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Cellectar Biosciences Announces CLR 131 Achieves Primary Efficacy Endpoints from Its Phase 2 CLOVER-1 Study in Relapsed/Refractory B-cell Lymphomas and Completion of the Phase 1 Relapsed/Refractory Multiple Myeloma Dose Escalation Study

42.8% ORR in multiple myeloma at the 75mCi total body dose

42.0% ORR and 11% CRR in all non-Hodgkin's lymphoma (NHL) patients

100% ORR seen in Lymphoplasmacytic Lymphoma/Waldenstrom's Macroglobulinemia (LPL/WM) patients

76.7% of the multiple myeloma patients across all doses tested experienced tumor reduction with a strong dose response

FLORHAM PARK, N.J., Feb. 19, 2020 (GLOBE NEWSWIRE) -- Cellectar Biosciences, Inc. (NASDAQ: CLRB), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of drugs for the treatment of cancer, today announced positive data from its Phase 2 CLOVER-1 study in patients with relapsed/refractory B-cell lymphomas. Additionally, the company announced the successful completion of its Phase 1 dose escalation study. Data from the studies demonstrated activity in all indications tested: multiple myeloma (MM), diffuse large B-cell lymphoma (DLBCL), chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), marginal zone lymphoma (MZL), mantle cell lymphoma (MCL), and lymphoplasmacytic lymphoma/Waldenstrom's macroglobulinemia (LPL/WM).

CLR 131 achieved notable response rates in patients with multiple myeloma - 34.5% overall response rate (ORR) over all therapeutic doses (n=33), and non-Hodgkin's lymphoma (NHL) - 42% ORR over all doses (n=20) while maintaining a well-tolerated safety profile across all patients. Based upon these positive results and corroborating data showing the potential to further improve upon current overall response rates and durability of those responses, the study has been expanded to test a two-cycle dosing optimization regimen of CLR 131.

Patients in the studies were heavily pre-treated, with multiple myeloma patients having a median of five prior treatment regimens (range: 3 to 17), which included immunomodulatory drugs, proteasome inhibitors and CD38 antibodies for the majority of patients. Additionally, a

majority of the patients (51%) were quad refractory or greater and 44% of all treated multiple myeloma patients were triple class refractory. NHL patients in the study were also heavily pre-treated, having had a median of 3 prior lines of treatment (range, 1 to 9) with the majority of patients being refractory to rituximab and/or ibrutinib. In both groups, the patients had a median age of 70 with a range of 51 to 86.

Relapsed/refractory multiple myeloma patients were treated with three different doses (<50mCi, ~50mCi and ~75mCi total body dose (TBD)); the <50mCi total body dose was a deliberately planned sub-therapeutic dose. Patients who received the highest dose of CLR 131 showed a 42.8% ORR, and those who received ~50mCi TBD had a 26.3% ORR with 100% of all evaluable patients (n=43) achieving clinical benefit (primary outcome measure) as defined by having stable disease or better. 85.7% of multiple myeloma patients receiving the higher total body dose levels of CLR 131 experienced tumor reduction. The 75mCi TBD demonstrated positive activity in both high-risk patients and triple class refractory patients with a 50% and 33% ORR, respectively.

“The data reported today are very promising and we believe the product profile for CLR 131 can improve further with the administration of a second cycle. These results are even more impressive considering the challenging patient population tested, as all were heavily pre-treated with the vast majority being refractory to their most recent therapy,” said James Caruso, president and CEO of Cellectar Biosciences. “Based upon these compelling data and the need for new and innovative treatment options for patients, we plan to execute upon a well-defined and approvable regulatory path forward in a prioritized hematologic indication. We hope that this potentially first-in-class PLE-targeted radiotherapeutic will provide a new and meaningful treatment option for patients living with multiple myeloma and/or NHL.”

The most frequently reported adverse events in relapsed/refractory multiple myeloma patients were cytopenias, which followed a predictable course and timeline. The most common grade ≥3 events at the highest dose (75mCi TBD) were hematologic toxicities including thrombocytopenia (65%), neutropenia (41%), leukopenia (30%), anemia (24%) and lymphopenia (35%). No patients experienced cardiotoxicities, neurological toxicities, infusion site reactions, peripheral neuropathy, allergic reactions, cytokine release syndrome, keratopathy, renal toxicities, or changes in liver enzymes. The safety and tolerability profile in patients with relapsed/refractory NHL was the same except for fewer cytopenias of any grade.

In addition to these findings, subtype assessments were completed in the r/r B-cell NHL patients. Patients with DLBCL demonstrated a 30% response rate with one patient achieving a complete response (CR), which continues at nearly 24 months post-treatment. The response rate for CLL/SLL/MZL patients was 33%. Only two mantle cell patients were enrolled, with stable disease as the best response.

Current data from the company’s Phase 2 CLOVER-1 clinical study show that four LPL/WM patients demonstrated 100% ORR with one patient achieving a complete response which continues at nearly 27 months. This may represent an important improvement in the treatment of relapsed/refractory LPL/WM as no approved or late-stage development treatments for second- and third-line patients have reported a complete response. LPL/WM is a rare, indolent and incurable form of non-Hodgkin’s lymphoma that is comprised of a niche patient population in need of new and better treatment options.

“For patients who have failed the current standard of care treatments for any of these indications, there is a need for additional treatment options,” said lead study investigator Sikander Ailawadhi, M.D., Division of Hematology/Oncology, Department of Internal Medicine, Mayo Clinic, Jacksonville, Florida. He added, “These data are impressive, especially in these very difficult to treat patient populations. CLR 131 offers a very attractive safety and efficacy profile.”

Summary of Results by Total Body Dose

	50mCi Total Body Dose	75mCi Total Body Dose
	ORR (# of Patients)	ORR (# of Patients)
Multiple Myeloma (MM)	26.3% (19)	42.8% (14)
Non-Hodgkin’s Lymphoma (NHL)	42.0% (12)	43.0% (7)
Lymphoplasmacytic Lymphoma/ Waldenstrom’s Macroglobulinemia (LPL/WM)	100% (2)	100% (2)

Conference Call Details

The management team will host a conference call for investors today, Wednesday, February 19 at 10:30 am Eastern Time to review the results and data from both the Phase 2 CLOVER-1 study and the Phase 1 r/r MM dose escalation study. The call will also include a presentation from lead investigator, Dr. Sikander Ailawadhi, M.D. Conference call, webcast and post-conference call replay details are as follows:

Domestic dial-in:	877-705-6003
International dial-in:	201-493-6725
Conference ID:	13697717
Webcast:	http://bit.ly/2uNAGWY

A webcast replay of the event will be available following the live event on theEvents section of the Cellectar website.

About the Phase 2 CLOVER-1 Study

CLOVER-1 is a Phase 2 study of CLR 131 being conducted in approximately 10 leading cancer centers in the United States in patients with relapsed/refractory B-cell hematologic cancers. The hematologic cancers being studied include multiple myeloma (MM), chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), lymphoplasmacytic lymphoma/ Waldenstrom’s macroglobulinemia (LPL/WM), marginal zone lymphoma (MZL), mantle cell lymphoma (MCL), and diffuse large B-cell lymphoma (DLBCL).

The study could enroll up to 80 patients with its primary endpoint being clinical benefit response (CBR), which is defined as the proportion of MM patients within three months following the initial infusion of CLR 131 with stringent complete response, complete response, very good partial response, partial response and stable disease per International Myeloma Working Group criteria, or the proportion of lymphomas patients (CLL/SLL, LPL, MZL, MCL, and DLBCL) within three months following the initial infusion of CLR 131 with CR, PR and SD per the Lugano classification CT-based response criteria. Additional endpoints include overall response rate (ORR), progression free survival (PFS), median overall survival (OS) and other markers of efficacy. Patients were treated with three different doses (<50mCi, ~50mCi and ~75mCi total body dose) administered in either a single 30-minute infusion or two 30-minute infusions at day 1 and day 7 (± 1), with the option for a

second dose cycle approximately 75-180 days later.

Based upon positive results and corroborating data showing the potential to further improve upon the current overall response rates and durability of those responses, the study has been expanded to test a two-cycle dosing optimization regimen of CLR 131. Patients will be administered a two-cycle regimen with a total of four infusions, to be administered on day 1 and day 15 (± 1) and again on day 57 and day 71 (± 1).

Cellectar was awarded approximately $2 million in non-dilutive grant funding from the National Cancer Institute to help fund the study. More information about the study, including eligibility requirements, can be found at www.clinicaltrials.gov, reference NCT02952508.

About the Phase 1 r/r MM Dose Escalation Study

The Phase 1 multicenter, open-label, dose-escalation study is designed to evaluate the safety and tolerability of CLR 131 administered as a 30-minute I.V. infusion, either as a single bolus dose or as two fractionated doses. The r/r multiple myeloma patients in this study received doses ranging from ≤25mCi to ~75mCi total body dose. To date, an independent Data Monitoring Committee determined that all doses have been safe and well-tolerated by patients.

About CLR 131

CLR 131 is a small-molecule Phospholipid Drug Conjugate™ designed to provide targeted delivery of iodine-131 directly to cancer cells, while limiting exposure to healthy cells unlike many traditional on-market treatment options. CLR 131 is the company's lead product candidate and is currently being evaluated in a Phase 2 study in B-cell lymphomas, and two Phase 1 dose-escalating clinical studies, one in multiple myeloma and one in pediatric solid tumors and lymphoma. The FDA granted CLR 131 Fast Track Designation for both r/r multiple myeloma and r/r DLBCL and Orphan Drug designation (ODD) for the treatment of multiple myeloma, lymphoplasmacytic lymphoma/Waldenstrom's macroglobulinemia, neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. CLR 131 was also granted Rare Pediatric Disease designations for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. Most recently, the European Commission granted an ODD for r/r multiple myeloma.

About Cellectar Biosciences, Inc.

Cellectar Biosciences is focused on the discovery, development and commercialization 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 lead PDC therapeutic, CLR 131, is currently in three clinical studies - one Phase 2 study, and two Phase 1 studies. The Phase 2 clinical study (CLOVER-1) is in relapsed/refractory (r/r) B-cell malignancies, including multiple myeloma (MM), chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), lymphoplasmacytic

lymphoma/Waldenstrom's macroglobulinemia (LPL/WM), marginal zone lymphoma (MZL), mantle cell lymphoma (MCL), and diffuse large B-cell lymphoma (DLBCL). The company is also conducting a Phase 1 dose escalation study in patients with r/r multiple myeloma and a Phase 1 study in pediatric solid tumors and lymphomas.

The company's product pipeline also includes one preclinical PDC chemotherapeutic program (CLR 1900) and several partnered PDC assets.

For more information, please visit www.cellectar.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. 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 CLR 131, the ability to attract and retain partners for our technologies, the identification of lead compounds, the successful preclinical development thereof, 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 CLR 131, 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, 2018 and Form 10-Q for the quarters ended March 31, 2019, June 30, 2019 and September 30, 2019. These forward-looking statements are made only as of the date hereof, and we disclaim any obligation to update any such forward-looking statements.

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