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Cellectar Biosciences Reports High Rate of Complete Remission in Investigator Initiated Phase I Study of Iopofosine in Combination with External Beam Radiotherapy in Recurrent Head and Neck Cancer

- **Complete Remission rate of 64% and Overall Response Rate of 73% demonstrated in highly refractory patients**
- **Durability of clinical activity achieved 67% Overall Survival and 42% Progression Free Survival at One Year**

FLORHAM PARK, N.J., March 04, 2024 (GLOBE NEWSWIRE) -- Cellectar Biosciences, Inc. (NASDAQ: CLRB), a late-stage clinical biopharmaceutical company focused on the discovery, development, and commercialization of drugs for the treatment of cancer, today announced that iopofosine I 131 in combination with external beam radiation therapy (EBRT) was safe and tolerated in a SPORE Grant supported investigator-initiated Phase 1 clinical trial.

The twelve patients treated for locoregionally recurrent head and neck squamous cell carcinoma previously received chemoradiation alone (42%), surgery (58%) or surgery combined with radiation or chemoradiation (92%). The data were presented in a poster at the 2024 Multidisciplinary Head and Neck Cancers Symposium held February 29-March 2, 2024, in Phoenix, AZ. (Click HERE for poster.)

Complete remission was achieved in 64% of patients, with an ORR of 73% (n=11). Prior to treatment with iopofosine I 131, six patients had multiple recurrence and one had metastatic disease both of which are indicative of poor outcomes. Additionally, the study demonstrated durability of tumor control with an overall survival of 67% and progression free survival of 42% at 12 months.

“The study results underscore an important quality of iopofosine to safely combine with external beam radiotherapy and enhance therapeutic effect without significantly increasing toxicity of treatment,” commented Andrei Shustov, SVP Medical. “The durability of responses demonstrated by impressive progression free and overall survival in this patient population suggests that the combination of iopofosine and EBRT may target the primary tumor as well as micrometastatic disease beyond the conventional radiation field. This might result in synergistic therapeutic benefit applicable to a variety of solid tumors.”

The patients received two therapeutic doses of iopofosine I 131 at a fixed fractionated dose of 15.6 mCi/m2 (days 1 and 8) with SPECT/CT imaging performed to quantitate the biodistribution of iopofosine I 131. Patients subsequently received EBRT to complete the designated radiation dose outlined in the reirradiation plan, which was 60-70 Gray.

“In addition to positive data previously reported in hematologic malignancies including recent results from our pivotal CLOVER WaM study in Waldenstrom’s macroglobulinemia, these data further demonstrate iopofosine’s broad clinical activity in solid tumors,” said James Caruso, president and CEO. “We are clearly pleased with these results which remain consistent with prior reported data demonstrating deep and durable responses with iopofosine treatment, including complete remissions, in a wide spectrum of malignancies.”

Overall, eleven patients (92%) experienced a treatment-related adverse event. The most common treatment-related adverse events of any grade were thrombocytopenia (92%), lymphopenia (75%), neutropenia (75%), and anemia (92%). Observed adverse events were consistent with the known toxicity profile of iopofosine I 131, with cytopenias being the most common with all patients recovering.

About Recurrent Head and Neck Cancer
Squamous cell carcinoma of the head and neck (SCCHN) represents the sixth most common malignancy worldwide and its mean incidence rate is about 20 per 100,000 people or almost 67,000 newly diagnosed cases each year. About 50% of these patients will experience a recurrence of disease. Patients with recurrent SCCHN have a median overall survival of approximately 12 months.

About Cellectar Biosciences, Inc.
Cellectar Biosciences is a late-stage clinical biopharmaceutical company focused on the discovery and development of proprietary drugs for the treatment of cancer, 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 the next-generation of cancer cell-targeting treatments, delivering improved efficacy and better safety as a result of fewer off-target effects.

The company’s product pipeline includes lead asset iopofosine I 131, a small-molecule PDC designed to provide targeted delivery of iodine-131 (radioisotope), proprietary preclinical PDC chemotherapeutic programs and multiple partnered PDC assets.

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 regarding the WM CLOVER-WaM pivotal trial. 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, 2022, and our Form 10-Q for the quarter ended September 30, 2023. 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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