07 / アドバンストメディカルソリューション部門 Advanced Medical Solutions

部門ビジョン / Vision

高度な製造・管理・分析技術を駆使したソリューションの提供を通じ、
“化学とバイオの力”で世界中の人々の健康と未来を支える

Leverage “the power of chemistry and biology” to support the health and potential of people worldwide through solutions that draw from advanced manufacturing, management and analysis technologies

2025～2027年度 中期経営計画 / Corporate Business Plan for FY2025 – FY2027

事業部門方針　Direction for the Business Sector

高度化低分子医薬CDMO*1　Advanced small molecule APIs*2 CDMO*1

- 当社の総合対応力を求める国内製薬企業が主要ターゲット顧客
- The main target customers are pharmaceutical companies in Japan, which need our comprehensive capabilities
- 顧客パイプラインや開発・購買方針の多角的な解析による、優先度をつけた濃淡あるプロモーションの推進
- Advance highly prioritized promotions through multi-faceted analysis of customer pipelines and development and buyout directions
- 新薬CDMOに力点を置いた、高利益体質事業への成長促進
- Encourage growth into a high-profit business with a focus on new drug CDMO
- 当社の強みである製造技術を活かした、高品質なジェネリック原薬の安定供給
- Stable supply of high-quality generic APIs that leverage manufacturing technologies, which are one of our strengths

医療用オリゴ核酸CDMO　Oligonucleotide CDMO

- 当社の強みである「高純度の長鎖核酸」「高度な分析技術」「強固なサプライチェーン」を活用した、遺伝子編集治療用gRNA分野での当社製品のデファクトスタンダード化
- Making our products the de facto standard in the field of gRNAs for genome editing by leveraging our strengths in high-purity long-chain oligonucleotides, advanced analysis technologies, and robust supply chains

再生・細胞医薬CDMO　Regenerative medicine/cell therapy CDMO

- 製造設備の拡充を通じた事業拡大
- Expand business by enhancing production facilities
- 将来の飛躍的成長に向けた組織強化、米国基盤構築等の推進
- Promote strengthening our organizations and building U.S. infrastructure for tremendous future growth

再生・細胞医薬（創薬）*3　Regenerative medicine/cell therapy (R&D)*3

- 世界初のiPS細胞由来パーキンソン病治療用製品の2025年度承認申請実施、承認取得
- Apply for approval and receive approval for the world’s first iPS cell-derived cell therapy for the treatment of Parkinson’s disease in FY2025
- 先行3製品（パーキンソン病治療用製品、網膜疾患治療用製品）の早期育成によるリーディングポジション確立
- Establish a leading position through the quick advancement of our first three products (a cell therapy for Parkinson’s disease and cell therapies for retinal disease)

2027年度計画 FY2027 Target

コア営業利益 Core Operating Income

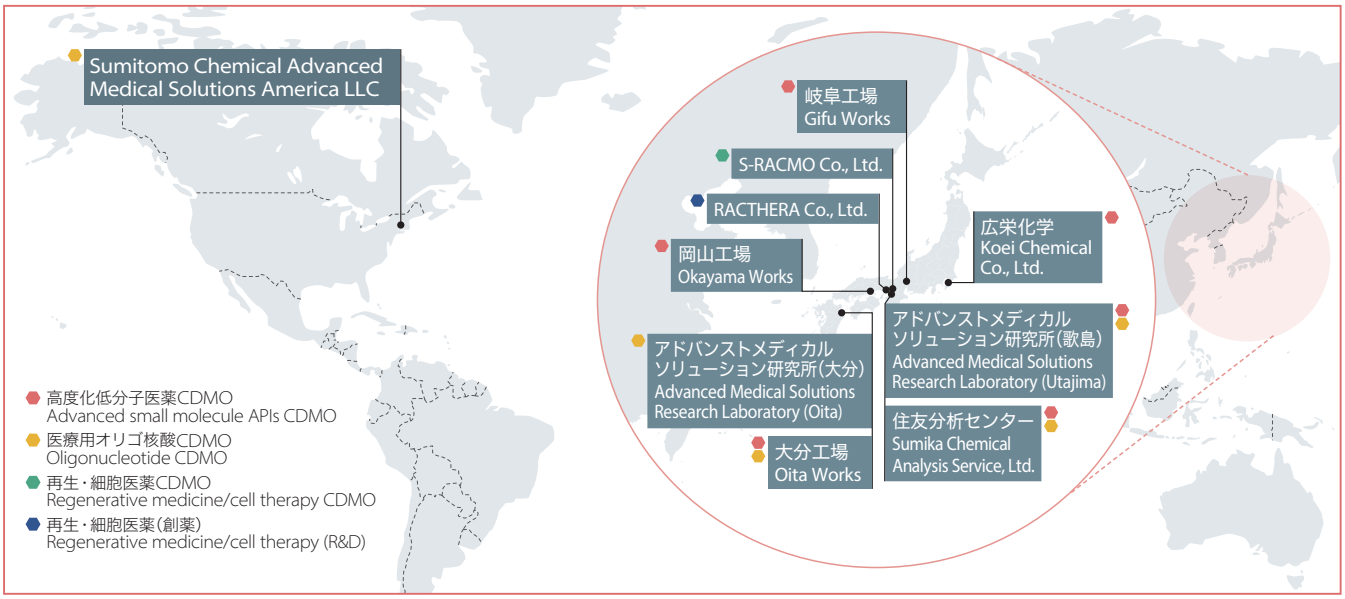
100億円
¥10.0 billion

ROIC

7%

*1 CDMO: Contract Development and Manufacturing Organization
*2 APIs: Active Pharmaceutical Ingredients
*3 再生・細胞医薬事業の創薬に係る費用は、当面の間全社共通費用として計上
The expenses related to regenerative medicine/cell therapy (R&D) will continue to be recorded as corporate shared expenses for the time being

戦略拠点 / Strategic Locations



住友化学レポート 2025　アドバンストメディカルソリューション
Annual Report 2025*　Advanced Medical Solutions

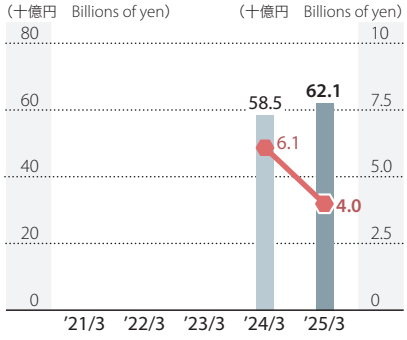
* Scheduled to be published at the end of October 2025

最近のトピックス / Topics

2022	■S-RACMO株式会社の再生・細胞医薬製造施設「FORCE」稼働開始。	■S-RACMO's regenerative medicine/cell therapy manufacturing facility, FORCE, began operations.
2023	■大分工場で医療用オリゴ核酸の製造プラントが稼働開始。	■Production plant for oligonucleotides began operations at Oita Works.
2024	■S-RACMO株式会社の持分比率を49%から66.6%に引き上げ、当社主導で再生・細胞医薬分野のCDMO事業を推進。	■Sumitomo Chemical increased its ownership ratio in S-RACMO from 49% to 66.6%, and has taken leadership of its regenerative medicine/cell therapy CDMO business.
	■大分工場で低分子医薬品の原薬および中間体の製造プラントが稼働開始。	■A manufacturing plant for active pharmaceutical ingredients and intermediates for small molecule drugs began operations at Oita Works.
	■ペプチスター社の株式を第三者割当増資により取得。当社が強みとする長鎖高純度gRNAの供給体制を拡充。	■Sumitomo Chemical acquired shares of PeptiStar Inc. through a private placement, which enhanced the capacity of its supply system for high-purity long-chain gRNA of our strengths.
2025	■住友ファーマとの合弁で、再生・細胞医薬事業の研究開発等を担う株式会社RACTHERAが2月に営業開始。	■Launched business operations of RACTHERA, a company that is a joint venture between Sumitomo Chemical and Sumitomo Pharma for the R&D and related activities of regenerative medicine/cell therapy, in February.
	■医療用オリゴ核酸CDMO事業の拠点として、4月にSumitomo Chemical Advanced Medical Solutions America LLC(SC-AMSA)を米国に設立。	■Established Sumitomo Chemical Advanced Medical Solutions America LLC ("SC-AMSA") in the United States as a base for Sumitomo Chemical's Oligonucleotide CDMO business in April.

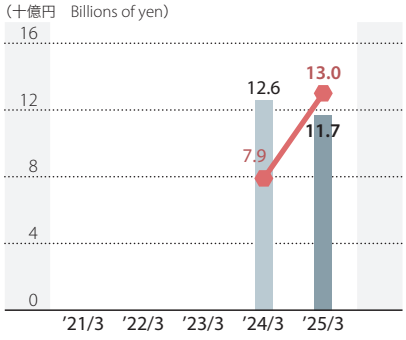
財務ハイライト / Financial Highlights

売上収益とコア営業利益 Sales Revenue & Core Operating Income



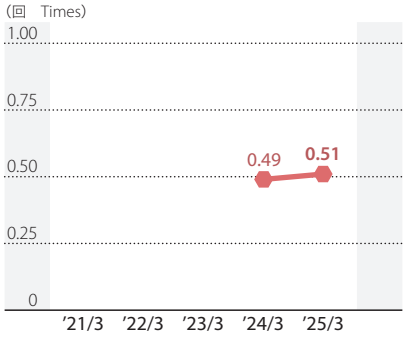
■■ 売上収益(左軸)　Sales revenue (left axis)
コア営業利益(右軸)
Core operating income (right axis)

償却前コア営業利益と資本的支出 Core Operating Income before Depreciation & Capital Expenditure

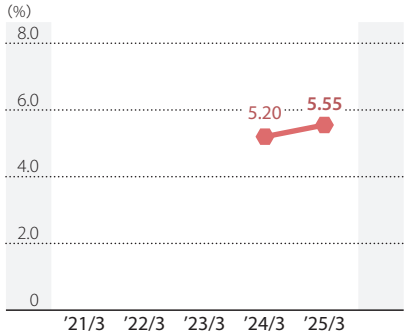


■■ 償却前コア営業利益
Core operating income before depreciation
資本的支出　Capital expenditure

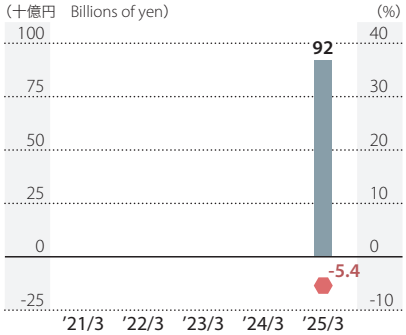
資産回転率 Asset Turnover



売上収益研究開発費比率 Ratio of R&D Expenses to Sales Revenue

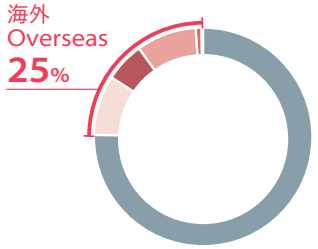


投下資本とROIC Invested Capital & ROIC



■ 投下資本(左軸)　Invested capital (left axis)
ROIC(右軸)　ROIC (right axis)

地域別売上収益比率(2024年度) Sales Revenue Ratio by Region (FY2024)



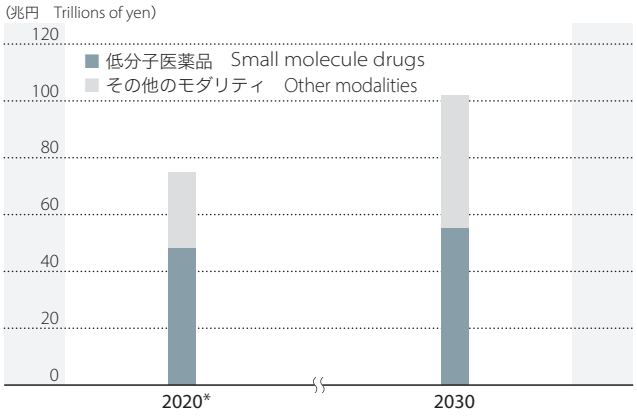
■日本　Japan
■アジア(含むインド)　Asia (including India)
■北米　North America
■欧州　Europe
■中南米　Central and South America
■中東・アフリカ　Middle East and Africa
■オセアニア他　Oceania and Others

各事業の詳細情報 / Detailed Information on Each Business

高度化低分子医薬CDMO　Advanced Small Molecule APIs CDMO

高度な有機合成技術、工業化技術および品質保証体制をベースに、製薬企業から低分子医薬品の原薬・中間体の製造を受託。
Based on our advanced organic synthesis technologies, industrialization technologies, and our quality assurance system, we have received orders from pharmaceutical companies for the manufacturing of active pharmaceutical ingredients and intermediates for small molecule drugs.

全モダリティにおける低分子医薬品の市場規模（世界）　The Global Market Size of Small Molecule Drugs Across All Modalities



- 低分子医薬品の市場規模は48兆円から55兆円程度に拡大
  The market size for small molecule drugs will expand from 48 trillion yen to 55 trillion yen
- 今後も一定の市場を維持し堅調に推移する見込み
  The market is expected to remain at a certain level and be strong in the future

* 低分子医薬は2016年の数値
Figures for small molecule drugs represent the 2016 data

（出所）内閣官房資料「医薬品関連の産業化に向けた課題及び課題解決に必要な取組みに関する調査（2021.3.29）」より住友化学作成
(Source) Created by Sumitomo Chemical based on the Cabinet Secretariat document, 'Investigation of the Issues Related to Industrialization of Medicine and the Initiatives Necessary for Solving These Issues (March 29, 2021)'

当社の強み　Sumitomo Chemical's Strengths

	強み　Strength
生産体制 Production system	国内3か所（岐阜・岡山・大分）の製造拠点による、生産キャパシティーの確保と柔軟な生産対応。50年以上の医薬原薬製造実績 Ensuring production capacity and flexible production through our three manufacturing sites in Japan (at Gifu Works, Okayama Works, Oita Works). We have more than 50 years of experience in manufacturing active pharmaceutical ingredients.
品質保証体制 Quality assurance system	GMP*1対応の高水準な信頼性保証体制。年間50件以上の顧客監査とFDA*2を含む各国当局による査察の受審実績（23年度はFDA査察2件ともに指摘事項無し） A system with a high level of reliability assurance compliant with GMP*1. We receive more than 50 customer audits and inspections by relevant authorities in various countries, including the FDA*2, annually. (In FY2023, there were no matters of concern issued in either of two FDA inspections).
サプライチェーン Supply chain	主要原料について、海外現地法人に必要な体制を整備し、現地監査を含めたサプライヤー管理を直接実施 Establishment of the necessary systems at subsidiaries outside of Japan and direct implementation of supplier management, including local audits for key raw materials.
研究開発体制 R&D system	長年培ってきた高度な有機合成技術・工業化技術・分析技術 The advanced organic synthesis technologies, industrialization technologies, and analysis technologies that we have cultivated over many years.

*1 GMP：医薬品の製造における品質、安全性、有効性を確保するための必須基準　GMP: essential standards to ensure quality, safety, and effectiveness in the production of drugs.
*2 FDA：米国の食品医薬品局。医薬品の安全性・有効性を確保するための政府機関
FDA: the U.S. Food and Drug Administration. It is a government agency responsible for ensuring the safety and effectiveness of drugs.

高度化低分子医薬CDMOの動向と事業方針　Trends and Business Policies for Advanced Small Molecule APIs CDMOs

国内CDMOへの需要は今後も旺盛
- 製薬企業における創薬へのリソース集中
- リスク分散のための複社購買化
- 開発剤の化学構造複雑化による製造分業化
- 地政学的リスク回避

Demand for CDMOs in Japan is expected to remain strong going forward
- Concentrating resources on drug discovery in the pharmaceutical companies
- Purchasing from multiple companies for risk diversification
- Dividing up the manufacturing process due to the increasing complexity of the chemical structures in developing drugs
- Avoiding geopolitical risks

▼

高利益な新薬CDMO事業の受注活動を強化
Strengthening order acquisition activities for the highly profitable CDMO business for new drugs
需要が堅調な高品質ジェネリック原薬の安定供給の継続
Continuing the stable supply of high-quality generic APIs for which demand is strong

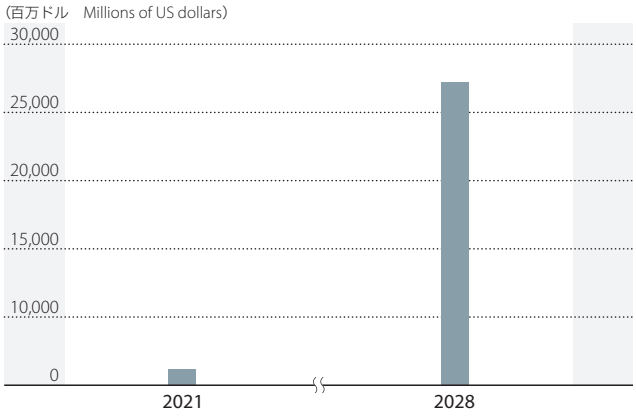
低分子プラント（大分工場）
Plant for small molecule APIs (Oita Works)

医療用オリゴ核酸CDMO　Oligonucleotide CDMO

米国の創薬ベンチャー企業を中心とした顧客から、高純度な医療用オリゴ核酸*の製造を受託。
Contracted to manufacture high-purity oligonucleotides* for customers, primarily drug discovery venture companies in the U.S.

* 最先端のゲノム編集医療に必要な核酸。一般的な核酸医薬と比較するとはるかに長い、100mer超のgRNAが典型例。医療用途では高純度品の必要性が指摘されている。
Nucleic acids required for cutting-edge genome-editing therapies. A typical example is gRNA exceeding 100mer, which is much longer than typical nucleic acid drugs. The necessity of high-purity products for medical applications has been highlighted.

遺伝子治療（in vivo）の市場規模（世界）　Global Market Size of In Vivo Gene Therapies



- 医療用オリゴ核酸のターゲットである遺伝子治療の市場は、世界で今後大きく成長する見込み
  The market for gene therapies, which are a target of oligonucleotides, is anticipated to have significant global growth going forward

（出所）経済産業省資料「バイオ医薬品・再生医療等製品の技術開発およびバリューチェーンに関する動向調査（2023.2.27）」より住友化学作成
(Source) Created by Sumitomo Chemical based on the Ministry of Economy, Trade and Industry's report 'Survey on the Trends of Technology Development and Value Chains for Biopharmaceuticals and Regenerative Medicine Products (February 27,2023)'

当社の強み　Sumitomo Chemical's Strengths

	強み　Strength
技術 Technologies	製造の難易度が非常に高い長鎖RNA（100mer超）の合成、精製、分析全般にわたる高い技術力。低分子医薬で培った医薬品原薬製造に関する製造技術・信頼性保証体制・ノウハウ We possess high-level technical capabilities in all aspects of the synthesis, purification, and analysis of long-chain RNA (exceeding 100mer), which is incredibly difficult to manufacture. In addition, we have the manufacturing technologies, reliability assurance system, and know-how for the manufacturing of active pharmaceutical ingredients cultivated through small molecule APIs.
製造拠点 Manufacturing locations	大分工場での自社製造設備に加え、ペプチスター社との協業による複数生産拠点の確保 In addition to our own manufacturing facility at Oita Works, we have also secured multiple manufacturing locations through our partnership with PeptiStar.
販売拠点 Sales locations	欧米顧客に近接した現地法人によるきめ細やかな顧客対応 Attentive customer service through local subsidiaries that are near customers in Europe and the U.S.

事業展開　Developing the Business

- 2014年に核酸医薬原薬の製造受託事業に参入し、RNAの合成等の研究に積極的に投資
  Entered the contract manufacturing business of active ingredient for nucleic acid drugs in 2014 and actively invested in research for RNA synthesis and related areas
- 100mer超の長鎖RNA（たとえばgRNA）を約90%の高純度かつ高収率で量産する技術を世界で初めて*確立
  Established a world-first* technology to produce long-chain RNA, such as gRNA, exceeding 100mer with approximately 90% purity and a high yield

* 当社調べ　Based on the results of an internal survey.

▼

当社の高純度gRNAに、多数のゲノム編集医療開発企業が注目
Our high-purity gRNA has drawn the attention of multitudes of companies developing genome-editing therapies

▼

増大する需要に対応するため、大分工場に医療用オリゴ核酸の製造プラントを新設し、2023年8月より稼働開始
Sumitomo Chemical has built a new manufacturing plant for oligonucleotides at its Oita Works, in order to meet increasing demand. The new plant started its operation in August 2023
顧客企業が集中する米国に開発サポートの拠点となる新会社（SC-AMSA）を2025年4月に設立
Established SC-AMSA, a new company to serve as a development support location in the U.S., where our customer companies are concentrated, in April 2025

当社グループの再生・細胞医薬事業　Our Regenerative Medicine/Cell Therapy Business

住友化学　Sumitomo Chemical

出資比率 Investment Ratio 66.6%

- ES/iPS細胞に係る技術基盤
  Fundamental technology related to ES/iPS cells
- 医薬原薬製造受託事業の知見
  Expertise on the contract manufacturing business for APIs
- 製品の分析・安全性評価
  Analysis and safety assessment of the products

住友ファーマ　Sumitomo Pharma

出資比率 Investment Ratio 33.4%

- 再生・細胞医薬に関する業界トップレベルの知見
  Industry-leading-level expertise on regenerative medicine/cell therapy
- iPS細胞製品の開発品
  iPS cell-derived cell therapies in development pipeline

創薬　R&D　RACTHERA

- iPS細胞等の幹細胞の分化誘導法の研究
  Research on the differentiation method for stem cells including iPS cells
- iPS細胞から各種分化細胞への効率的な分化・生産方法の研究
  Research to develop effective methods for producing various cell types by differentiation of iPS cells

CDMO　S-RACMO

- 世界初の他家iPS細胞由来の再生・細胞医薬品専用の商業用製造施設
  The world's first facility dedicated to the commercial manufacture of regenerative medicine/cell therapy products derived from allogeneic iPS cells

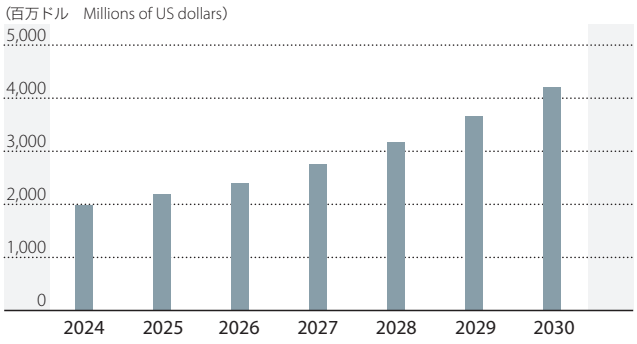
▼

グループ一体となり、次世代の成長ドライバーとすべく事業育成を進める
The Group will come together to advance the development of businesses that will become next-generation growth drivers

再生・細胞医薬CDMO　Regenerative Medicine/Cell Therapy CDMO

再生・細胞医薬分野における製法開発、製造などの受託（CDMO）事業を行う
Operate the CDMO business, including the development of production methods and product manufacturing, in the field of regenerative medicine/cell therapy

再生・細胞CDMO市場規模　Market Size for Regenerative Medicine/Cell Therapy CDMOs



- 再生・細胞医薬の社会実装には高度な製造技術を持つCDMOが必要不可欠
  CDMOs with advanced manufacturing technologies will be essential for the societal implementation of regenerative medicine/cell therapy

↓

CDMO市場は世界で今後大きく成長見込み
The market for CDMOs is anticipated to experience significant global growth

（出所）経済産業省資料「バイオ政策のアクションプラン（2024.8）」より住友化学作成
(Source) Created by Sumitomo Chemical based on the Ministry of Economy, Trade and Industry document, 'Action Plan for Bio-Policy (August 2024)'

当社の取り組み　Sumitomo Chemical's Initiatives

- 住友化学と住友ファーマの持つ強みを組み合わせた高度な技術・ノウハウを武器にシェアを獲得し、再生・細胞医薬CDMOのデファクト・スタンダードを目指す。
- 国内承認品を含めて多くの受注を獲得し黒字継続、順調に事業拡大中。
- 住友ファーマ所有の再生・細胞医薬製造施設「SMaRT」をS-RACMOが譲受。また、S-RACMOにおいて製造新棟が2025年7月に完成。

- We will leverage our advanced technologies and know-how that combine the strengths of Sumitomo Chemical and Sumitomo Pharma, and aim to become the de facto standard for regenerative medicine/cell therapy CDMOs.
- The CDMO has received many orders, including for products that have been approved in Japan, and continues to be profitable. Its business is also gradually expanding.
- S-RACMO inherited the regenerative medicine/cell therapy production facility, SMaRT, owned by Sumitomo Pharma. In addition, a new manufacturing building at S-RACMO was completed in July 2025.

再生・細胞医薬（創薬）　Regenerative Medicine/Cell Therapy (R&D)　（2025年5月13日現在　As of May 13, 2025）

再生・細胞医薬分野の事業化計画　Regenerative Medicine/Cell Therapy Business Plan

予定適応症 等 Proposed indication, etc.	連携先 Partnering	予定地域 Region (planned)	細胞種 Cell type	実施状況 Status
パーキンソン病［先駆け審査指定制度対象（日本のみ）］ Parkinson's disease [Designated as a "SAKIGAKE" (Japan only)]	京都大学iPS細胞研究所（CiRA） Kyoto University CiRA カリフォルニア大学サンディエゴ校 University of California San Diego School of Medicine	Global	他家iPS細胞由来ドパミン神経前駆細胞 Allo iPS cell-derived dopaminergic neural progenitor cells	医師主導治験（第Ⅰ/Ⅱ相臨床試験）終了（日本） Completed: Investigator-initiated clinical study (phase Ⅰ/Ⅱ clinical study) (Japan) 医師主導治験・企業治験（第Ⅰ/Ⅱ相臨床試験）実施中（米国） In progress: investigator-initiated clinical study and company-sponsored clinical study (Phase Ⅰ/Ⅱ clinical study) (U.S.)
網膜色素上皮裂孔 Retinal pigment epithelium tear	理化学研究所　RIKEN ヘリオス　Healios	日本 Japan	他家iPS細胞由来網膜色素上皮細胞 Allo iPS cell-derived retinal pigment epithelial cells	企業治験（第Ⅰ/Ⅱ相臨床試験）実施中（日本） In progress: company-sponsored clinical study (Phase Ⅰ/Ⅱ clinical study) (Japan)
網膜色素変性 Retinitis pigmentosa	理化学研究所　RIKEN 神戸アイセンター病院 Kobe City Eye Hospital	Global	他家iPS細胞由来網膜シート（立体組織） Allo iPS cell-derived photoreceptor (3D)	臨床研究実施中（日本） In progress: clinical research (Japan) 企業治験（第Ⅰ/Ⅱ相臨床試験）実施中（米国） In progress: company-sponsored clinical study (Phase Ⅰ/Ⅱ clinical study) (U.S.)
脊髄損傷 Spinal cord injury	慶應義塾大学 大阪医療センター Keio University, Osaka National Hospital	Global	他家iPS細胞由来神経前駆細胞 Allo iPS cell-derived neural progenitor cells	臨床研究終了（亜急性期）（日本） Completed: clinical research (Sub-Acute Phase) (Japan) 非臨床試験実施中（慢性期） In progress: pre-clinical study (Chronic Phase)
腎不全 Kidney failure	東京慈恵会医科大学 The Jikei University School of Medicine バイオス　Bios Co., Ltd.	日本 Japan 北米 North America	自家／他家iPS細胞由来ネフロン前駆細胞（立体臓器） Auto/Allo iPS cell-based induced nephron progenitor cells (organ)	非臨床試験実施中 In progress: pre-clinical study
先天性無胸腺症（リサイミック）*1 Congenital athymia (RETHYMIC®)*1	デューク大学 Duke University	Global	培養胸腺組織 Cultured thymus tissue	2022年3月販売開始（米国） Launched in March 2022 (U.S.)

2025年度 承認申請実施、承認取得目標（日本）　Targeting FY2025 for applying for approval and receiving approval (Japan)

再生・細胞医薬事業全体（グローバル）で、2030年代後半に売上収益3,500億円*2を目指す
We aim for 350 billion yen*2 in revenue from the overall (global) regenerative medicine/cell therapy business by the second half of the 2030s

*1 住友ファーマ保有事業　Business owned by Sumitomo Pharma
*2 成功確率調整前、開発中の複数製品上市実現時　Before adjusting for success rates and assuming the launch of multiple products under development

iPS細胞を用いたパーキンソン病の細胞移植治療　Cell Transplantation Therapy for Parkinson's Disease Using iPS Cells

提携先：京都大学CiRA（髙橋 淳 先生）　Collaboration partner: CiRA, Kyoto University (Prof. Jun Takahashi)

- 運動障害をきたす神経変性疾患で最多
- 患者数：米国100万人/日本25.0万人（令和5年厚労省患者調査の結果）、要介護5：10.4%（4位）
- 主な症状は運動機能障害、黒質-線条体ドパミン神経の変性に伴って出現
- 胎児由来のドパミン神経細胞移植による有効性は確認済み

- Most common neurodegenerative disease that causes motor symptoms
- Number of patients: one million in the U.S., 250,000 in Japan (Patient Survey, 2023 conducted by Ministry of Health, Labour and Welfare); The 4th cause for nursing care level 5 (10.4%)
- Major symptoms are motor symptoms associated with degeneration of substantia nigra-striatal dopaminergic neurons.
- Efficacy of implanted embryonic dopaminergic neurons has been confirmed.