

Aculys Pharma Signs 4.4 Billion Yen Series C Funding Round Agreement

- **March 24, 2025**
- The additional funding will be used to prepare for regulatory approval and commercialization of diazepam nasal spray and pitolisant

Tokyo, Japan, March 24, 2025 – Aculys Pharma, Inc. (“Aculys”), a clinical stage biopharmaceutical company focused on the development and commercialization of innovative therapeutics in the fields of neurological and psychiatry, announced that it has entered into a Series C funding round agreement totaling 4.4 billion yen. This increased capital is expected to bring the cumulative amount of funding to 14 billion yen once the Series C round is completed.

Existing investors Catalys Pacific and HBM Healthcare Investments are joined in this round by KB Investment (Headquarters: Seoul, Republic of Korea, CEO: Young Seok Song), and MEDIPAL HOLDINGS CORPORATION (Headquarters: Chuo-ku, Tokyo, Representative Director, President and CEO: Shuichi Watanabe, “MEDIPAL”), which is participating via its MEDIPAL Innovation Fund. The funds raised in this round will be used to accelerate regulatory application and commercialization preparations for diazepam nasal spray and pitolisant in Japan.

Speaking on the announcement, Hidemasa Tanigaki, Chief Executive Officer of Aculys, said, “We are deeply grateful for the support we have received from investors who have shared our vision through the Series C round. To expeditiously deliver diazepam nasal spray and pitolisant to patients and their families in Japan, we continue to accelerate the application, approval, and commercialization of these medicines.”

BT Slingsby, Executive Chairman of Aculys’ Board of Directors, added, “Our mission is to provide important treatment options to the hands of neurologists and psychiatrists, and ultimately to patients in Japan. Our goal is to transform the quality of lives for patients and their families.”

Aculys is currently applying for approval of the manufacture and sale of diazepam nasal spray, an anticonvulsant drug in development for patients with status epilepticus and epileptic seizure which may progress to status epilepticus. Approval would make the drug the first intranasally administered antiepileptic drug and, in adult patients, the first rescue treatment option outside of a hospital setting in Japan. In addition, Aculys successfully conducted clinical Phase 3 trials in Japan and is on track to apply for marketing approval for the histamine H3 receptor antagonist/reverse agonist pitolisant for excessive daytime sleepiness associated with narcolepsy, a type of hypersomnia, and obstructive sleep apnea.

[Related News]

Aculys Pharma Files New Drug Application for Diazepam Nasal Spray in Japan: An Antiepileptic Drug for the Treatment of Epileptic Seizures (Aculys Pharma, September 2, 2024)

<https://aculys.com/en/20240902/>

Aculys Pharma Delivers Positive Results in Domestic Phase III Clinical Trial of Pitolisant for Narcolepsy Patients (Aculys Pharma, October 21, 2024)

<https://aculys.com/en/20241021/>

Aculy's Pharma Announces Positive Results in Japan Phase III Clinical Trial of Pitolisant in Patients with Obstructive Sleep Apnea Syndrome (OSAS) (Aculy's Pharma, January 9, 2025)
<https://aculy.com/en/20250109/>

■About diazepam and diazepam nasal spray

Diazepam has been used in Japanese medical practice for about 60 years as a treatment for epileptic seizures as an injection as well as other forms. It is also administered as a suppository by non-medical personnel, such as patients and caregivers, outside medical institutions. Diazepam nasal spray was developed by the U.S. pharmaceutical company Neurelis, Inc. Aculy's Pharma holds an exclusive license to develop and commercialize this treatment in Japan and the Asia-Pacific region* (excluding Greater China and Singapore).

(*Asia-Pacific region: Australia, Brunei, Cambodia, Indonesia, South Korea, Laos, Malaysia, Myanmar, New Zealand, Philippines, Thailand, Vietnam).

■About pitolisant

Pitolisant is an antagonist/inverse agonist that selectively binds to the histamine H3 receptor, an autoreceptor located in the presynaptic region of the histamine-containing neurons in the human brain that plays a critical role in regulating sleep and wake rhythm. As of September 2024, pitolisant has obtained regulatory approval in 38 countries including US and EU for narcolepsy, and in 29 countries in EU for OSAS.

■About Catalys Pacific

Catalys Pacific is an independent venture capital firm focusing on early-stage investments in life sciences. The firm's mission is to improve the lives of patients around the world and contribute to the advancement of healthcare and life sciences through the provision of innovative healthcare solutions. Founded in 2019, the firm is a trusted partner based in Japan and the U.S., pursuing its mission through the creation of new biotech companies and cross-border partnerships.

<https://catalyspacific.com/en>

■About HBM Healthcare Investments

HBM Healthcare Investments is a venture capital firm that focuses on investing in advanced technologies in the fields of medicine, biotechnology, medical technology, diagnostics and related fields. Founded in 2001 and listed on the SIX Swiss Exchange, the firm holds and manages an international portfolio of promising companies.

<https://www.hbmhealthcare.com/en>

■About KB Investment

KB Investment is the leading investment arm of KB Financial Group with a core focus on biotechnology and therapeutics that drive groundbreaking scientific innovations to improve patient health. Founded in 1990, the firm manages a diverse portfolio of high-potential companies worldwide. With a strong global presence, KB Investment goes beyond supporting good companies as it helps create great and innovative enterprises that shape the future.

<http://www.kbic.co.kr/main/index>

■About MEDIPAL HOLDINGS CORPORATION

As a holding company, MEDIPAL controls, administers and supports the operating activities of companies in which it holds shares in the Prescription Pharmaceutical Wholesale Business; the Cosmetics, Daily Necessities and OTC Pharmaceutical Wholesale Business; and the Animal Health Products and Food Processing Raw Materials Wholesale Business, and conducts business development for the MEDIPAL Group.

<https://www.medipal.co.jp/english/>

■About Aculy's Pharma, Inc.

Aculy's Pharma is a biopharmaceutical company that is pioneering ways to eliminate drug lag/drug loss in Japan, and is working to resolve social issues related to neurological and psychiatry diseases. Its corporate name was created from the philosophy of serving as a "Catalyst to Access." Aiming to act as a bridge for innovative medical care in the field of neuropsychiatry, Aculy's Pharma develops and commercializes novel pharmaceuticals introduced from the US and European countries and provides innovations for better medical care to patients, their families, healthcare professionals, and society. Aculy's Pharma is based in Tokyo, Japan, and was founded by Catalys Pacific.

Company name: Aculy's Pharma, Inc.

Location: 2-14-4 Kita-Aoyama, Minato-ku, Tokyo, Japan

Representative: Hidemasa Tanigaki

Established: January 2021

URL: <https://aculy.com>

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