

December 13, 2021



Cellecstar Presented Data from its Ongoing Phase 2 CLOVER-1 Study of Iopofosine I-131 at the 63rd ASH Annual Meeting and Exposition

Poster highlighted data from 11 patients with at least triple class refractory multiple myeloma

Mean ORR of 45.5%, CBR of 72.7% and DCR of 100% and the subset of quad/penta drug refractory patients had an ORR of 80% and CBR of 100%

FLORHAM PARK, N.J., Dec. 13, 2021 (GLOBE NEWSWIRE) -- Cellecstar Biosciences, Inc. (NASDAQ: CLRB), a late-stage clinical biopharmaceutical company focused on the discovery, development and commercialization of targeted drugs for the treatment of cancer, presented data from 11 multiple myeloma patients from the company's ongoing Phase 2 CLOVER-1 study of iopofosine I-131 in a poster at the American Society of Hematology (ASH) Annual Meeting and Exposition.

The multiple myeloma patients were at least triple class refractory (defined as refractory to an immunomodulatory agent, proteasome inhibitor and monoclonal antibody) with data current as of the end of May 2021. Patients had a median of greater than 7 prior therapies with 50% classified as high risk. Initial results in these patients showed an overall response rate (ORR) of 45.5%, a clinical benefit rate (CBR) of 72.7% and a disease control rate (DCR) of 100%. Median progression free survival (PFS) was 3.4 months. In a subset of 5 quad/penta drug refractory patients, efficacy increased, demonstrating an ORR of 80% and CBR of 100% in this highly treatment refractory group. The most commonly observed treatment emergent adverse events were cytopenias that included Grade 3 or 4 thrombocytopenia (62.5%), anemia (62.5%), neutropenia (62.5%) and decreased white blood cell count (50%). Treatment emergent adverse events were mostly limited to bone marrow suppression in line with prior observations. No patients experienced a treatment emergent adverse event of neuropathy, arrhythmia, cardiovascular event, bleeding, ocular toxicities, renal function, alterations in liver enzymes, or infusion-site reactions or adverse events.

"These results in heavily pre-treated, highly refractory patients are very encouraging, and show that iopofosine I-131 has the potential to be a meaningful part of the treatment regimen in multiple myeloma," said Dr. Sikander Ailawadhi, professor of medicine, Lead, International Cancer Center, Division of Hematology/Oncology, Departments of Medicine and Cancer Biology at Mayo Clinic Jacksonville, Florida and principal investigator of the Phase 2 CLOVER-1 study.

James Caruso, president and CEO of Cellecstar, said, "Unfortunately, there remains a need for additional therapies and treatment options for patients with refractory multiple myeloma. We believe iopofosine I-131's demonstrated ability to specifically target cancer cells

potentially represents an important advancement in cancer-targeting treatments. We look forward to sharing additional data as the Phase 2 CLOVER-1 study matures. In parallel, we continue to execute on our ongoing pivotal study in Waldenstrom's macroglobulinemia where we anticipate announcing results of a futility analysis in the first quarter of 2022."

Patients in the study received up to 4, approximately 20 minute IV infusions of iopofosine I-131 over 3 months, with doses given 14 days apart in each cycle and a maximum of 2 cycles. Low dose dexamethasone 40mg weekly (20mg in patients ≥ 75), was provided for up to 12 weeks. Following treatment with iopofosine I-131, approximately 91% of patients experience a reduction in tumor marker with approximately 73% experiencing greater than 37% reduction.

A copy of the poster will be available after the presentation on the [Posters and Presentations](#) section of the company's website.

About iopofosine I-131

Iopofosine is a small-molecule Phospholipid Drug Conjugate™ designed to provide targeted delivery of iodine-131 (radioisotope) directly to cancer cells, while limiting exposure to healthy cells. We believe this profile differentiates iopofosine from many traditional on-market treatments. Iopofosine is currently being evaluated in the CLOVER-WaM Phase 2 pivotal study in patients with relapsed/refractory (r/r) Waldenstrom's macroglobulinemia (WM), a Phase 2b study in r/r multiple myeloma (MM) patients and the CLOVER-2 Phase 1 study for a variety of pediatric cancers. The U.S. Food and Drug Administration granted iopofosine Fast Track Designation for WM patients having received two or more prior treatment regimens, as well as r/r MM and r/r diffuse large B-cell lymphoma (DLBCL). Orphan Drug Designations (ODDs) have been granted for WM, MM, neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. Iopofosine was also granted Rare Pediatric Disease Designation (RPDD) for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. The European Commission granted an ODDs for r/r MM and WM.

About Cellerar Biosciences, Inc.

Cellerar Biosciences is focused on the discovery and development of drugs for the treatment of cancer. The company is developing proprietary drugs independently and through research and development collaborations. The company's core objective is to leverage its proprietary Phospholipid Drug Conjugate™ (PDC) delivery platform to develop PDCs that specifically target cancer cells, delivering improved efficacy and better safety as a result of fewer off-target effects. The company's PDC platform possesses the potential for the discovery and development of the next-generation of cancer-targeting treatments, and it plans to develop PDCs independently and through research and development collaborations.

The company's product pipeline includes iopofosine, a small-molecule PDC designed to provide targeted delivery of iodine-131 (radioisotope), and proprietary preclinical PDC chemotherapeutic programs and multiple partnered PDC assets. The company is currently investigating iopofosine in a global, pivotal expansion cohort in relapsed or refractory WM patients who have received at least two prior lines of therapy, including those who have failed or had a suboptimal response to Bruton tyrosine kinase inhibitors. The WM cohort will enroll up to 50 patients to evaluate the efficacy and safety of iopofosine for marketing approval. The company is also evaluating iopofosine in highly refractory multiple myeloma patients in its Phase 2 CLOVER-1 study and relapsed/refractory pediatric cancer patients with sarcomas or brain tumors in the Phase 1 CLOVER-2 study.

The Phase 1 pediatric study is an open-label, sequential-group, dose-escalation study to evaluate the safety and tolerability of iopofosine in children and adolescents with relapsed or refractory cancers, including malignant brain tumors, neuroblastoma, sarcomas, and lymphomas (including Hodgkin's lymphoma). The Phase 1 study is being conducted internationally at seven leading pediatric cancer centers.

For more information, please visit www.cellectar.com and www.wmclinicaltrial.com or join the conversation by liking and following us on the company's social media channels: [Twitter](#), [LinkedIn](#), and [Facebook](#).

Forward-Looking Statement Disclaimer

This news release contains forward-looking statements. You can identify these statements by our use of words such as "may," "expect," "believe," "anticipate," "intend," "could," "estimate," "continue," "plans," or their negatives or cognates. These statements are only estimates and predictions and are subject to known and unknown risks and uncertainties that may cause actual future experience and results to differ materially from the statements made. These statements are based on our current beliefs and expectations as to such future outcomes including our expectations of the impact of the COVID-19 pandemic. Drug discovery and development involve a high degree of risk. Factors that might cause such a material difference include, among others, uncertainties related to the ability to raise additional capital, uncertainties related to the disruptions at our sole source supplier of iopofosine, the ability to attract and retain partners for our technologies, the identification of lead compounds, the successful preclinical development thereof, patient enrollment and the completion of clinical studies, the FDA review process and other government regulation, our ability to maintain orphan drug designation in the United States for iopofosine, the volatile market for priority review vouchers, our pharmaceutical collaborators' ability to successfully develop and commercialize drug candidates, competition from other pharmaceutical companies, product pricing and third-party reimbursement. A complete description of risks and uncertainties related to our business is contained in our periodic reports filed with the Securities and Exchange Commission including our Form 10-K for the year ended December 31, 2020, and our Form 10-Q for the quarter ended September 30, 2021. These forward-looking statements are made only as of the date hereof, and we disclaim any obligation to update any such forward-looking statements.

Contacts

Investors:

Monique Kosse
Managing Director
LifeSci Advisors
212-915-3820
monique@lifesciadvisors.com



Source: Cellectar Biosciences