January 16, 2024

Cellectar Biosciences Broadens Pipeline with Targeted Alpha Therapy (TAT) for Solid Tumors and Releases Promising Preclinical Data

Proprietary TAT Phospholipid Conjugate Demonstrates Potent Activity in Resistant Pancreatic Cancer

Initiating IND-enabling Studies for First-in-Human Phase I Clinical Study

FLORHAM PARK, N.J., Jan. 16, 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 promising preclinical data for its proprietary novel alpha-emitting phospholipid radiotherapeutic conjugate, CLR 121225 (^{225}Ac-CLR 121225) an actinium-labeled phospholipid ether (PLE), in pancreatic cancer models. The development of this compound will expand the company's clinical pipeline of PLE cancer targeting compounds to include targeted alpha therapies (TATs), complementing its beta-emitting phospholipid radiotherapeutic conjugate, iopofosine I 131, which achieved its primary endpoint in the CLOVER WaM pivotal study in highly refractory Waldenstrom's macroglobulinemia patients.

Cellectar's PLE platform may provide unique advantages which overcome the issues experienced by existing TAT delivery platforms. While current TAT platforms, such as antibodies and peptides, possess the potential to be effective for treating cancers with low tumor volume, they are challenged to treat higher volume or bulky tumors due to insufficient penetration and the need for high quantities of the target epitope. Cellectar's PLE's possess biochemical properties that enable penetration of the TAT payload deep into the tumor mass and the abundance of lipid rafts on tumor cells provides near universal delivery and enhanced outcomes.

"The advancement of our TAT program is part of our overall strategy to develop a comprehensive portfolio of first- and best-in-class radiotherapeutics designed to treat both blood cancers and solid tumors that now includes both alpha and beta-emitting radiotherapeutics," commented James Caruso, president and CEO of Cellectar. "Our promising preclinical data with actinium-225 highlights the potential utility of our PLE platform to provide targeted delivery to nearly any isotope resulting in compounds with excellent activity and tolerability. Our novel TAT compounds, including actinium-225, lead-212 and others, have demonstrated this potential in pancreatic cancer, triple-negative breast cancer and other types of tumor models which allows us to deliver the optimal radioisotope based on tumor biology to maximize outcomes. These data provide further evidence supporting the continued development of CLR 121225, which is expected to enter a Phase 1 first-in-human study later this year or early next year."

In preclinical studies, CLR 121225 demonstrated potent anti-tumor activity in refractory pancreatic cancer mouse xenograft models. A single administration at each dose level (100nCi, 250nCi and 500nCi) resulted in tumor volume reduction in a dose dependent manner with the highest dose providing near complete eradication of the tumor. Additionally, it was shown that CLR 121225 demonstrated excellent biodistribution; approximately 15 – 20% of the infused drug accumulated in the tumor within four hours and continued to accumulate over 72 – 96 hours. The mice had no end organ toxicities demonstrating good tolerability. The data are consistent with experiments using other alpha emitters conjugated to the company's proprietary PLE targeted delivery platform.

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 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.

Contacts

MEDIA:
Claire LaCagnina
Bliss Bio Health
315-765-1462
clacagnina@blissbiohealth.com

INVESTORS:
Chad Kolean
Chief Financial Officer
investors@cellectar.com

Source: Cellectar Biosciences