# Financial Results for the Second Quarter of the Fiscal Year Ending January 31, 2027

**SanBio Company Limited**

**TSE Growth: 4592**

September 17, 2026

SanBio
Pioneering Regenerative Medicine

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# Cell Therapy Product Aiming for "Brain Regeneration" Launch of AKUUGO® Injection for Intracerebral Transplantation

# AKUUGO® National Launch Commemorative Seminar

- Held on August 22 at Toranomon Hills Forum
- Invited Professor David O. Okonkwo of the University of Pittsburgh; he enrolled nine cases in the TBI-01 study
- Lectures and Q&A on TBI classification, treatment challenges and the role of AKUUGO®


アクーゴ® 発売記念
全国講演会

開催日
2026年8月22日(土) 13:00～15:20
※会の終了後に情報交換会を予定しております。

開催場所
虎ノ門ヒルズフォーラム 5階「メインホール」
〒105-6305 東京都港区虎ノ門1-23-3 虎ノ門ヒルズ森タワー5階　TEL:03-6406-6226

13:00～13:05 Opening

13:05～13:10 Opening remarks
樋口 佳則 先生(千葉大学 大学院医学研究院 脳神経外科学 教授)

13:10～13:30 講演① (質疑応答込み)
座長 田中 將太 先生(岡山大学学術研究院薬学域 脳神経外科学 教授)
演者 末廣 栄一 先生(国際医療福祉大学成田病院 救急科 教授)
「日本頭部外傷データバンクP2023からみた日本の重症頭部外傷診療の現状」

※ 本講演は同時通訳対応しております。

13:30～14:10 講演② (質疑応答込み)
座長 貴島 晴彦 先生(大阪大学大学院 医学系研究科 脳神経外科学 教授)
演者 David O Okonkwo MD, PhD
(Executive Vice President, UPMC Enterprises Professor of Neurological Surgery University of Pittsburgh)
「New Framework for Classifying Traumatic Brain Injury (TBI) in the US & Overview of the Successful STEMTRA Stem Cell Trial for TBI」

14:10～14:25 休憩

14:25～14:50 講演③ (質疑応答込み)
座長 山本 哲哉 先生(横浜市立大学大学院医学系研究科 脳神経外科学 主任教授)
演者 川堀 真人 先生(北海道大学大学院医学研究院 脳神経外科 講師)
「外傷性脳損傷患者に対するアクーゴ®の治験データとサブ解析」

14:50～15:10 講演④ (質疑応答込み)
座長 藤村 幹 先生(北海道大学大学院医学研究院 脳神経外科 教授)
演者 末永 潤 先生(横浜市立大学大学院医学系研究科 脳神経外科学 講師)
「アクーゴ®導入初期における適応と実施体制:PMCT・PMSを踏まえた現状と今後」

15:10～15:15 Closing remarks
小林 正人 先生(埼玉医科大学病院 脳神経外科 主任教授)

15:15～15:20 謝　辞 森 敬太(サンバイオ株式会社 代表取締役社長)

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# 1. Financial Results for the Second Quarter of the Fiscal Year Ending January 31, 2027

# Financial Highlights: Consolidated Statements of Income

- **R&D expenses of ¥1,226 million were recorded, mainly for manufacturing-related expenses for AKUUGO®.**

| Million Yen | FY2026.1 Q2 Results(A) | FY2027.1 Q2 Results(B) | (B)-(A) |
|---|---|---|---|
| Revenue | – | – | – |
| R&D expenses | 1,346 | 1,226 | ▲120 |
| Operating expenses | 1,888 | 1,909 | 21 |
| Operating income | ▲1,888 | ▲1,909 | ▲21 |
| Net income | ▲1,997 | ▲1,791 | 205 |
| Yen/US$ exchange rate | 146.96 | 159.14 | |

# Financial Highlights: Consolidated Balance Sheets

■ Maintain a prudent level of Cash & cash equivalents to meet foreseeable short- to medium-term needs.

| Million yen | As of January 31, 2026(A) | As of July 31, 2027(B) | (B)-(A) |
|---|---|---|---|
| Cash & cash equivalents | 15,083 | 12,748 | ▲2,335 |
| Current assets | 15,489 | 13,380 | ▲2,108 |
| Non-current assets | 131 | 264 | 132 |
| Total assets | 15,621 | 13,645 | ▲1,976 |
| Current liabilities | 534 | 339 | ▲194 |
| Non-current liabilities | 1,482 | 1,580 | 98 |
| Total liabilities | 2,016 | 1,920 | ▲96 |
| Net assets | 13,604 | 11,724 | ▲1,879 |
| Total liabilities and net assets | 15,621 | 13,645 | ▲1,976 |

# Revision of Consolidated Earnings Forecast

■ Loss was smaller than initially forecast due to the timing shift of certain manufacturing-related R&D expenses to the second half.

| Million yen | FY2027.1 Q2 Forecast (A) | FY2027.1 Q2 Results (B) | (B)-(A) | FY2027.1 Forecast |
|---|---|---|---|---|
| Revenue | – | – | – | 396 |
| Operating expenses | 2,906 | 1,909 | ▲996 | 5,625 |
| R&D expenses | 2,038 | 1,226 | ▲812 | 4,110 |
| Other | 867 | 683 | ▲184 | 1,515 |
| Operating income | ▲2,906 | ▲1,909 | 996 | ▲5,229 |
| Ordinary income | ▲2,908 | ▲1,730 | 1,178 | ▲5,074 |
| Net income | ▲2,909 | ▲1,791 | 1,188 | ▲5,133 |

# 2. Progress in the First Half Year

# Toward Practical Use of a Cell Therapy Aiming to Regenerate the Brain

AKUUGO® is a regenerative medicine product intended to improve chronic motor paralysis associated with traumatic brain injury. It received conditional and time-limited marketing approval in Japan on July 31, 2024. Following NHI price listing on May 20, 2026, sales began on May 21, 2026.


ヒト体性幹細胞加工製品

薬価基準収載

アクーゴ®

脳内移植用注

新発売

バンデフィテムセル

指定再生医療等製品

# AKUUGO® NHI Price Listing and Launch (May 2026)

| | |
|---|---|
| **Brand name** | **AKUUGO® Suspension for Intracerebral Implantation** |
| **Generic name** | Vandefitemcel |
| **Indication** | Improvement of chronic motor paralysis associated with traumatic brain injury |
| **NHI price** | 72,716,528 yen |
| **Dosage and administration** | In adults, implant 300μL of a cell preparation containing 5 x 106 viable human (allogeneic) bone marrow-derived mesenchymal stem cells into the peri-lesional area of the damaged brain tissue by stereotactic surgery using the dedicated administration device set. Through three implantation trajectories extending from a single burr hole in the skull to the peri-lesional area, administer 100μL of the cell suspension per trajectory at five sites spaced 5–6 mm apart, starting from the deepest point, with 20μL administered at each site. The infusion rate should be approximately 10μL/min. Perform the following procedures during implantation. 1. Prior to surgery, attach the guide-and-stop assembly and the stylet-equipped inserter of the dedicated administration device set to the invasive neurosurgical head fixation device. 2. Thaw the intracerebral implantation cell product and wash it using the dedicated preparation solution. Prepare the product with the dedicated preparation solution to achieve a transplantation concentration of 1.67 x 106 cells/100μL, thereby creating the cell suspension. After cleansing the microsyringe fitted with the administration cannula of the dedicated administration device set using the dedicated preparation solution, load the cell suspension into the microsyringe. |

ヒト体性幹細胞加工製品
薬価基準収載
アクーゴ® 脳内移植用注
バンデフィテムセル
指定再生医療等製品
新発売

| | |
|---|---|
| **Summary of efficacy evaluation** | International Phase 2 clinical trial (TBI-01 study: the U.S., Japan, and Ukraine) Multicenter, randomized, double-blind, sham surgery-controlled study in which subjects were randomized in a 3:1 ratio to the product group or the sham surgery group (product group: 2.5 x 106 cell group, 5.0 x 106 cell group, and 10.0 x 106 cell group). Study results Efficacy: For the primary endpoint, the change from baseline in FMMS at Week 24 was 8.3 ± 10.6 in the pooled SB623 group (n = 46) across all dose cohorts, compared with 2.3 ± 4.7 in the sham surgery group (n = 15), with a statistically significant difference observed between the groups (mean ± standard deviation; p=0.0401). |
| **Date of marketing approval** | July 31, 2024 |

# Establishing Treatment Access and Supply Systems for AKUUGO® Adoption

| Building the Business Foundation | Current Status (as of September 2026) | Target by Fiscal Year-End (FY2027) |
|---|---|---|
| Secure patient access and expand treatment opportunities | Preparing introduction mainly at eight sites: five universities (Hokkaido, Tokyo, Yokohama City, Osaka and Okayama) plus three additional facilities | Start dosing the first patient<br>Expected six cases this fiscal year |
| Achieve stable supply | Build an integrated supply and logistics system with distributors, from manufacturing to product delivery aligned with each patient dosing date | Establish stable operations |

# Expanding Patient Access through Regional Collaboration

## AKUUGO® Smart Regional Medical Collaboration

**Facilities Patients Regularly Visit**

Recovery-phase / chronic-phase facilities Clinics

**Patients Receiving Home Care**

No current connection to a medical institution

**Call Center**

Consultation & Referral Desk

**1 Partner Facility (Designated by Region)**

- Information for patients and healthcare institutions
- Consultation and referral services
- MRI scan

**2 Treatment Facility**

- Eligibility assessment and treatment
- Safe and appropriate treatment delivery

**3 Rehabilitation Facility**

- Post-treatment rehabilitation
- Support for maintaining and improving daily function

**Specialists Supporting Care Coordination**

**Therapists** (Physical and occupational therapists, etc.)

**Medical Social Workers (MSWs)**

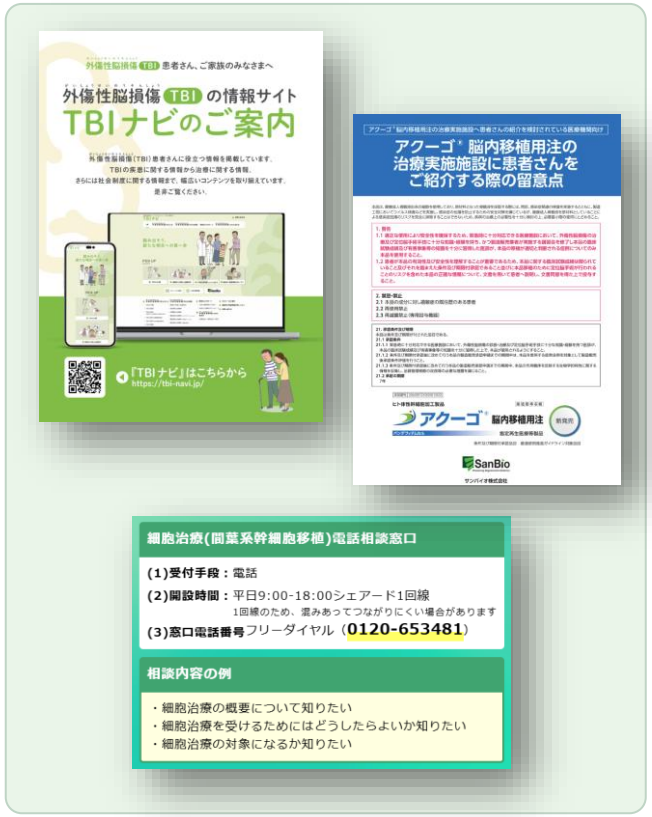
**Higher Brain Dysfunction Support Coordinators**

**Patient Associations and Advocacy Groups**

# AKUUGO® Information and Support System

## Patient Access / Medical Collaboration

**Patient / HCP information**
**Consultation and referral pathway**

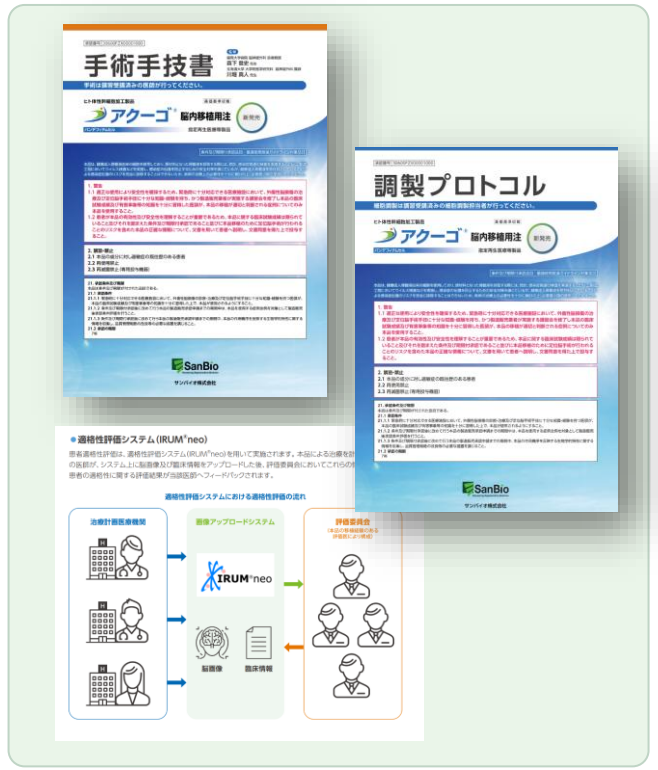



## Information for Physicians

**Product information**
**Appropriate use support**


## AKUUGO® Administration / Follow-up

**Procedure and preparation support**
**Eligibility and follow-up system**



# Outreach to Healthcare Professionals and Society

■ **Objective: Connect multidisciplinary HCPs through lectures and events to build medical collaboration**

■ **Results: More than 1,000 cumulative participants in media and physician seminars**




Rehabilitation Medicine Congress
SanBio Booth


**[Completed]**

- **2026/6/6 JARM Annual Meeting Luncheon Seminar (Fukuoka)**
- **2026/6/10 Media Launch Seminar (Tokyo)**
- **2026/7/6 AKUUGO® Regional Seminar (Sapporo)**
- **2026/8/21 AKUUGO® Launch Seminar (Fukuoka)**
- **2026/8/22 AKUUGO® National Launch Seminar (Tokyo)**
- **2026/9/13 JSBT Annual Meeting Luncheon Seminar (Tokyo)**

**[Upcoming]**

- **2026/10/22 JNS Annual Meeting Luncheon Seminar (Sapporo)**
- **2026/10/22 AKUUGO® Regional Seminar (Okayama)**
- **2026/11/29 Public Seminar**

# Strengthening Manufacturing and Supply Systems

## Minaris Advanced Therapies, LLC.

**Transfer upstream processes to Japan following closure of Minaris Mountain View facility in the U.S.**

↓

**Domestic manufacturing at Minaris Yokohama**

## JCR Pharmaceuticals Co., Ltd.

**Concluded a trial manufacturing agreementaimed at commercial production of AKUUGO®**

↓

**Manufacturing system for commercial production**

**Strengthen Manufacturing/Supply for Stable Supply and Global Expansion**

# Progress in SB623 Development and Commercialization

| |  |  |  |
|---|---|---|---|
| **Traumatic brain injury (TBI)** | NHI price listing / Product Launch | Agreed with FDA on Phase 3 trial design | Discussion on the timing of the start of clinical trials |
| **Ischemic stroke** | Plan to discuss with PMDA to start clinical trials | Preparing to start clinical trials | Discussion on the timing of the start of clinical trials |
| **Hemorrhagic stroke** | Plan to discuss with PMDA to start clinical trials | Discussion on the timing of the start of clinical trials | Discussion on the timing of the start of clinical trials |

*All diseases are in the chronic phase

# 3. Toward Becoming a Global Leader in Regenerative Medicine

# Three Pillars of Growth Strategy

- **Japan as “home base” –Starting point for expansion**
- **Realization of U.S. Business**
- **Success in Ischemic Stroke Program**

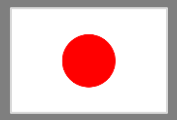
# Japan as “home base” for Global Expansion

1. Secure patient access to AKUUGO® through smart regional medical collaboration

2. Build an integrated supply system from manufacturing to logistics and sales

→ Apply to Future Global Expansion

# U.S. Expansion of SB623 and Indication Expansion

| |  |  |  |
|---|---|---|---|
| **Traumatic brain injury (TBI)** | Initial dosing / adoption Post-marketing clinical study | **Trial design agreed with FDA Preparing for clinical trial start next fiscal year** | Discussion on the timing of the start of clinical trials |
| **Ischemic stroke** | **Trial design agreement with PMDA planned next fiscal year; preparing for clinical trial initiation** | Preparing to start clinical trials | Discussion on the timing of the start of clinical trials |
| **Hemorrhagic stroke** | Plan to discuss with PMDA to start clinical trials | Discussion on the timing of the start of clinical trials | Discussion on the timing of the start of clinical trials |

*All diseases are in the chronic phase

# Leveraging U.S. Track Record to Drive Business

| Year | Event |
|---|---|
| 2010 | Signed an option agreement with Sumitomo Dainippon Pharma Co., Ltd. for cerebral infarction in the U.S. and Canada |
| 2011～2015 | Ischemic stroke*: Phase 1/2a trial in the U.S. (18 cases at 5 sites) |
| 2015 | Received milestone proceeds of US$5 million from co-development partner Sumitomo Dainippon Pharma under the option agreement |
| 2016～2018 | Ischemic stroke*: Phase 2 trial in the U.S. (163 cases at 65 sites) |
| 2016 | Ischemic stroke*: Phase 1/2a Paper Receives “Innovation Award 2016”. |
| 2016～2019 | Phase 2b (STEMTRA study) of traumatic brain injury in Japan, US, and Ukraine (21 sites in US, 5 sites in Japan, 1 site in Ukraine, 63 cases) |
| 2017 | Received the maximum grant available ($20M) from the California Institute for Regenerative Medicine (CIRM) |
| 2019 | Granted RMAT (Regenerative Medicine Advanced Therapy) Designation from the U.S. FDA for SB623 |
| 2022 | Final Analysis of the STEMTRA Study Presented in Plenary Session at the American Academy of Neurology (AAN) Annual Meeting |
| 2016～2018 | Ischemic stroke*: Phase 2 trial in the U.S. (163 cases at 65 sites) |

Before treatment, patient unable to raise arm

Patient can now raise arm

Patient able to resume normal activities

(YouTube)

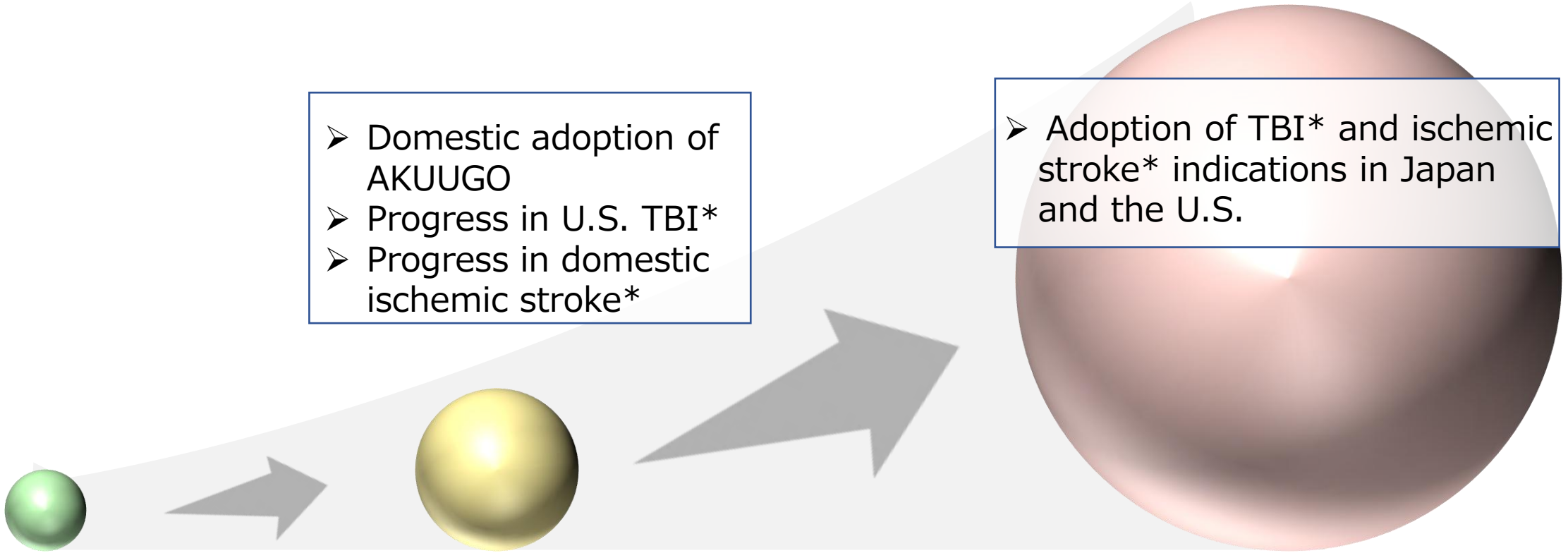

Facilities for the STEMTRA study: 21 facilities

Red - Facility Blue - Multiple facilities (numbers are number of facilities)

Major facilities :
UCLA, Stanford University, University of Pittsburgh, New York University, Northwestern University, etc. (ClinicalTrial.gov)

* Chronic phase

# Corporate Growth Trajectory



**Previous fiscal year**

**Present**

- Domestic adoption of AKUUGO
- Progress in U.S. TBI*
- Progress in domestic ischemic stroke*

**Four years and beyond**

- Adoption of TBI* and ischemic stroke* indications in Japan and the U.S.

*Chronic phase

## SanBio's Vision

# Becoming a global leader in regenerative medicine

SanBio Develops Regenerative Medicines, Creating Benefits for Patients and Value for Stakeholders.

# Q&A
## (For institutional investors and analysts)

# Financial Results
# for the Second Quarter of the Fiscal Year
# Ending January 31, 2027

**SanBio Company Limited**

**(TSE Growth: 4592)**

Question and Answer session for the press
is available at
will begin at 5:00 p.m.

Please wait a moment.

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# Q&A
## (For the press)

# Patient Inquiry Contact

## “TBI Navi”

Search for “TBI Navi” or visit https://tbi-navi.jp/


### 細胞治療（間葉系幹細胞移植）電話相談窓口

外傷性脳損傷（TBI）から生じる慢性期の運動麻痺に対する治療として、細胞治療（間葉系幹細胞移植）があります。TBIによる運動麻痺がある患者さんやそのご家族の方で、細胞治療についてより詳しく知りたい方は、下記窓口までお気軽にご相談ください。

| | |
|---|---|
| 受付手段 | 電話 |
| 開設時間 | 平日9:00-18:00 シェアード1回線<br>※1回線のため、混みあってつながりにくい場合があります |
| 窓口電話番号 | フリーダイヤル（0120-653481） |

**相談内容の例**

- 細胞治療の概要について知りたい
- 細胞治療を受けるためにはどうしたらよいか知りたい
- 細胞治療の対象になるか知りたい

# Disclaimer

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