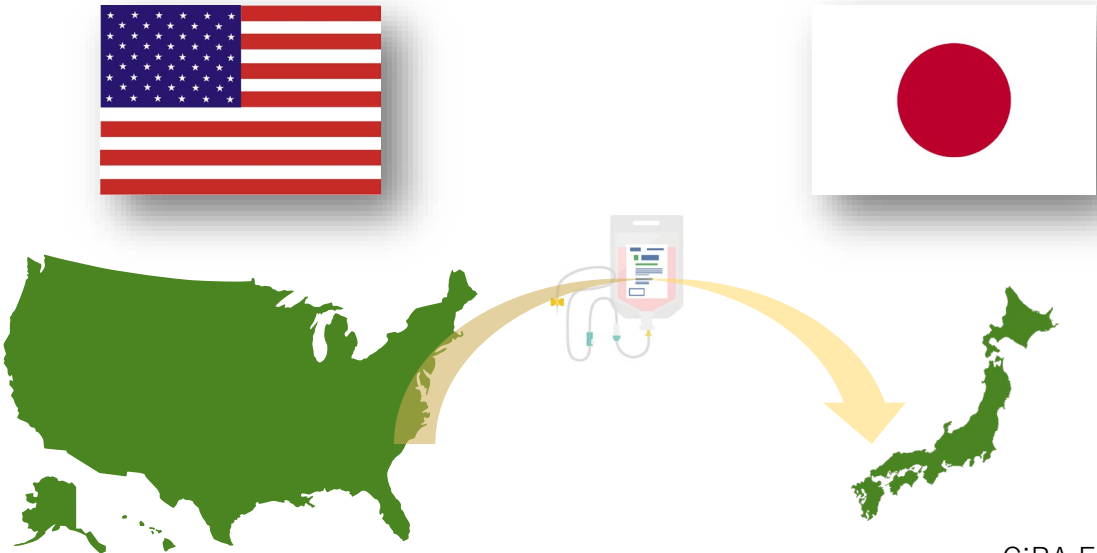
	1 st Approval	2 nd Approval
Drug Name	TerraCiRA	TerraCiRA
Differentiated Cells	T cells	T cells
Raw Material	iPSC Stock	iPSC Stock
Manufacturing Method	With A method in A factory	With A method in A factory
Efficacy/Effect	Acute Lymphoblastic Leukemia	Acute Lymphoblastic Leukemia Large Cell Lymphoma

Interpretation of “UNIT” –Overseas Products-

■ Occasions when we regard as the same UNIT

3. When their names aren’t similar, but they aim for the same clinical positioning (e.g. as same as manufacturing methods, efficacy, etc.)

	Approval in Country A	Approval in Country B
Drug Name	TerraCiRA	Zaidaan
Differentiated Cells	T cells	T cells
Raw Material	iPSC Stock	iPSC Stock
Manufacturing Method	With A method in A factory	With A method in A factory
Efficacy/Effect	Acute Lymphoblastic Leukemia	Acute Lymphoblastic Leukemia



Main Points of Ownership Transfer Agreement

■ Financial Terms of the Ownership Transfer

After executing the Ownership Transfer Agreement, the possessory right (real right) will be set at the time of notification of the clinical trial, and the ownership will be transferred at the time of **approval of manufacturing and marketing**. Payment of consideration is not required when setting the possessory right, and **JPY 50M is required** when transferring the ownership. (Half price for venture companies that have less than 100 employees. One-time payment through Japan, the US, and Europe.) Early transfer of ownership is possible if prepayment is conducted before the predetermined timing of the consideration payment (the time of manufacturing and marketing approval).

In addition, please note that the transferred ownership is subject to a covenant not to be re-transferred.

Ownership is transferred on **a management unit basis**. Even if the products come from the same iPSC Stock, JPY 50M shall be paid for each approval as long as the product is a different management unit. However, **the maximum is 3 management units**, and in principle, we will not receive consideration for the 4th product or later.

Contact us

■ About iPS Cell Stock

ips-stock-shinsa*cira-foundation.or.jp
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