
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 6-K

Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16
under the Securities Exchange Act of 1934

For the month of May 2025

Commission File Number: 002-023311

ASCENTAGE PHARMA GROUP INTERNATIONAL
(Translation of Registrant's name into English)

68 Xinqing Road
Suzhou Industrial Park
Suzhou, Jiangsu
China

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F

Form 40-F

On May 22, 2025, Ascentage Pharma Group International issued a press release entitled, “Ascentage Pharma Announces Clinical Data of Lixaftoclax, Which Shows Therapeutic Potential in Venetoclax-Refractory Patients, Selected for Oral Report at ASCO 2025.” A copy of the announcement is furnished as Exhibit 99.1 to this Report.

In addition, on May 23, 2025, the Ascentage Pharma Group International issued a Hong Kong Stock Exchange voluntary announcement entitled, “Ascentage Pharma Presents Results from Two Clinical Studies at 2025 ASCO Annual Meeting, Including an Oral Presentation on Lixaftoclax”. A copy of the announcement is furnished as Exhibit 99.2 to this Report.

INDEX TO EXHIBITS

Exhibit Number	Exhibit Title
99.1	Press Release dated May 22, 2025
99.2	Hong Kong Stock Exchange Voluntary Announcement dated May 23, 2025

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: May 23, 2025

ASCENTAGE PHARMA GROUP INTERNATIONAL

/s/ Dajun Yang

Name: Dajun Yang

Title: Chief Executive Officer



Ascentage Pharma Announces Clinical Data of LISAFTOCLAX, Which Shows Therapeutic Potential in Venetoclax-Refractory Patients, Selected for Oral Report at ASCO 2025

ROCKVILLE, Md. and SUZHOU, China, May 22, 2025 – Ascentage Pharma (NASDAQ: AAPG; HKEX: 6855), a global biopharmaceutical company dedicated to addressing unmet medical needs in cancers, today announced that new clinical data from two ongoing investigational studies evaluating lisaftoclax in various blood cancers and alrizomadlin in solid tumors will be presented during an oral presentation and poster presentation, respectively, at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting, taking place May 30 - June 3 in Chicago, Ill., USA. Both lisaftoclax and alrizomadlin demonstrated antitumor activity, and the data support their further clinical development.

The Bcl-2 inhibitor lisaftoclax and the MDM2-p53 inhibitor alrizomadlin are both key drug candidates in Ascentage Pharma's apoptosis-targeted pipeline. The oral report on lisaftoclax will feature results from a Phase 1b/2 study evaluating lisaftoclax in combination with azacitidine in patients with treatment-naïve (TN) or prior venetoclax-exposed myeloid malignancies. Data from this global, multicenter study that has enrolled nearly one hundred patients show that lisaftoclax in combination with azacitidine was well tolerated with preliminary efficacy. Moreover, this study released the first dataset of lisaftoclax in patients with venetoclax-refractory acute myeloid leukemia (AML) or myelodysplastic syndromes (MDS), and it also demonstrated promising therapeutic potential.

Dr. Yifan Zhai, Chief Medical Officer of Ascentage Pharma, commented: “We are pleased that results from the ongoing Phase 1b/2 study of lisaftoclax will be featured in an oral presentation at the 2025 ASCO Annual Meeting, which will highlight how lisaftoclax demonstrated significant activity when combined with azacitidine in patients with various myeloid malignancies. This novel Bcl-2 inhibitor has shown antitumor activity in both previously untreated patients and those who were treated with venetoclax, addressing a critical treatment gap for these difficult-to-treat conditions. The recent new drug application submission for lisaftoclax in China was a milestone for our program, and, if approved, lisaftoclax would become the second Bcl-2 inhibitor to be approved anywhere in the world. We are grateful to the patients who participated in these trials and the investigators for sharing our commitment to developing innovative therapies that can make a meaningful difference for patients with cancer who have limited options.”

Highlights of the two abstracts selected for presentations at ASCO 2025 are as follows:

Phase 1b/2 Study of LISAFTOCLAX (APG-2575) Combined with Azacitidine (AZA) in Patients with Treatment-Naïve or Prior Venetoclax-Exposed Myeloid Malignancies

- **Abstract #:** 6505
 - **Format:** Oral Presentation
 - **Session Title:** Hematologic Malignancies—Leukemia, Myelodysplastic Syndromes, and Allotransplant
 - **Date and Time:** Monday, June 2, 2025, 3:00 PM-6:00 PM, Central Time (Tuesday, June 3, 2025, 4:00 AM-7:00 AM, Beijing Time)
-

Principal Authors: Michael Francis Leahy, MBChB, Royal Perth Hospital, Australia; Shaun Fleming, MBBS(Hons), PhD, The Alfred Hospital & Australian Centre for Blood Diseases, Australia; Patricia Kropf, MD, Novant Health Cancer Institute, United States, et al.

Highlights:

The Phase 1b/2 study was designed to evaluate the safety and efficacy of lisaftoclax in combination with azacitidine in patients with treatment-naïve (TN) or relapsed/refractory (R/R) acute myeloid leukemia (AML)/mixed phenotype acute leukemia (MPAL) or high-risk myelodysplastic syndromes (HR-MDS)/chronic myelomonocytic leukemia (CMML). Lisaftoclax is a novel investigational oral selective Bcl-2 inhibitor that has shown enhanced treatment response when combined with azacitidine in prior preclinical and clinical studies.

The combination of lisaftoclax and azacitidine was well tolerated, with initial signals of clinical activity. As of the data cutoff date of January 6, 2025, 97 patients were enrolled, with a median treatment duration of two cycles. In patients with TN-MDS/CMML, the overall response rate (ORR) was 64%, with complete response (CR) and marrow CR achieved by 29% and 36% of patients, respectively; in patients with R/R AML treated with lisaftoclax for 28 days or 14 days of repeated 28-day cycles, the ORRs were 39% and 50%, respectively, including CR rates of 28% and 37.5%, respectively; in patients with diseases refractory to venetoclax, the ORR was 17% in patients with AML/MPAL and 50% in patients with HR-MDS.

The maximum tolerated dose (MTD) was not reached, and no dose-limiting toxicities (DLTs) were observed. Common grade 3/4 treatment-emergent adverse events (TEAEs) included neutropenia (40%), febrile neutropenia (31%), and thrombocytopenia (22%). Febrile neutropenia was the most commonly reported serious adverse event (SAE) (26.8%). Only 3% of participants experienced neutropenia that led to a dose reduction of lisaftoclax. There was no reported 60-day mortality.

A Phase 2 Study of Novel MDM2 Inhibitor Alrizomadlin (APG-115) with or without Toripalimab in Patients with Advanced Adenoid Cystic Carcinoma (ACC) or Other Solid Tumors

Abstract #: 6102

Format: Poster Presentation

Session Title: Head and Neck Cancer

Date and Time: Monday, June 2, 2025, 9:00 AM-12:00 PM, Central Time (Monday June 2, 2025, 10:00 PM – 1:00 AM the next day, Beijing Time)

Principal Authors: Ye Guo, MD, Department of Medical Oncology, Shanghai East Hospital, China; Ning Li, MD, Chinese Academy of Medical Sciences Cancer Hospital, China; Xing Zhang, MD, Melanoma and Sarcoma Medical Oncology Unit, Sun Yat-sen University Cancer Center, China; Meiyu Fang, MD, Department of Rare Cancer & Head and Neck Medical Oncology, Cancer Hospital of the University of Chinese Academy of Sciences, China; Shuhang Wang, MD, Chinese Academy of Medical Sciences Cancer Hospital, China, et al.

Highlights:

Alrizomadlin is a novel investigational oral MDM2 inhibitor that has shown a manageable safety profile with initial clinical activity in ACC.

As of the data cutoff date of January 5, 2025, 54 patients with advanced ACC, malignant peripheral nerve sheath tumor (MPNST), liposarcoma (LPS), biliary-tract cancer (BTC) and other tumors were enrolled. Alrizomadlin monotherapy showed antitumor activity in patients with advanced ACC or MPNST. Alrizomadlin in combination with toripalimab was also well tolerated and demonstrated antitumor activity in patients with MPNST, BTC and LPS.

In the monotherapy arm, 14 patients were efficacy-evaluable. The ORR was 22.2% and the disease control rate (DCR) was 100% in 9 patients with ACC. The DCR was 100% in all patients with MPNST, all 5 of whom achieved stable disease (SD). Grade 3 or higher treatment-related adverse events (TRAEs) included neutropenia (13.6%) and thrombocytopenia (9.1%). No treatment-related SAEs were reported.

In the combination arm, 28 patients were efficacy-evaluable. The ORR was 20% and DCR was 80% in 5 patients with BTC. The ORR was 16.7% and DCR was 66.7% in 6 patients with LPS. The ORR was 14.3% and DCR was 53.6% in patients with MPNST; furthermore, 2 patients with MPNST had confirmed partial responses (PR) with prolonged progression free survival (PFS) of 60+ weeks and 96+ weeks, respectively. Grade 3 or higher TRAEs included thrombocytopenia (38.5%) and neutropenia (34.6%). Treatment-related SAEs were reported in 8 patients, with thrombocytopenia being the most common (n=6). One patient discontinued treatment because of grade 4 thrombocytopenia. No treatment-related deaths were reported.

* *Lisaftoclax (APG-2575) and alrizomadlin (APG-115) are investigational compounds and have not been approved by the U.S. FDA.*

About Ascentage Pharma

Ascentage Pharma (NASDAQ: AAPG; HKEX: 6855) is a global biopharmaceutical company dedicated to addressing unmet medical needs in cancers. The company has built a rich pipeline of innovative drug candidates that includes inhibitors targeting key proteins in the apoptotic pathway, such as Bcl-2 and MDM2-p53 and next-generation kinase inhibitors.

The lead asset, olverembatinib, is the first third generation BCR-ABL1 inhibitor approved in China for the treatment of patients with CML in chronic phase (CML-CP) with T315I mutations, CML in accelerated phase (CML-AP) with T315I mutations, and CML-CP that is resistant or intolerant to first and second-generation TKIs. It is covered by the China National Reimbursement Drug List (NRDL). The Company is currently conducting an FDA-cleared, global registrational Phase 3 trial, or POLARIS-2, of olverembatinib for CML, as well as global registrational Phase 3 trials for newly diagnosed Ph+ ALL patients and SDH-deficient GIST patients.

The second lead asset, lisaftoclax, is a novel Bcl-2 inhibitor for the treatment of various hematological malignancies. The NDA for the treatment of relapsed and/or refractory CLL and SLL was accepted with Priority Review designation by China's National Medical Products Administration. The Company is currently conducting an FDA-cleared, global registrational Phase 3 trial, or GLORA, of lisaftoclax in combination with BTK inhibitors for patients with CLL/SLL previously treated with BTK inhibitors for more than 12 months with sub-optimal response, as well as global registrational Phase 3 trials for newly diagnosed CLL/SLL, AML and MDS patients.

Leveraging its robust R&D capabilities, Ascentage Pharma has built a portfolio of global intellectual property rights and entered into global partnerships and other relationships with numerous leading biotechnology and pharmaceutical companies, such as Takeda, AstraZeneca, Merck, Pfizer and Innovent, in addition to research and development relationships with leading research institutions, such as Dana-Farber Cancer Institute, Mayo Clinic, National Cancer Institute and the University of Michigan. For more information, visit <https://ascentage.com/>

Forward-Looking Statements

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical facts, contained in this press release may be forward-looking statements, including statements that express Ascentage Pharma's opinions, expectations, beliefs, plans, objectives, assumptions or projections regarding future events or future results of operations or financial condition. These forward-looking statements are subject to a number of risks and uncertainties as discussed in Ascentage Pharma's filings with the SEC, including those set forth in the sections titled "Risk factors" and "Special note regarding forward-looking statements and industry data" in its Registration Statement on Form F-1, as amended, filed with the SEC on January 21, 2025, and the Form 20-F filed with the SEC on April 16, 2025, the sections headed "Forward-looking Statements" and "Risk Factors" in the prospectus of the Company for its Hong Kong initial public offering dated October 16, 2019, and other filings with the SEC and/or The Stock Exchange of Hong Kong Limited we made or make from time to time that may cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. The forward-looking statements contained in this presentation do not constitute profit forecast by the Company's management.

As a result of these factors, you should not rely on these forward-looking statements as predictions of future events. The forward-looking statements contained in this press release are based on Ascentage Pharma's current expectations and beliefs concerning future developments and their potential effects and speak only as of the date of such statements. Ascentage Pharma does not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

Contacts

Investor Relations:

Hogan Wan, Head of IR and Strategy
Ascentage Pharma
Hogan.Wan@ascentage.com
+86 512 85557777

Stephanie Carrington
ICR Healthcare
Stephanie.Carrington@icrhealthcare.com
+1 (646) 277-1282

Media Relations:

Sean Leous
ICR Healthcare
Sean.Leous@icrhealthcare.com
+1 (646) 866-4012

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ASCENTAGE PHARMA GROUP INTERNATIONAL

亞盛醫藥集團

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 6855)

VOLUNTARY ANNOUNCEMENT

Ascentage Pharma Presents Results from Two Clinical Studies at 2025 ASCO Annual Meeting, Including an Oral Presentation on LISAFTOCLAX

Ascentage Pharma Group International (the “**Company**” or “**Ascentage Pharma**”) is pleased to announce that new clinical data from two ongoing investigational studies evaluating lisaftoclax in various blood cancers and alrizomadlin in solid tumors will be presented during an oral presentation and poster presentation, respectively, at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting, taking place from May 30, 2025 to June 3, 2025 in Chicago, Illinois, USA. Both lisaftoclax and alrizomadlin demonstrated antitumor activity, and the data support their further clinical development.

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Cautionary Statement required by Rule 18A.05 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited:

We cannot guarantee that we will be able to obtain further approval for, or ultimately market APG-2575 and APG-115 successfully.

By order of the Board
Ascentage Pharma Group International
Dr. Yang Dajun
Chairman and Executive Director

Suzhou, People's Republic of China, May 23, 2025

As at the date of this announcement, the Board comprises Dr. Yang Dajun as chairman and executive Director, Dr. Wang Shaomeng and Dr. Lu Simon Dazhong as non-executive Directors, and Mr. Ye Changqing, Mr. Ren Wei, Dr. David Sidransky, Ms. Marina S. Bozilenko, Dr. Debra Yu and Marc E. Lippman, MD as independent non-executive Directors.

Note: Dr. Wang Shaomeng and Dr. Lu Simon Dazhong are independent directors under NASDAQ rules.