Sumitomo Pharma

Sumitomo Pharma America Announces First Patient Receives Treatment in Phase 1/2a Study for its Investigational Therapy DSP-3077 for Retinitis Pigmentosa

– DSP-3077 is an investigational allogeneic iPS cell-derived retinal sheet (3-dimensional [3D] retina) that is administered via subretinal injection –
-- The Phase 1/2a study is evaluating safety and tolerability of DSP-3077 as well as engraftment and potential therapeutic response at two dose levels --
– Retinitis pigmentosa (RP) is a group of genetic eye disorders characterized by the progressive degeneration of photoreceptor cells in the retina, leading to vision loss[1] –

MARLBOROUGH, Mass., August 12, 2026 – Sumitomo Pharma America, Inc. (SMPA) today announced that the first patient in its study evaluating DSP-3077 in the treatment of non-syndromic retinitis pigmentosa (RP) has undergone subretinal implantation. DSP-3077 is an investigative regenerative cell therapy that leverages allogeneic retinal sheets derived from induced pluripotent stem (iPS) cells.

This Phase 1/2a, open-label, single-arm, uncontrolled, dose-escalation study (NCT06891885) is evaluating two dose levels of allogeneic iPS cell-derived retinal sheets (DSP-3077) administered with a single subretinal, uniocular injection in adults with RP. The primary objective of the study in adults with RP is to evaluate the safety and tolerability of two dose levels of DSP-3077; other objectives are to evaluate the safety, engraftment, and potential therapeutic response of DSP-3077 and to evaluate DSP-3077-delivery device performance. Study participants will be treated in three cohorts, with each cohort defined by visual acuity (VA) criteria and dose level of DSP-3077. Each cohort will include four participants for a total of 12 participants.

“We are encouraged by the potential that iPS cells may hold for treating degenerative, debilitating conditions like RP that currently have few therapeutic options, and this first patient treated is a notable milestone for our company,” said Tsutomu Nakagawa, Ph.D., President and Chief Executive Officer of SMPA. “Being able to provide this investigational treatment to our first study participant is not only a great honor, but a very important milestone in the development of DSP-3077, one that will aid in better understanding how it and future iPSC therapies could help improve the lives of RP patients and their families.”

RP is a rare progressive blinding hereditary condition affecting approximately 1 in 4,000 individuals with no curative treatments and very few, if any, efficacious therapeutic options available. RP first results in loss of night and peripheral vision but ultimately affects central vision in most cases. Although the progression of RP is highly variable among individuals, common pathology includes progressive degeneration (cell death) of rod photoreceptors (cells responsible for scotopic vision) and cone photoreceptors (cells responsible for photopic vision, visual resolution, and color vision).[1,2,3]

The technology underlying DSP-3077 is based on the self-organizing cell culture technique, known as the SFEBq method, a robust differentiation method to generate 3D neural tissues and organoids from pluripotent stem cells. This technology was originally developed by Dr. Yoshiki Sasai's research group at RIKEN, Japan's leading national comprehensive research institute[4]. Sumitomo Chemical Co., Ltd. conducted joint research with RIKEN from 2010 to 2014 to improve this technology[5,6]. To leverage this technology for clinical applications, Sumitomo Pharma Co., Ltd. (Sumitomo Pharma) took over joint research with RIKEN starting in 2013 and developed a manufacturing process to generate iPS cell-derived retinal sheets[7]. Following the completion of the joint research, Sumitomo Pharma Co., Ltd., RACTHERA Co., Ltd. (RACTHERA), S-RACMO Co., Ltd. (S-RACMO) and SMPA are conducting research with the goal of further improving the technology and expanding its applications in retinal regenerative therapy.

About DSP-3077

DSP-3077 is an investigational allogeneic iPS cell-derived regenerative cell therapy, based on a 3D retinal organoid produced using a self-organizing cell culture technique. This 3D organoid is processed into multilayered retinal sheets with retinal tissue structure, including abundant photoreceptor precursors. DSP-3077 is being investigated in a Phase 1/2 clinical study (NCT06891885). The study involves implanting the retinal sheets in the subretinal space of patients with RP. The FDA granted Orphan Drug Designation for DSP-3077 for the treatment of RP in March, 2026. In the research and development of DSP-3077, SMPA and Sumitomo Pharma Co. have been working closely with RACTHERA and S-RACMO leveraging RACTHERA's technologies and expertise.

About Sumitomo Pharma

Sumitomo Pharma Co., Ltd. is a global pharmaceutical company based in Japan with key operations in the U.S. (Sumitomo Pharma America, Inc.) and Canada (Sumitomo Pharma Canada, Inc.) focused on addressing patient needs in oncology, urology, women's health, rare diseases, cell & gene therapies and CNS. With several marketed products in the U.S., Canada, and Europe, a diverse pipeline of early- to late-stage assets, we aim to accelerate discovery, research, and development to bring novel therapies to patients sooner. For more information on SMPA, visit our website https://www.us.sumitomo-pharma.com or follow us on LinkedIn.

About RACTHERA

RACTHERA is a joint venture between Sumitomo Chemical Co., Ltd. (Head Office: Chuo-ku, Tokyo, Japan; "Sumitomo Chemical") and Sumitomo Pharma Co., Ltd ("Sumitomo Pharma").

The company began operations on February 1, 2025, after inheriting intellectual property and other assets related to the regenerative and cellular medicine business from Sumitomo Pharma. RACTHERA serves as the core organization for research and development in the Sumitomo Chemical Group's regenerative and cellular medicine business and is engaged in the development of innovative therapies utilizing iPS cells and other modalities. For more information on RACTHERA, visit its website https://www.racthera.co.jp/english/.

About S-RACMO

S-RACMO is a joint venture between Sumitomo Chemical Co., Ltd. (Head Office: Chuo-ku, Tokyo, Japan; "Sumitomo Chemical") and Sumitomo Pharma Co., Ltd. ("Sumitomo Pharma"). The company began operations on September 1, 2020, as a contract development and manufacturing organization (CDMO) specializing in regenerative and cell therapy products. The company combines extensive expertise in advanced process and formulation development cultivated through multiple regenerative and cell therapy projects at Sumitomo Pharma (including RACTHERA) with Sumitomo Chemical's core technologies in iPS/ES cells and its know-how in pharmaceutical contract manufacturing.

References

[1] O'Neal TB, Tripathy K, Luther EE. Retinitis pigmentosa. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024. Updated February 12, 2024. Accessed August 3, 2026. https://www.ncbi.nlm.nih.gov/books/NBK519518/

[2] Frick KD, Roebuck MC, Feldstein JI, McCarty CA, Grover LL. Health services utilization and cost of retinitis pigmentosa. Arch Ophthalmol. 2012;130(5):629-634. doi:10.1001/archophthalmol.2011.2820

[3] Parmeggiani F, Sato G, De Nadai K, Romano MR, Binotto A, Costagliola C. Clinical and rehabilitative management of retinitis pigmentosa: up-to-date. Curr Genomics. 2011;12(4):250–259. doi:10.2174/138920211795860125

[4] Eiraku M, Takata N, Ishibashi H, et al. Self-organizing optic-cup morphogenesis in three-dimensional culture. Nature. 2011;472:51-56. https://www.nature.com/articles/nature09941

[5] Nakano T, Ando S, Takata N, et al., Self-formation of optic cups and storable stratified neural retina from human ESCs. Cell Stem Cell 2012; 10(6): P771-785. https://www.cell.com/cell-stem-cell/fulltext/S1934-5909(12)00242-1

[6] Kuwahara A, Ozone C, Nakano T, Saito K, Eiraku M, Sasai Y., Generation of a ciliary margin-like stem cell niche from self-organizing human retinal tissue. Nat Commun. 2015; 6; 6286. https://www.nature.com/articles/ncomms7286

[7] Watari K, Yamasaki S, Tu HY et al.; Self-organization, quality control, and preclinical studies of human iPSC-derived retinal sheets for tissue-transplantation therapy. Commun Biol. 2023;6;164. https://www.nature.com/articles/s42003-023-04543-5

SOURCE Sumitomo Pharma America

Sumitomo Pharma

For further information: SMPA CONTACT: Dave Murdoch, Sumitomo Pharma America, Inc., david.murdoch@us.sumitomo-pharma.com, +1 (774) 405-5570

###