Abstracts on six studies of Ascentage Pharma’s three drug candidates under development (Olverembatinib, APG-2575, and APG-1252) have been selected for oral presentation and poster presentations at the 63rd American Society of Hematology (ASH) Annual Meeting

Ascentage Pharma Group International (the “Company” or “Ascentage Pharma”) is pleased to announce that abstracts on six studies of the Company’s three drug candidates under development (Olverembatinib, APG-2575, and APG-1252) have been selected for oral presentation and poster presentations at the 63rd American Society of Hematology (ASH) Annual Meeting. Abstracts on three clinical trials of the Company’s novel drug candidate under development, Olverembatinib (HQP1351), have been selected for poster presentations and one oral presentation at the 63rd American Society of Hematology (ASH) Annual Meeting. Presenter, Qian Jiang, MD, and Xiaojun Huang, MD, from the Hematology Department of Peking University People’s Hospital are the principal investigators of the study selected for oral presentation. This is the fourth consecutive year in which studies of olverembatinib were selected for oral presentation by the ASH Annual Meeting, demonstrating strong recognition of the drug candidate’s promising efficacy and safety by the international hematology community. In addition, these data include those from two clinical studies of the Company’s novel Bcl-2-selective inhibitor Lisaftoclax (APG-2575) which is under development, and the results of one preclinical study of the dual Bcl-2/Bcl-xL inhibitor Pelcitoclax (APG-1252).
Olverembatinib is a novel Class I drug, and is a novel third-generation BCR-ABL tyrosine kinase inhibitor (TKI) being developed by Ascentage Pharma for the treatment of patients with chronic myeloid leukemia (CML) resistant to first- and second-generation TKIs, especially those with the T315I mutation, which confers resistance against these agents. As at the date of this announcement, the New Drug Application (NDA) submitted by Ascentage Pharma for Olverembatinib for the treatment of patients with T315I-mutated CML in chronic-phase (CML-CP) or accelerated-phase (CML-AP) is currently under review in China and has already been granted the Priority Review status. Moreover, Olverembatinib was granted a Breakthrough Therapy designation by the Center for Drug Evaluation (CDE) of China National Medical Products Administration (NMPA) for the treatment of patients with CML-CP resistant to and/or intolerant of first- and second-generation TKIs.

In addition, the multicenter, open-label Phase I study of APG-2575 in patients with hematologic malignancies has demonstrated favorable tolerability of APG-2575, without any tumor lysis syndrome (TLS). As of data cutoff on July 27, 2021, 9 of the 25 patients who had received at least one tumor evaluation (of all 31 enrolled patients) achieved complete response (CR) or partial response (PR). At doses ≥ 200 mg, all 6 patients with chronic lymphocytic lymphoma (CLL) have achieved objective responses, including 1 with CR and 5 with PR.

The ASH Annual Meeting is one of the largest international academic gatherings of the international hematology field, bringing together the latest and most cutting-edge research and other scientific and clinical developments in hematology. The 63rd ASH Annual Meeting will take place from December 11, 2021 to December 14, 2021, both virtually and in-person in Atlanta, United States. This year, six abstracts on three of Ascentage Pharma’s drug candidates under development (Olverembatinib, APG-2575, and APG-1252) have been selected by the ASH Annual Meeting for poster or oral presentations.

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These abstracts selected for presentations at 2021 ASH Annual Meeting are as follows:

**Updated Safety and Efficacy Results of Phase 1 Study of Olverembatinib (HQP1351), a Novel Third-Generation BCR-ABL Tyrosine Kinase Inhibitor (TKI), in Patients with TKI-Resistant Chronic Myeloid Leukemia (CML)**

- **Format**: Oral Presentation
- **Abstract**: 311
- **Session**: 632. Chronic Myeloid Leukemia: Clinical and Epidemiological: Mechanisms of resistance and expanded therapies
- **Time**: Saturday, December 11, 2021; 5:00 PM EDT
- **Highlights**:
  - This Chinese, open-label, multicenter, Phase I trial evaluated the safety and efficacy of olverembatinib in adults with CML-CP or CML-AP. Eligible patients have CML-CP or CML-AP that is resistant or intolerant to first- and second-generation TKIs. Olverembatinib was orally administered once every other day (QOD) in 28-day cycles at 11 dose cohorts ranging from 1 to 60 mg. This study reports data on patients with long-term follow-up.
From October 26, 2016, through February 2, 2021 (data cut-off date), 101 patients with CML-CP (n=86) and CML-AP (n=15) were enrolled and treated with olverembatinib. 71 (70.3%) patients were male, the median age was 40 (range, 20-64) years, and the median (range) interval from diagnosis to initial olverembatinib treatment was 6.0 (0.3-15.2) years. 84 (83.2%) patients received ≥ 2 prior lines of TKI-therapies, and 63 (62.4%) harbored the T315I mutation. At baseline, compound mutations were detected in 11 (10.9%) patients, of whom 7 (63.6%) had the BCR-ABL1 T315I genotype. A total of 20 (19.8%) patients had 2 (n=13) or ≥ 3 (n=7) mutations. The median follow-up was 30.8 (1.2-51.8) months. As of the data cutoff date, 81 (80.2%) of 101 patients continued on the treatment, 18 (17.8%) were treated for > 3 years and 5 (5%) for > 4 years.

Of evaluable patients without baseline responses, 97.0% had complete hematologic responses (CHR), 62.1% had complete cytogenetic responses (CCyR), and 51.0% had major molecular responses (MMR).

— Among patients in CML-CP, most evaluable patients with T315I mutations experienced 100% for CHR, 83.7% for MCyR, and 71.2% for MMR.

— While among patients in CML-AP, 80.0% for CHR and 54.5% each for MCyR and MMR.

At 36 months, the progression-free survival (PFS) rate was 96.3% (89.1%-98.8%) in patients with CML-CP and 71.4% (40.6%-88.2%) in those with CML-AP.

Treatment responses were durable and unaffected by baseline BCR-ABL1 mutational status. Corresponding values in patients with > 4 years of treatment were 100% (CHR), 80% (CCyR), and 60% (MMR). The mean PFS rate was 100% at 36 months, 100% at 48 months, and not reached (NR-NR) at 60 months.

Most treatment-related adverse events (TRAEs) were grade 1 or 2.

— The most frequent nonhematologic adverse event (AE) was (mostly grade 1 or 2) skin hyperpigmentation (86.1%). Grade ≥ 3 nonhematologic AEs included hypertriglycerideridemia (10.9%), pyrexia (6.9%), and proteinuria (5.0%).

— The most common hematologic TRAE was thrombocytopenia in 78 (77.2%) patients, including 52 (51.5% of total population) with grade ≥ 3. Leukopenia was grade ≥ 3 in 21 (20.8%) patients but not serious, while anemia was grade 3 or higher in 16 (15.8%) patients.
Conclusions: In patients with TKI-resistant CML-CP or CML-AP and long-term treatment, olverembatinib was efficacious and well tolerated.

Updated Results of Pivotal Phase 2 Trials of Olverembatinib (HQP1351) in Patients (Pts) with Tyrosine Kinase Inhibitor (TKI)-Resistant BCR-ABL1^{T315I}-Mutated Chronic- and Accelerated-Phase Chronic Myeloid Leukemia (CML-CP and CML-AP)

- Format: Poster Presentation
- Abstract: 3598
- Session: 632. Chronic Myeloid Leukemia: Clinical and Epidemiological: Poster III
- Time: Monday, December 13, 2021; 6:00 PM - 8:00 PM EDT
- Highlights:

  - HQP1351-CC201 and HQP1351-CC202 are Chinese open, single-arm, multicenter pivotal Phase II trials evaluating the safety and efficacy of olverembatinib in adults with TKI-resistant (BCR-ABL1^{T315I}-mutated) CML-CP and CML-CP, respectively. Olverembatinib was administered at 40 mg orally on alternate days for 28-day cycles.

  - As of the data cutoff on August 25, 2020, HQP1351-CC201 enrolled a total of 41 patients with CML-CP, of whom 32 (78%) completed ≥ 12 cycles. The median follow-up was 13 (3.1-16.3) months. After ≥ 12 treatment cycles in patients without responses at baseline, all experienced CHR; 31/41 (75.6%) MCyR; 28/41 (68.3%) CCyR; and 23/41 (56.1%) MMR. At 12 months, the PFS rate was 89.3%, and the overall survival (OS) was 100%.

  - As of the data cutoff on July 27, 2020, HQP1351-CC202 enrolled a total of 23 patients with CML-CP, of whom 14 (61%) had completed ≥ 12 cycles. The median (range) follow-up was 13.5 (1.4-15.2) months. After ≥ 12 treatment cycles in patients without responses at baseline, 17/23 (73.9%) experienced MaHR; 12/23 (52.2%) MCyR; 11/23 (47.8%) CCyR; and 9/23 (39.1%) MMR. At 12 months, the PFS rate was 74.1%, and the OS was 91.3%.

  - In HQP1351-CC201, the most frequent TRAE of grade 3-4 was thrombocytopenia (48.8%), and no treatment-related deaths occurred.
In HQP1351-CC202, the most frequent TRAE of grade 3-4 was thrombocytopenia (56.5%).

Conclusions: Olverembatinib was efficacious and well tolerated when administered as monotherapy in patients with TKI-resistant CML-CP and CML-AP and the BCR-ABL\textsuperscript{T315I} mutation.

Trial in Progress: Phase 1b Bridging Study of the Pharmacokinetic (PK), Safety, and Efficacy of Orally Administered Olverembatinib (HQP1351) in Patients with Refractory Chronic Myeloid Leukemia (CML) and Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia (Ph\textsuperscript{+} ALL)

- Format: Poster Presentation
- Abstract: 2551
- Session: 632. Chronic Myeloid Leukemia: Clinical and Epidemiological: Poster II
- Time: Sunday, December 12, 2021; 6:00 PM - 8:00 PM EDT
- Highlights:
  - This open-label bridging trial in the US is evaluating the PK, efficacy, and safety of olverembatinib administered orally QOD in adults who have CML-CP, CML-AP or blast-phase CML (CML-BP) and Ph\textsuperscript{+} ALL.
  - This study is currently recruiting patients and enrolled patients are being allocated to three dose cohorts: 30, 40, or 50 mg. Endpoints of this study include PK, antitumor activity, and safety.

A Phase 1 Study to Evaluate the Safety, Pharmacokinetics (PK) and Pharmacodynamics (PD) of Lisaftoclax (APG-2575), a Novel BCL-2 Inhibitor (BCL-2i), in Patients (pts) with Hematologic Malignancies (HMs)

- Format: Poster Presentation
- Abstract: 3730
- Session: 642. Chronic Lymphocytic Leukemia: Clinical and Epidemiological: Poster III
• Time: Monday, December 13, 2021;

• Highlights:

➢ This Chinese, multicenter, open-label, single-agent, Phase I trial is evaluating the safety (including dose-limiting toxicity DLT and maximum tolerated dose MTD), efficacy, PK, and PD of lisaftoclax in adults with R/R chronic lymphocytic leukemia (CLL) or non-Hodgkin’s lymphoma (NHL).

➢ As of July 27, 2021, 31 patients had been enrolled and treated with lisaftoclax at doses ranging from 20mg to 800 mg. Patients had a median (range) of 4 (1-14) prior lines of treatment and diagnoses of CLL/SLL (n=9), mantle cell lymphoma (MCL; n=6), marginal zone lymphoma (MZL; n=3), follicular lymphoma (n=8), diffuse large B-cell lymphoma (n=2), lymphoplasmacytic lymphoma/Waldenstrom macroglobulinemia (n=1), angioimmunoblastic T-cell lymphoma (n=1) or mycosis fungoides (MF; n=1). DLT, MTD, and laboratory/clinical tumor lysis syndrome (TLS) have not been observed. The recommended Phase II dose (RP2D) is 600 mg.

➢ Lisaftoclax was generally well tolerated. Treatment-related adverse events (TRAEs) were reported in 28 patients, most of which were mostly grade 1 or 2. Any grade TRAEs in > 10% of patients include thrombocytopenia (34.4%), neutropenia (21.9%), leukopenia (21.9%), anemia (28.1%), hyperuricemia (15.6%), hyperphosphatemia (12.5%), hypertriglyceridemia (12.5%), and diarrhea (15.6%). Grade 3-4 TRAEs were reported in 7 patients, including thrombocytopenia (18.8%), neutropenia (12.5%), leukopenia (9.4%), and anemia (6.3%). Serious TRAEs occurred in 1 patient and included anemia and thrombocytopenia (in 3.1% each).

➢ Among the 25 patients who have received at least one tumor evaluation, 9 achieved CR or PR, with a median (range) time to response of 2 (2-4) cycles. The highest response rates were seen in patients with CLL/SLL (ORR 66.7%). At doses ≥ 200 mg, an ORR of 100% (6/6 including 1 CR and 5 PRs) was observed. Responses were also observed in MZL, with a PR in 2 of 3 patients (ORR, 66.7%), and MCL, with a PR in 1 of 4 patients (ORR, 25%). In 1 patient with MF, skin tumor shrinkage was observed after 1 lisaftoclax treatment cycle. Favorable absolute lymphocyte count (ALC) profiles included reductions at lisaftoclax doses as low as 100 mg/day.
The preliminary PK profile showed that exposures increased with lisaftoclax doses from 20 to 800 mg, with an average half-life of 4 to 6 hours. On BH3 profiling, lisaftoclax rapidly triggered changes in BCL-2 complex in CLL/SLL patient samples, which were consistent with rapid clinical reductions in ALCs.

- Conclusions: Lisaftoclax was well tolerated up to 800 mg/day. No TLS was observed, even with the daily ramp-up schedule. There were no significantly new or unmanageable safety findings. Lisaftoclax showed single-agent antitumor activity in CLL/SLL, MZL, and MCL. The BCL-2i lisaftoclax offers a treatment alternative for patients with R/R HMs, with a daily ramp-up schedule that may be more patient friendly with a favorable preliminary safety profile.

Trial in Progress: Phase 1b Study of Lisaftoclax (APG-2575) As a Single Agent or Combined with Other Therapeutic Agents in Patients with Relapsed and/or Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (R/R CLL/SLL)

- Format: Poster Presentation
- Abstract: 1554
- Session: 642. Chronic Lymphocytic Leukemia: Clinical and Epidemiological
- Time: Saturday, December 11, 2021; 5:30 PM - 7:30 PM EDT
- Highlights:
  - This new study is a global, open-label, multicenter, two-part Phase Ib dose escalation and dose expansion study to assess the safety and tolerability of lisaftoclax (Part 1) and lisaftoclax combined with rituximab or acalabrutinib (Part 2).
  - In a standard “3+3” dose escalation design (Part 1), lisaftoclax is being administered orally once daily in a 28-day cycle, with full doses of 200 mg to 1,200 mg (by 200-mg increments at 4 dose levels (400 mg, 600 mg, 800 mg, and 1,000 mg) in parallel. To lower the risk of TLS, lisaftoclax was administered with a daily dose ramp up.
  - Part 2 includes a further standard 3+3 dose escalation of lisaftoclax combined with rituximab, or acalabrutinib (in separate cohorts), with a further planned dose expansion at RP2D of these combination regimens.
As of July 19, 2021, 71 patients have been enrolled (of 144 planned).

The abstract of pelcitoclax selected for presentations at 2021 ASH Annual Meeting is as follows:

**Antitumor Activity of Dual BCL-2/BCL-Xl Inhibitor Pelcitoclax (APG-1252) in Natural Killer/T-Cell Lymphoma (NK/TCL)**

- Format: Poster Presentation
- Abstract: 2062
- Session: 20. Lymphocytes and Acquired or Congenital Immunodeficiency Disorders
- Time: 6:00-8:00 pm, December 12, 2021. Eastern Time
- Highlights:

  ➢ This study evaluated the potential antitumor effect of APG-1252 in preclinical models of NK/TCL. Cell-based antiproliferation studies showed activity of APG-1252 and its more potent metabolite APG-1252-M1 toward NK/TCL cell lines that overexpressed BCL-xL. Half-maximal inhibitory concentrations (IC) for APG-1252 in SNK-1, SNK-6, and SNK-8 (EBV-positive NK/TCL) cell lines were 2.652 ± 2.606 μM, 1.568 ± 1.109 μM, and 0.557 ± 0.383 μM, respectively. Corresponding values for APG-1252-M1 were 0.133 ± 0.056 μM, 0.064 ± 0.014 μM, and 0.020 ± 0.008 μM, respectively.

  ➢ Mechanistic studies demonstrated that APG-1252 and APG-1252-M1 disrupted the complex of BCL-xL/BCL-2-associated X protein (Bax) and BCL-xL/BCL-2 homologous antagonist killer protein (Bak) in SNK-6 cells, thereby liberating these proapoptotic proteins and further activating downstream apoptosis pathways by cleaving poly-ADP ribose polymerase-1 (PARP-1) and caspase-3. In an SNK-6 xenograft model, administration of APG-1252 at 65 mg/kg and 100 mg/kg either twice or once weekly resulted in significant antitumor effects, with tumor growth rate (T/C%) values ranging from 13.7% to 30.7%.
Furthermore, the combination of APG-1252 with HDAC inhibitor chidamide or DDGP (dexamethasone, cisplatin, gemcitabine, and pegasparagase) chemotherapy demonstrated synergistic effects. Pharmacokinetic assessment in mice showed that APG-1252 had a long half-life in plasma (127 hours) and tumor tissues (25.2 hours), justifying intermittent dosing schedules used in vivo. Importantly, the transformation of APG-1252 to APG-1252-M1 was 16 times higher in tumor tissues compared to plasma (22% vs. 1.3%) after administration of APG-1252, thereby suggesting that APG-1252 can reduce platelet toxicity caused by APG-1252-M1 in plasma.

• In conclusion, APG-1252 has promising antitumor effects in NK/TCL, either as a single agent or in combination with an HDAC inhibitor or chemotherapy. These findings provide evidence to further evaluate APG-1252 as a potential treatment for NK/TCL.

About Olverembatinib (HQP1351)

Olverembatinib is a novel, orally active, potent third-generation BCR-ABL inhibitor designed to effectively target BCR-ABL mutants, including T315I, and the first China-developed third-generation BCR-ABL inhibitor targeting drug-resistant CML. In July 2019, Olverembatinib was cleared by the U.S. Food and Drug Administration (the “FDA”) to enter a Phase Ib clinical study. In May 2020, Olverembatinib was granted an Orphan Drug Designation and a Fast Track Designation by the FDA. In October 2020, Olverembatinib was granted “Priority Review” designation by the CDE in China for the treatment of adult patients resistant to TKI and with T315I-mutant chronic phase CML or accelerated phase CML. In December 2020, clinical trial results of Olverembatinib were selected for oral presentation at the American Society of Hematology Annual Meeting for the third consecutive year. These data further demonstrated the favorable safety and promising efficacy profiles of Olverembatinib.

About Lisaftoclax (APG-2575)

APG-2575 is a novel, orally administered small-molecule Bcl-2-selective inhibitor being developed by Ascentage Pharma. APG-2575 is designed to treat hematologic malignancies and solid tumors by selectively blocking antiapoptotic protein Bcl-2 to restore the normal apoptotic process in cancer cells. APG-2575 is the first China-developed Bcl-2 inhibitor entering clinical development in China.
APG-2575 is being studied in multiple clinical studies in countries and regions including the U.S., China, Australia, and the EU, for a range of hematologic malignancies and solid tumors such as chronic lymphocytic leukemia, acute myeloid leukemia, and breast cancer. Lisaftoclax has been granted Orphan Drug Designations for five indications including Waldenström macroglobulinemia, chronic lymphocytic leukemia, multiple myeloma, acute myeloid leukemia, and follicular lymphoma.

About Pecitoclax (APG-1252)

APG-1252 is a novel drug being developed by Ascentage Pharma, which is designed to restore apoptosis through selective inhibition of Bcl-2 and Bcl-xL proteins. In preclinical animal models of EGFR-mutant non-small cell lung cancer (NSCLC), APG-1252 plus Osimertinib has demonstrated synergistic effects in models that were either sensitive or resistant to Osimertinib, thus indicate APG-1252’s potential as a new treatment option to this patient population.

About Ascentage Pharma (6855.HK)

Ascentage Pharma is a China-based, globally focused, clinical-stage biotechnology company engaged in developing novel therapies for cancers, CHB (Chronic hepatitis B), and age-related diseases. On October 28, 2019, Ascentage Pharma became listed on the Main Board of The Stock Exchange of Hong Kong Limited with the stock code: 6855.HK.

Ascentage Pharma has its own platform for developing therapeutics that inhibit protein-protein interactions to restore apoptosis or programmed cell death. The Company has built a pipeline of eight type I small molecule clinical drug candidates which have entered the clinical development stage, including novel, highly potent Bcl-2, and dual Bcl-2/Bcl-xL inhibitors, as well as candidates aimed at IAP and MDM2-p53 pathways, and next-generation tyrosine kinase inhibitors (TKIs). Ascentage Pharma is also the only company in the world with active clinical programs targeting all three known classes of key apoptosis regulators. The Company is conducting more than 40 Phase I/II clinical trials in China, the US, Australia and Europe. The Company has been designated for multiple major national R&D projects in China, including five Major New Drug Development Projects, one Enterprise Innovative Drug Incubator Base status, four Innovative Drug Research and Development Programs, and one Major Project for the Prevention and Treatment of Infectious Diseases. HQP1351, the Company’s core drug candidate developed for the treatment of drug-resistant chronic myeloid leukemia (CML), has been granted an Orphan Drug Designation (ODD) and a Fast Track Designation (FTD) by the US FDA, and a New Drug Application (NDA) for the drug candidate has been submitted and subsequently granted Priority Review status and a Breakthrough Therapy Designation (BTD) by the Center for Drug Evaluation (CDE) in China. As at the date of this announcement, Ascentage Pharma has obtained a total of 12 ODDs from the US FDA for 4 of the Company’s investigational drug candidates.
Leveraging its robust research and development capabilities, Ascentage Pharma has built a portfolio of global intellectual property rights, and entered into global partnerships with numerous leading biotechnology and pharmaceutical companies and research institutes such as UNITY Biotechnology, MD Anderson Cancer Center, Mayo Clinic, Dana-Farber Cancer Institute, MSD, and AstraZeneca. The Company has built a global and talented team with experience in the research and development of innovative drugs and clinical development, and is setting up its commercial manufacturing and sales and marketing teams with high standards. Ascentage Pharma aims to continuously strengthen its research and development capabilities and accelerate the clinical development progress of its product pipeline to fulfil its mission of ‘addressing unmet clinical needs of patients in China and around the world’ for the benefit of more patients.

**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, Olverembatinib, APG-2575 and APG-1252 successfully.

By order of the Board

Ascentage Pharma Group International

Dr. Yang Dajun

Chairman and Executive Director

Suzhou, People’s Republic of China, November 5, 2021

As at the date of this announcement, the Board of Directors of the Company comprises Dr. Yang Dajun as Chairman and executive Director, Dr. Wang Shaomeng, Dr. Tian Yuan, Dr. Lu Simon Dazhong and Mr. Liu Qian as non-executive Directors, and Mr. Ye Changqing, Dr. Yin Zheng, Mr. Ren Wei and Dr. David Sidransky as independent non-executive Directors.