

Sumitomo Pharma Co., Ltd.

Conference on Establishment of RACTHERA, the Regenerative Medicine and Cell Therapy Business Joint Venture

December 17, 2024

Event Summary

[Company Name]	Sumitomo Pharma Co., Ltd.	
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[Event Name]	Conference on Establishment of RACTHERA, the Regenerative Medicine and Cell Therapy Business Joint Venture SUMITOMO CHEMICAL COMPANY, LIMITED and Sumitomo Pharma Co., Ltd. had hold jointly.	
[Date]	December 17, 2024	
[Time]	16:30 – 17:06 (Total: 36 minutes, Presentation: 15 minutes, Q&A: 21 minutes)	
[Venue]	Webcast	
[Number of Speakers]	3	
	Keiichi Iwata	Representative Director & President, SUMITOMO CHEMICAL COMPANY, LIMITED
	Toru Kimura	Representative Director, President and CEO
	Shunji Kobayashi	General Manager, Corporate Communications Dept. SUMITOMO CHEMICAL COMPANY, LIMITED
[Analyst Names]	Takato Watabe	Morgan Stanley MUFG Securities
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Shigeki Okazaki
Fumiyoshi Sakai
Hiroyuki Matsubara

Nomura Securities
UBS Securities
Nomura Securities

Presentation

Kobayashi: It is now time to begin, so we will start the conference on the establishment of RACTHERA, the regenerative medicine and cell therapy business joint venture. Thank you very much for taking time out of your busy schedules and for attending today despite the short notice.

This conference is being streamed live via Zoom webinar, and we will proceed in the order of presentations, followed by a Q&A session.

To start, I apologize for the inconvenience, but in preparation for the Q&A session later, we kindly ask you to adjust your Zoom display name to reflect your company name and your own name. We greatly appreciate your cooperation in this matter.

Now, let us begin.

To start, I would like to introduce today's participants. First, we have Keiichi Iwata, Representative Director and President of SUMITOMO CHEMICAL COMPANY, LIMITED, and Toru Kimura, Representative Director, President, and CEO of Sumitomo Pharma Co., Ltd. I, Kobayashi, from SUMITOMO CHEMICAL, will serve as the moderator for today's session.

Now, to begin, I would like to invite President Iwata of SUMITOMO CHEMICAL to explain the purpose of today's conference. President Iwata, the floor is yours.

Iwata: Hello, everyone. I'm Keiichi Iwata, President of SUMITOMO CHEMICAL. Thank you very much for attending this joint press conference of SUMITOMO CHEMICAL and Sumitomo Pharma despite the short notice.

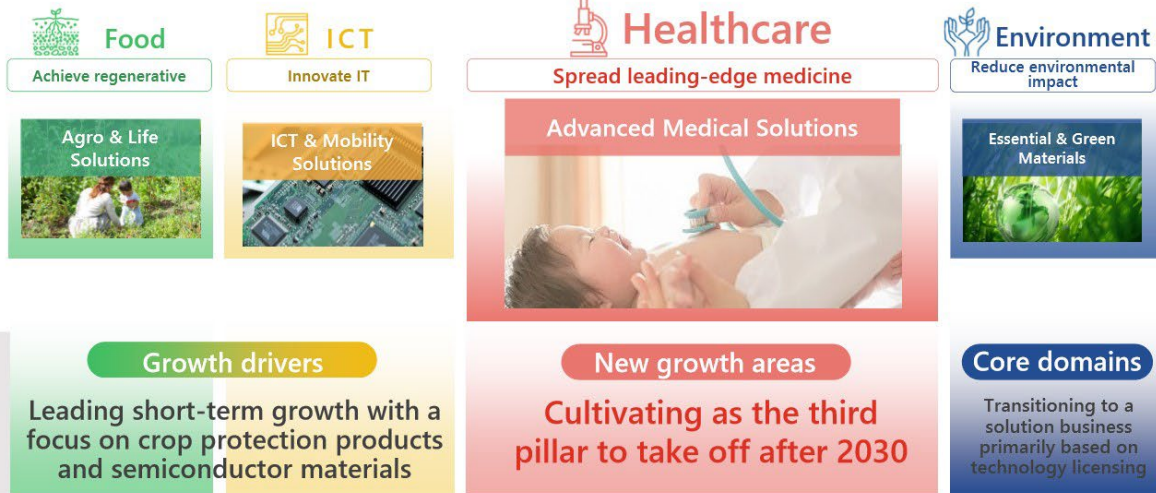
First, allow me to explain the purpose of today's conference.

Our group experienced a very challenging business performance last year in FY2023. However, by implementing short-term, focused measures to improve performance, such as business restructuring, and by working together as one group, we have been able to make progress toward a V-shaped recovery this fiscal year.

Long-term vision and positioning of each business sector

Innovative Solution Provider

~A company that solves social issues with innovative technology~



Looking ahead, as the immediate growth drivers for our group, as shown on the left side of this slide, we have agro and life solutions, which focuses on crop protection chemicals and semiconductor materials, as well as ICT and mobility solutions.

Following these areas, we are committed to cultivating a new growth area, shown in the center, which is the advanced medical solutions division, aimed at healthcare. This is a field we intend to nurture steadily with a medium- to long-term perspective.

Full entry into the regenerative medicine & cell therapies business

Regenerative medicine & cell therapies business

Market

- The global market for cell therapies was estimated to be worth approximately \$2.0 billion as of 2022.
- It is expected to continue growing at an annual rate of 10% to 15% in the coming years.

Advantage

Sumitomo Pharma

- The technologies and advanced knowledge acquired through their activities as a front runner in regenerative medicine and cell therapy
- ◆ Developing the world's first iPS cell-derived cell therapy (Parkinson's disease)
- ◆ October 2021: Approval of RETHYMIC® (with approximately 40 procedures already performed) (pediatric congenital athymia)



SUMITOMO CHEMICAL

- Development support based on expertise in industrial engineering, analysis and evaluation, and quality management
- Resources at the Environmental Health Science Laboratory and the Bioscience Research Laboratory

The entire Sumitomo Chemical Group is promoting development and business expansion.
We aim for a business scale of over 350[※] billion yen by the late 2030s

※ The estimation of the business value assumes that the multiple products that are under development will be successfully launched and does not make any adjustment based on probability of success

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The main topic of today's discussion—the regenerative medicine and cell therapies business—will serve as the core of this growth division.

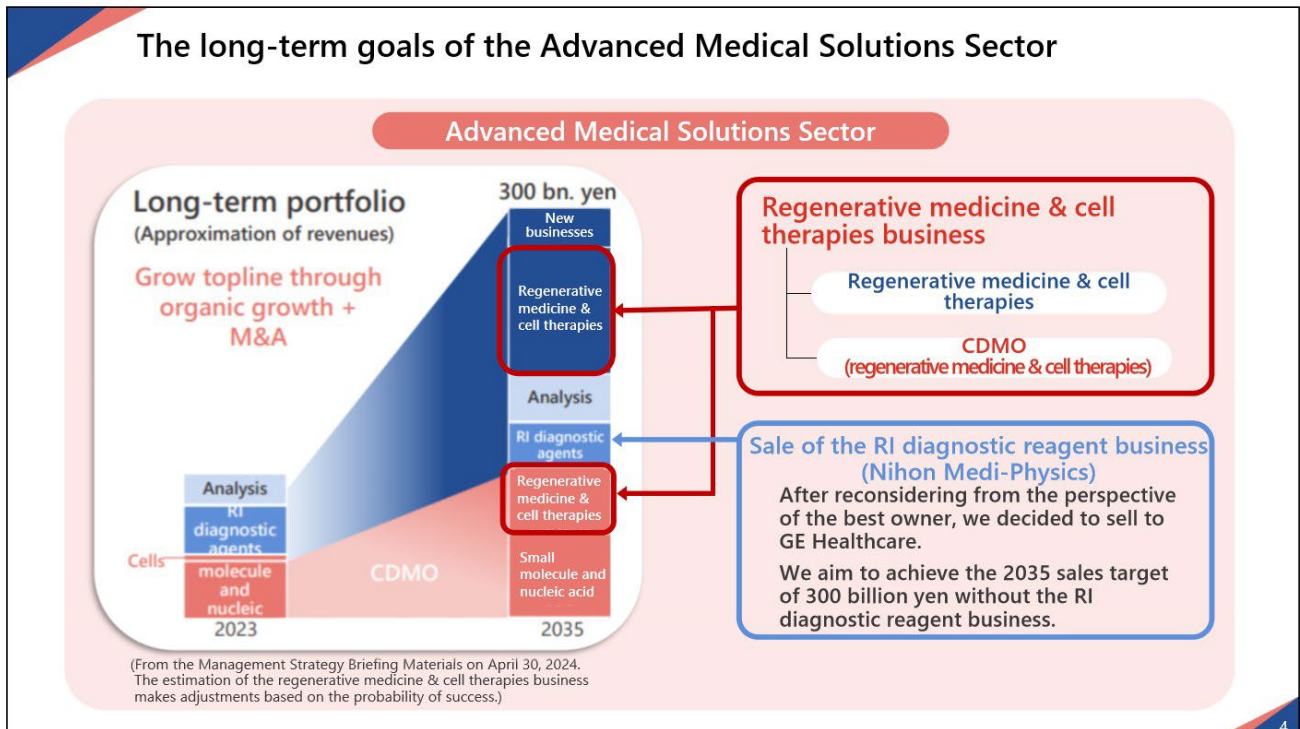
First, from a market perspective, the global market for cell therapy was valued at approximately USD2 billion in FY2022, and it is considered a promising field that is expected to expand rapidly going forward.

From a development perspective, Sumitomo Pharma has been leading the way globally with its long-standing efforts, such as being the first in the world to develop iPS cell-derived products targeting Parkinson's disease.

Combined with SUMITOMO CHEMICAL's industrialization technologies, expertise in analysis and quality control, and its bio-related knowledge, we can leverage these strengths across the Group.

By harnessing these advantages and accelerating the global rollout of this business as a group, we aim to provide new treatment options to patients worldwide while also building a large-scale business valued at up to JPY350 billion by the latter half of the 2030s. Please note that this figure has not been adjusted for the probability of success.

The long-term goals of the Advanced Medical Solutions Sector



This slide, which we presented in April, illustrates our vision.

As part of the advanced medical solutions division, which we expect to serve as our third pillar, we are focusing on regenerative and cell therapy, which we will explain today.

In addition, the division includes the regenerative and cellular CDMO, which was reorganized in October, as well as businesses like small molecule and nucleic acid CDMO and analysis services.

Our target to achieve sales of JPY300 billion by 2035 remains unchanged.

While this is not directly related to today's discussion, as we announced in a recent press release, we have decided to transfer our shares in Nihon Medi-Physics, a 50%-owned subsidiary, to our long-standing partner GE Healthcare.

Nihon Medi-Physics, since its establishment in 1973, has built a strong reputation for the stable supply of high-quality products, and it has grown to become the leading company in the domestic market for radiopharmaceutical diagnostics.

Going forward, from the perspective of identifying the best owner, we believe that under GE Healthcare, which has an extensive lineup of diagnostic pharmaceuticals and medical devices and operates one of the largest businesses in this field globally, Nihon Medi-Physics will achieve even more sustainable growth.

Now, I would like to hand it over to President Kimura of Sumitomo Pharma, who will explain the establishment of the new company for regenerative and cell therapy.

Kobayashi: Now, President Kimura, if you would please.

Kimura: I am Toru Kimura, Representative Director, President, and CEO of Sumitomo Pharma. I would like to take this opportunity to explain the establishment of RACTHERA, the joint venture company for Sumitomo Pharma’s regenerative medicine and cell therapy business.

We have placed a very strong emphasis on regenerative medicine. This commitment stems from our firm belief that, among the many drugs that exist today, regenerative medicine is the only viable treatment for diseases and disorders where cells or tissues have been lost. Our goal is to deliver regenerative medicine products as quickly as possible to patients who are waiting for these treatments to be realized.

Today, I would like to introduce RACTHERA, which we have established to accelerate these efforts.

RACTHERA Co., Ltd. 「Regenerative And Cellular THERApy」	
Mainly seconding human resources from Sumitomo Pharma Collaborate closely with Sumitomo Pharma and promote research and development of regenerative medicine and cell therapy field	
Date of establishment	November 15, 2024 (Scheduled to start business on February 1, 2025)
Representative¹	Atsushi Ikeda, Representative Director and President, Toru Kimura, Chairperson of the Board ² (Scheduled to take office on February 1, 2025) <small>1: Sumitomo Chemical is also expected to appoint one representative director, 2: Chairperson of the Board of S-RACMO</small>
Capital	1 million JPY
Location	2-7-1, Nihonbashi, Chuo-ku, Tokyo, Japan (in Sumitomo Pharma Tokyo Head Office)
Shareholders	Sumitomo Pharma: 100% (From February 1, 2025, Sumitomo Chemical: 66.6%; Sumitomo Pharma: 33.4%)
Scope of business	Research, development, manufacture, sales, and import and export of regenerative medicine and cell therapy products, cell processing products, and regenerative medicine and cell therapy-related products

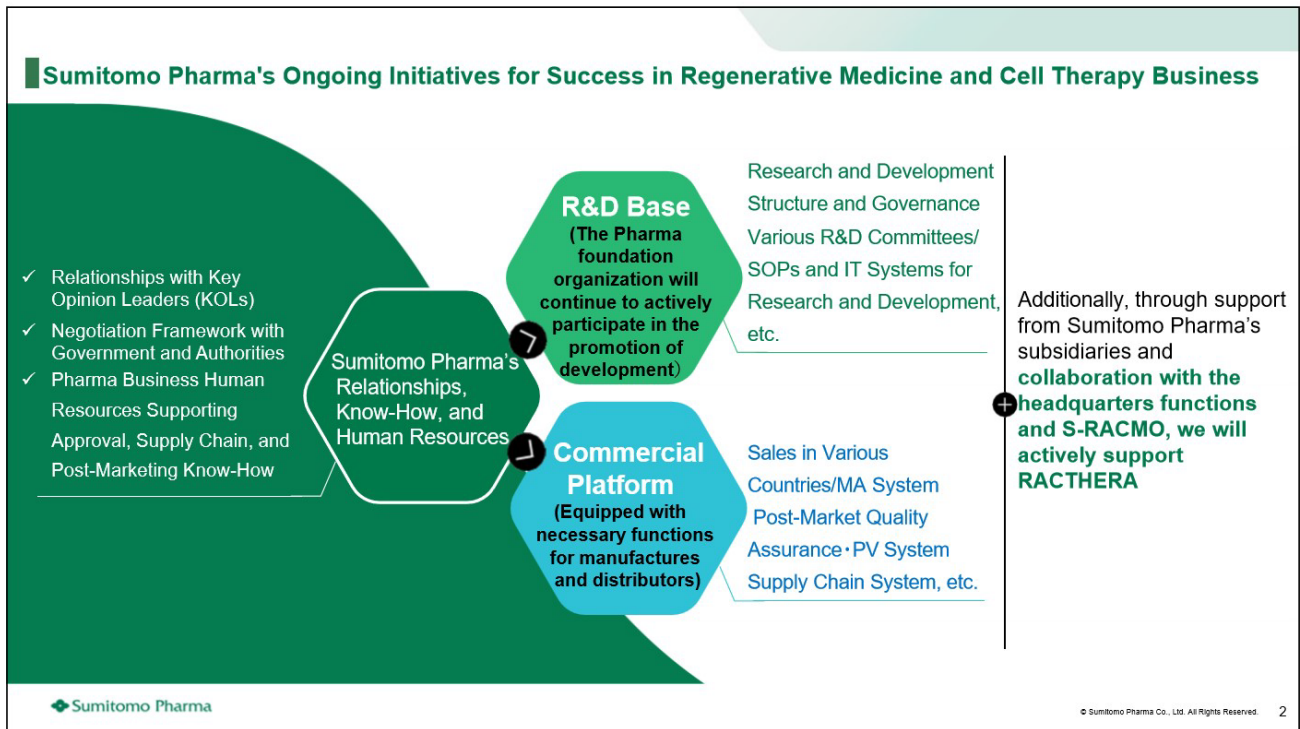
Next, I would like to provide an overview of RACTHERA.

As you can see here, the name RACTHERA combines the initials of Regenerative And Cellular THERApy.

The company will primarily comprise personnel from Sumitomo Pharma and will work in close collaboration with Sumitomo Pharma to spearhead the research and development of regenerative and cell therapy.

The President and CEO of this new company will be Ikeda, currently the Director of Sumitomo Pharma’s Kobe Center, and I myself will serve as the Chairman of the Board, as I intend to be involved in RACTHERA’s operations.

The company has already been established as a 100%-owned subsidiary of Sumitomo Pharma. However, as of February 1 next year, we plan to transition to a joint venture, with SUMITOMO CHEMICAL holding 66.6% of the shares and Sumitomo Pharma holding 33.4%.



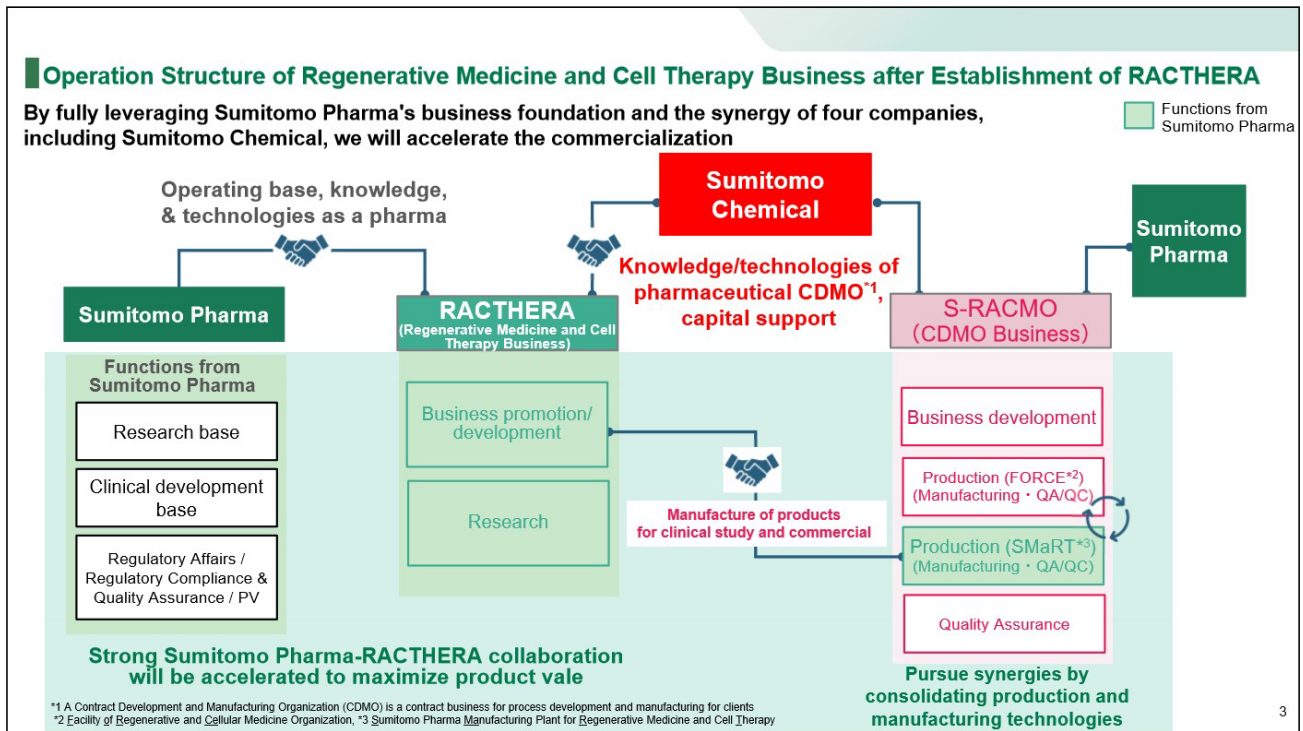
Next, while it goes without saying that RACTHERA will play a central role in the success of the regenerative and cell therapy business, it is absolutely essential that Sumitomo Pharma take ownership and proactively drive this initiative.

Sumitomo Pharma has a well-established foundation for R&D, including safety research, as well as a strong foundation for clinical development.

In addition, we have built relationships with KOLs, experience in negotiating with governments and regulatory authorities, and other knowledge, personnel, and functions unique to a pharmaceutical company.

Naturally, we also possess a solid commercial platform, and I believe that close collaboration with RACTHERA will be the key to success.

Furthermore, we are determined to ensure the success of this business through our collaboration with S-RACMO and SUMITOMO CHEMICAL.



Next, I would like to briefly outline the operational framework for the regenerative and cell therapy business, following the establishment of RACTHERA.

While it may appear somewhat complex, at the center lies RACTHERA. This company will focus on driving the regenerative and cell therapy business, specifically its research and development.

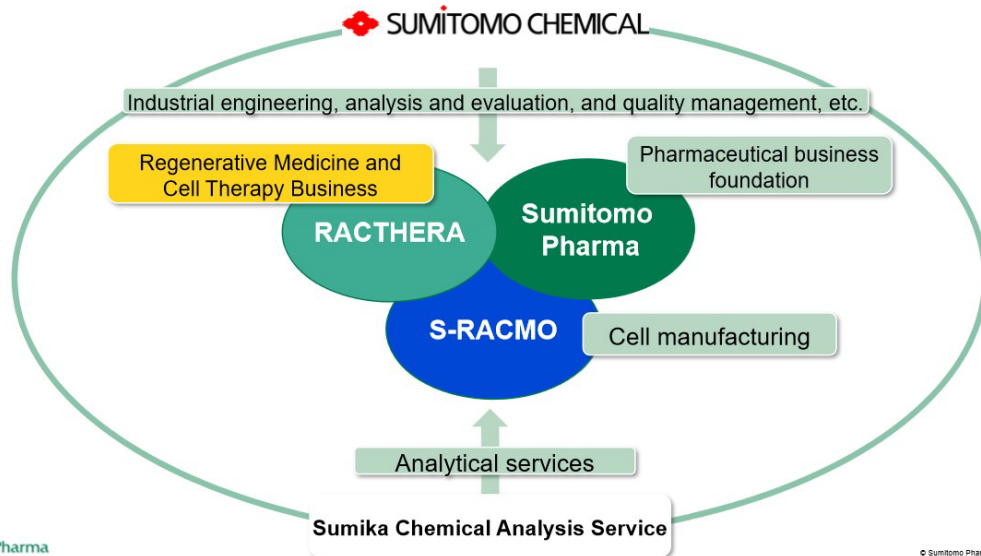
At the same time, as I mentioned earlier, close collaboration with Sumitomo Pharma, which possesses the full range of pharmaceutical functions, will be essential.

Additionally, we already have the regenerative medicine CDMO business company, S-RACMO, which was established by SUMITOMO CHEMICAL and Sumitomo Pharma. Here, we plan to transfer Sumitomo Pharma's existing production facility, SMaRT, which utilizes iPS cells. By consolidating production and manufacturing technologies under S-RACMO, we aim to pursue synergies and achieve more advanced technology to produce stable, high-quality products at a lower cost.

Sumitomo Pharma, RACTHERA, S-RACMO, and SUMITOMO CHEMICAL—these four companies will work as one to contribute to the development of this business.

Regenerative Medicine and Cell Therapy Business in Sumitomo Chemical Group

Aiming for the success of the RACTHERA business by uniting the strengths of the entire Sumitomo Chemical Group



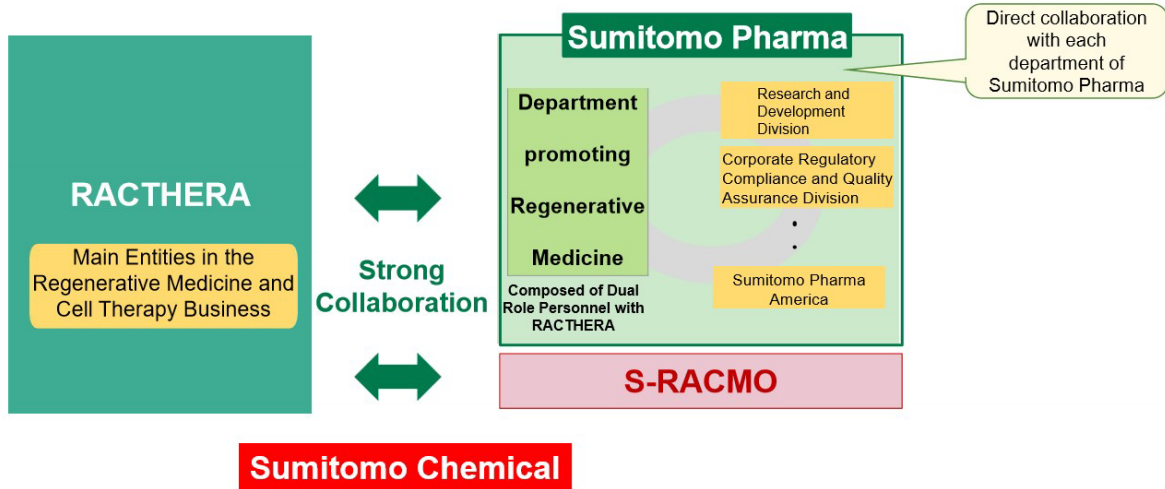
Next, regarding RACTHERA, Sumitomo Pharma, S-RACMO, and SUMITOMO CHEMICAL, this is not simply a capital relationship.

The industrialization technologies, analytical techniques, and quality control capabilities possessed by SUMITOMO CHEMICAL are essential for the development of the regenerative and cell therapy business.

Additionally, SUMITOMO CHEMICAL GROUP's Sumika Chemical Analysis Service holds a wealth of analytical technologies. By integrating these resources, we intend to nurture this business as a collective effort of the SUMITOMO CHEMICAL GROUP.

Structure for Promoting the Regenerative Medicine and Cell Therapy Business

- The Sumitomo Chemical Group will continue to unite, strengthening collaboration with Sumitomo Pharma and S-RACMO to drive the business forward
- As a hub for promoting development, Sumitomo Pharma will establish a department promoting regenerative medicine, led by a person concurrently in charge of RACTHERA



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Next, I will present the operational framework for the regenerative and cell therapy business.

While RACTHERA serves as the core entity for the regenerative and cell therapy business, as I have mentioned repeatedly, Sumitomo Pharma possesses a variety of functions as a pharmaceutical company. Ensuring strong collaboration between these entities will be a critical key to success.

To address this, the program leaders for RACTHERA will also hold positions within Sumitomo Pharma, specifically in the department promoting regenerative medicine. This arrangement will ensure strong coordination with the pharmaceutical functions of Sumitomo Pharma, as we advance research and development.

Establishment of RACTHERA: Significance for Sumitomo Pharma and the Regenerative Medicine and Cell Therapy Business



Sumitomo Pharma

- To reduce the investment burden in research and development and capital expenditure through investment burden based on shareholding ratio
- In addition to RACTHERA's business revenue, revenue from transfer consideration, development milestones (up to approximately 4 billion JPY), and sales milestones (up to approximately 150 billion JPY)
- Flexibility in research and development strategies (Oncology, Psychiatry & Neurology)
- To continue Regenerative Medicine and Cell Therapy Business within Sumitomo Chemical Group and ensuring continued involvement of employees



Regenerative Medicine and Cell Therapy Business

- Securing a stable source of funding for research and development and capital expenditure, which is more stable than when Sumitomo Pharma is operating independently, through the acceptance of capital from Sumitomo Chemical
- Optimal operational structure that can maximize the utilization of the technologies, know-how, and human resources of Sumitomo Pharma, Sumitomo Chemical, RACTHERA, and S-RACMO respectively

Next, while I have already touched on this, I would like to clarify the significance of RACTHERA's establishment for both Sumitomo Pharma and the regenerative and cell therapy business.

For Sumitomo Pharma, the ownership ratio in RACTHERA will be 1/3, which means that the investment burden will also be reduced to 1/3. When compared to the idea of independently developing the regenerative and cell therapy business, this structure reduces the burden associated with R&D and capital investments.

In addition, with the establishment of RACTHERA, the business proceeds of [inaudible] will naturally include up-front payments of JPY2 billion for the transfer price, milestone payments of up to JPY4 billion for development, and if the business progresses, sales milestones of up to JPY150 billion.

At the same time, as we expand the regenerative and cell therapy business and reduce the burden, we will be able to allocate more resources to our other two priority focus areas—oncology and neurology and psychiatry.

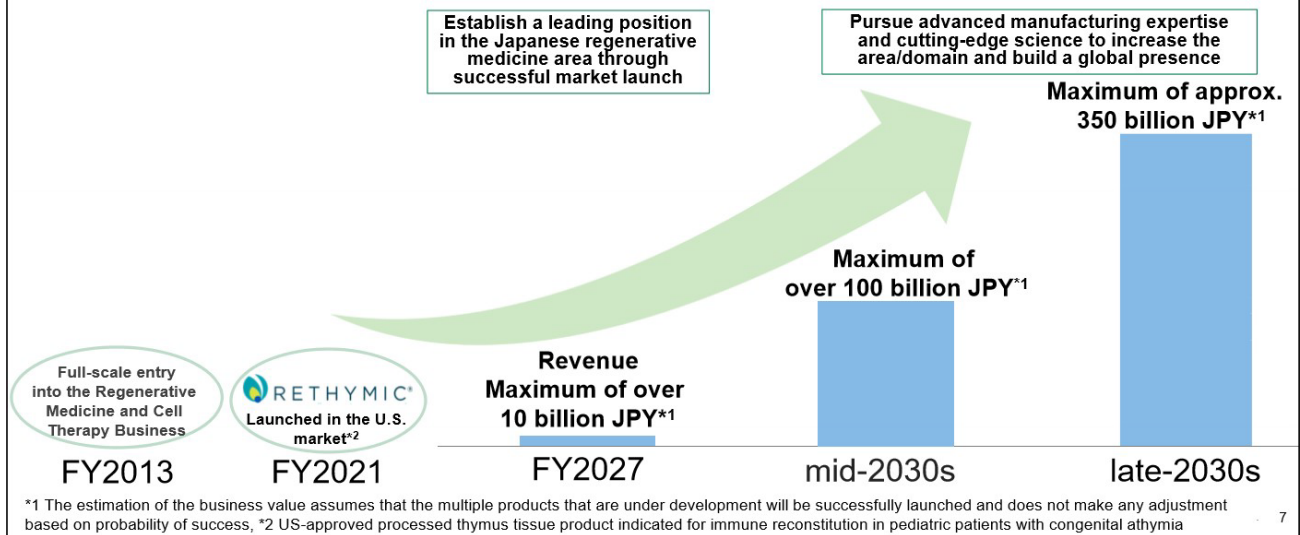
Furthermore, the employees engaged in the regenerative and cell therapy business—whether they remain at Sumitomo Pharma, transfer to RACTHERA, or move to S-RACMO—will continue to develop their teamwork, allowing us to expand this business even further.

From the perspective of the regenerative and cell therapy business, the establishment of RACTHERA will allow us to secure stable funding for research and development as well as capital investments, without being constrained by the very challenging financial situation that Sumitomo Pharma currently faces.

Compared to pursuing this business independently, receiving capital from SUMITOMO CHEMICAL enables us to more effectively maximize the synergies of the technologies, expertise, and human capital held by Sumitomo Pharma, SUMITOMO CHEMICAL, RACTHERA, and S-RACMO.

Outlook for the Regenerative Medicine and Cell Therapy Business

- As a frontrunner in regenerative and cell therapy, we provide new value that can only be realized through regenerative medicine
- Aiming to expand revenue to maximum of approximately 350 billion JPY*1 by the late 2030s



This is our outlook for the business.

We take pride in being a front-runner in the world of regenerative and cell therapy using iPS cells, and we aim to deliver new value to patients and society that can only be achieved through regenerative medicine.

By the latter half of the 2030s, we aim to grow this business to achieve revenue of up to JPY350 billion.

We entered the regenerative and cell therapy business in earnest in 2013. In 2021, we launched RETHYMIC, a treatment for congenital athymia, in the US.

For FY2027, we aim for revenue of JPY10 billion, and by the mid-2030s, we aim to grow this business to as much as JPY100 billion, and by the latter half of the 2030s, as I mentioned earlier, to JPY350 billion.

Sumitomo Pharma's Regenerative Medicine/Cell Therapy Launched Product and Development Pipeline (as of December 17, 2024)								
Brand name/Cell type Product code	Indications	JP/ US	Pre-clinical	Clinical research	Phase 1/2	Phase 3	Approval application	Approval→ Launch
RETHYMIC®	Congenital athymia	US						●
Dopaminergic neural progenitor cells (Allo iPS cell-derived) CT1-DAP001/DSP-1083	Parkinson's disease	JP US			● ¹ ● ⁴ ● ⁵			Launch timing under consideration
Retinal pigment epithelial cells (Allo iPS cell-derived) HLCR011	Retinal pigment epithelium tear	JP			● ⁵			
Retinal sheet (3D retinal tissue) (Allo iPS cell-derived) DSP-3077	Retinitis pigmentosa	JP US		● ²	● ⁵			
Neural progenitor cells (Allo iPS cell-derived)	Spinal cord injury	JP US		● ³				
Nephron progenitor cells (organ) (Auto/ Allo iPS cell-based induced)	Kidney failure	JP/ US	●					

1. Kyoto University Hospital 2. Kobe City Eye Hospital 3. Keio University Hospital 4. University of California San Diego School of Medicine 5. Company-sponsored clinical study

Lastly, I would like to present a list of the products we have launched and are developing within Sumitomo Pharma's regenerative and cell therapy business.

At the top is RETHYMIC, a product already launched and being sold in the US. All of the other products are regenerative medicine therapies using iPS cells, including treatments for Parkinson's disease, retinal pigment epithelial tears, retinitis pigmentosa, spinal cord injury, and others. These are all areas where RACTHERA will take the lead in advancing research and development going forward.

A recent highlight is program 3077, which is a retinal sheet for retinitis pigmentosa. We have begun clinical trials for this product in the US at Mass Eye and Ear, the ophthalmology teaching hospital affiliated with Harvard.

By continuing to move forward with these projects while increasing the speed of their practical implementation, we aim to significantly expand the regenerative and cell therapy business.

That concludes my explanation.

Kobayashi: Thank you very much.

Question & Answer

Kobayashi [M]: We will now move on to the Q&A session.

Due to time constraints today, we ask that each person limit themselves to one question at a time. However, you are welcome to ask additional questions if you'd like.

Now, who would like to begin?

First, Mr. Watabe from Morgan Stanley MUFG Securities, please go ahead.

Watabe [Q]: I'm Watabe from Morgan Stanley. Thank you for the explanation. I have a question for President Iwata.

Regarding Sumitomo Pharma, it was positioned as one of the businesses for which you're seeking the best owner, but on the other hand, you're now actively engaging in the regenerative and cell therapy business. Could you explain the background on this and how you see your strengths relative to other companies?

Iwata [A]: Thank you for your question.

As for the question from Mr. Watabe regarding the positioning of this regenerative cell therapy business from the perspective of finding the best owner, I've consistently stated that when it comes to drug development, the contribution that a chemical manufacturer can make is, frankly, very limited. Because of that, I believe it's always necessary to consider a framework or structure that will allow a drug company to achieve sustainable growth. That belief remains unchanged.

Now, as for regenerative cell therapy, I believe this is a field where SUMITOMO CHEMICAL can make significant technological contributions. Furthermore, iPS technology is a remarkable achievement that originated in Japan—a technology that Japan can take great pride in. When it comes to implementing this technology in society, our starting point was the idea that the SUMITOMO CHEMICAL GROUP would dedicate its full strength to making this a reality.

As President Kimura mentioned earlier, Sumitomo Pharma possesses world-leading expertise and technology in this field, built through years of accumulated efforts. Now, regarding the contributions SUMITOMO CHEMICAL can make, while evidence of the drug's efficacy—essentially proving that the drug works—is something that Sumitomo Pharma will take the lead in, ensuring the stability of product quality and cost-efficiency is extremely important. Establishing production technologies in these areas is a crucial factor, and this awareness is something that Sumitomo Pharma and SUMITOMO CHEMICAL share.

For example, back in 2012, if I recall correctly, SUMITOMO CHEMICAL achieved the production of retinal sheets using ES cells, and that served as the starting point for Sumitomo Pharma's work in regenerative cell therapy.

Since then, we have continued to have close exchanges in terms of personnel, and I believe that we can make sufficient technological contributions, not only from a technological perspective, but also from a human resources perspective, in advancing this regenerative cell therapy business.

To add a bit more, when it comes to the large-scale cultivation of regenerative cells while maintaining stable quality, areas like digitalization, robotics, and AI—essentially the integration of DX technologies—will become

absolutely essential going forward. In this regard as well, I believe that SUMITOMO CHEMICAL's expertise will play a meaningful role.

Watabe [M]: Understood. Thank you very much. I look forward to seeing the results.

Kobayashi [M]: Thank you, Mr. Watabe.

Next, Mr. Wada from SMBC Nikko Securities, please go ahead.

Wada [Q]: This is Hiroshi Wada from SMBC Nikko Securities.

My question is regarding the development milestones and sales milestones that were mentioned. You've set the development milestones at a maximum of JPY4 billion, but is this amount allocated across the entire pipeline you presented earlier? Or is it specifically tied to certain pipeline programs that are expected to come to market earlier?

Kimura [A]: I'll answer that.

In addition to the pipeline I showed earlier, there are actually numerous research themes underway. That said, in terms of progress, some programs are already in the clinical trial stage, while others are still at the in vitro experimentation stage, far earlier in development.

So, to clarify, the development milestones are also set with regions or countries in mind, but I think it's fair to say that the Parkinson's program, which is the furthest along, is the most immediate candidate.

On the other hand, for programs that are still at the in vitro stage, it's impossible to predict what their future sales might look like. Taking that into account, I think it's realistic to view the development milestones as being tied to Parkinson's and a few of the leading programs that are currently at the forefront.

Wada [M]: Understood. Thank you very much.

Kobayashi [M]: Thank you, Mr. Wada.

Next, Mr. Okazaki from Nomura Securities, please go ahead.

Okazaki [Q]: This is Okazaki from Nomura Securities. Thank you for this valuable opportunity today.

From the Sumitomo Pharma materials, you've projected JPY10 billion in revenue for FY2027. Given that Parkinson's disease was mentioned as being at the forefront earlier, can I confirm whether this amount incorporates revenue from domestic Parkinson's disease treatments? I also understand that the timeline for the domestic approval application was delayed, so could you provide an update on the launch timing and the breakdown of that JPY10 billion figure?

Additionally, for the target of up to JPY350 billion in revenue by the latter half of the 2030s, could you share a breakdown of this figure and your assessment of its attainability, within a reasonable range?

Kimura [A]: This is Kimura. Thank you very much for your questions.

First, regarding whether the JPY10 billion revenue target for FY2027 includes Parkinson's disease, yes, it does.

In November, we announced that we would be reviewing the schedule for the approval application. However, since then, there have been several developments, and we are once again working toward submitting the application according to a revised timeline.

As things stand now, we believe that we will be able to submit the application, or potentially secure approval, sometime next fiscal year. We are now making every effort to achieve that goal.

Given this timeline, with next fiscal year being FY2025, it is reasonable to expect that by FY2027, we will have some revenue from Parkinson's disease treatments in Japan. While the approval will likely come with certain conditions and the revenue initially may not be substantial, it is safe to say that it is included in the JPY10 billion target.

At the same time, we are also advancing development in the US, but realistically speaking, I don't think we'll be able to obtain approval there by FY2027.

On another note, although we haven't established a formal schedule for the regenerative and cell therapy business, the US revenue from RETHYMIC, which is already generating several billion yen, could also be incorporated into RACTHERA, depending on the timing and approach as the business progresses. Factoring all of this in, I believe that the JPY10 billion revenue target for FY2027 is quite solid.

As for the JPY350 billion target for the latter half of the 2030s, this figure assumes a POS of 100. In our projections, Parkinson's disease accounts for the largest share, followed by program 3077, the retinal sheet product that recently began clinical trials in the US. We also expect that other products will obtain approval or reach the market by that time, so we anticipate contributions from multiple products.

Okazaki [M]: That makes perfect sense. Thank you very much. That's all from me.

Kobayashi [M]: Thank you, Mr. Okazaki.

Are there any other questions?

Mr. Okazaki from Nomura Securities, I see you've raised your hand again.

Okazaki [M]: May I ask another question?

Kobayashi [M]: Yes, please go ahead.

Okazaki [Q]: This time, it's about the CDMO section on page four of SUMITOMO CHEMICAL's materials. Regarding your contract manufacturing status and competitive landscape, I assume competitors include companies like Takara Bio or Nikon and Lonza. Could you please explain your group's competitive strengths compared to such companies?

Iwata [A]: This is Iwata. Thank you for your question.

The CDMO business is another pillar, or should I say, a growing division under the advanced medical solutions division, which we are positioning as our third pillar. This CDMO is divided into three categories.

The first is regenerative cells, which, as discussed today, has been restructured into a separate entity called S-RACMO.

The second category is nucleic acids, particularly those that are cutting-edge, with very long molecular structures, specifically nucleic acids with sequences exceeding 100 units. We are working on commercializing this area. While most of our partners here are still in academia or start-ups and there are relatively few cases where these technologies have been applied to actual pharmaceuticals, we believe that as development progresses and these technologies connect to pharmaceuticals, the business will expand significantly. That's the potential we see as we focus on nucleic acid CDMO.

The third category, which is currently the largest in terms of revenue, is small molecules. SUMITOMO CHEMICAL has been engaged in small-molecule businesses for a long time. In fact, when it comes to CDMO companies in Japan, including our group companies, I believe that the SUMITOMO CHEMICAL GROUP ranks first in terms of sales scale. Historically, this was a CMO business, purely focused on manufacturing. However, we are now also handling the D, the development aspect, which allows us to deliver added value unique to SUMITOMO CHEMICAL.

In the pipeline for new drug candidates or development projects, small molecules remain the majority, making up more than half of all candidates. Given this, we believe that by adding development capabilities to our small-molecule CDMO, we can grow this area into a major pillar of our business. That's our goal as we work to nurture this field.

Okazaki [Q]: Could you briefly explain SUMITOMO CHEMICAL's competitive strengths compared to other companies in nucleic acid or regenerative cell CDMO?

Iwata [A]: Regarding nucleic acids, there are various types, but the key competitive factor now is how long you can extend the molecular sequences. SUMITOMO CHEMICAL has the technology to link sequences exceeding 100 units at an extremely high level of purity. This is a capability that, on a global scale, is likely possessed by only one or two companies, and in Japan, it is unique to SUMITOMO CHEMICAL. We aim to leverage this technological advantage to push the business forward.

As for the strengths of S-RACMO in regenerative cell CDMO, I'd like to defer to President Kimura, who is most familiar with this area.

Kimura [A]: This is Kimura speaking.

I also serve as the Chairman of S-RACMO, and I believe there are two key strengths of S-RACMO as a CDMO for regenerative cells.

First, we are already contracted to manufacture approved products. For example, there is a product called Vyznova, which is a corneal endothelial cell product launched by Aurion Biotech. Since its launch this fall, it has been very well received, and we've heard that a large number of patients are using it.

The second strength is our regulatory expertise and know-how in obtaining approvals. In fact, for Vyznova, both Sumitomo Pharma and S-RACMO worked together with Aurion Biotech to achieve regulatory approval. This is one of our key accomplishments.

While S-RACMO itself is not directly manufacturing it, the current RETHYMIC product in the US from Sumitomo Pharma involved significant contributions from the Japanese team in obtaining approval. The members who played a major role in navigating regulatory processes with the FDA and PMDA are now at S-RACMO. This means that we can provide clients with regulatory services and the expertise to achieve approvals, which sets us apart from other CDMO companies. Clients highly value this point, and I believe it is one of our strongest differentiators.

Okazaki [M]: I see. Thank you very much for the detailed explanation. That's very clear.

Kobayashi [M]: Thank you, Mr. Okazaki.

Next, Mr. Sakai from UBS Securities, please go ahead.

Sakai [Q]: This is Sakai from UBS Securities.

I have a question for President Kimura. On page eight of Sumitomo Pharma's materials, there's a list of development pipeline products. Could you explain how the intellectual property rights for these products will be handled, specifically where these rights will be assigned and in what form? I imagine that, depending on the product, the ownership structure could be quite complex. Is it correct to assume that all of these rights will be transferred to the new company?

Kimura [A]: For this transfer, RETHYMIC, which is at the top of the list, will not be moved to RACTHERA.

As for all the other products, the intellectual property rights currently held by Sumitomo Pharma will, in principle, be transferred to RACTHERA. For patents that have been jointly filed with academia or other partners, we will obtain the necessary agreements. While most of these cases do not require any special consent, for those that do, we will secure such agreements before transferring the rights to RACTHERA.

Sakai [Q]: In that process, there will be some form of compensation, some transfer value that generates revenue for Sumitomo Pharma. Is that understanding correct?

Kimura [A]: This will take place as part of an absorption-type company split, so in essence, it will simply be separated out of Sumitomo Pharma.

On the other hand, after this separation, SUMITOMO CHEMICAL will purchase 2/3 of RACTHERA's shares from Sumitomo Pharma. At that point, as I mentioned earlier, we will receive compensation based on the value of the intellectual property, development assets, related data, and overall business value.

This payment will include a portion as an up-front payment, but the majority will be received through sales milestones as the regenerative and cell therapy business grows under RACTHERA. In total, Sumitomo Pharma is expected to receive up to JPY150 billion.

Sakai [Q]: Understood. So, to confirm, any additional revenue or transfer profit will be recognized in the fiscal year ending March 2025. Is that correct?

Kimura [A]: Yes, I believe most of it will be recorded in the fiscal year ending March 2025.

Sakai [M]: Got it. Thank you very much.

Kobayashi [M]: Thank you, Mr. Sakai.

Are there any other questions?

I see one more hand raised. Mr. Matsubara from Nomura Securities, please go ahead.

Matsubara [Q]: This is Matsubara from Nomura Securities.

During the earlier discussion about S-RACMO, you mentioned that it is manufacturing Vyznova, and I understand that producing clinical-grade products is something that other companies are also able to do. However, I'm wondering whether you might consider expanding into a business where you sell the supernatant as well. Is that something you're looking at?

Kimura [A]: I have heard that there are companies engaged in that kind of business, but as for S-RACMO, we are strictly focused on manufacturing medical-use products, and we do not have any plans to use the supernatant for other purposes.

Matsubara [M]: Understood. Thank you very much.

Kobayashi [M]: Thank you, Mr. Matsubara.

If there are no further questions, we will now conclude today's conference regarding the establishment of RACTHERA, the joint venture for the regenerative medicine and cell therapy business.

The video recording of today's conference, including the Q&A session, will be available on the websites of SUMITOMO CHEMICAL and Sumitomo Pharma starting tomorrow. Please feel free to make use of it.

With that, we will bring this session to a close. Thank you very much for attending today, especially on such short notice.

[END]