September 18, 2023

Cellectar Biosciences Receives European Medicines Agency Priority Medicines (PRIME) Designation for Iopofosine for Waldenstrom's Macroglobulinemia

The EMA's PRIME status is granted to drug candidates that may offer a major therapeutic advantage over existing treatments, or benefit patients without treatment options

FLORHAM PARK, N.J., Sept. 18, 2023 (GLOBE NEWSWIRE) -- Cellectar 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, today announced that the European Medicines Agency (EMA) has granted Priority Medicines (PRIME) designation to iopofosine I 131, the company's lead small-molecule drug candidate, for Waldenstrom's macroglobulinemia (WM) in patients who have received two or more prior treatment regimens.

The PRIME program aims to optimize development plans and speed up evaluation of medicines that may offer a major therapeutic advantage over existing treatments or benefit patients without treatment options. These medicines are considered priority medicines by the EMA and are intended to reach patients earlier. To be accepted for PRIME, new therapies must demonstrate the potential to significantly address an unmet medical need in clinical trials.

"PRIME designation from the EMA further underscores our confidence in iopofosine I 131 to provide a differentiated and highly needed new treatment option for patients with WM," said James Caruso, president and CEO of Cellectar. "We expect to release top-line data from the CLOVER-WaM pivotal trial in the fourth quarter of 2023 and submit our NDA in March, 2024. With PRIME designation now in hand we look forward to advancing our EU strategy to bring this potential targeted treatment option to patients in the US and EU as quickly as possible."

The U.S. Food and Drug Administration (FDA) has granted Cellectar's lead asset iopofosine I 131, a small-molecule Phospholipid Drug Conjugate™ (PDC) designed to provide targeted delivery of iodine-131 (radioisotope), Fast Track Designation for WM patients having received two or more prior treatment regimens, as well as relapsed (or refractory) multiple myeloma and relapsed (or refractory) diffuse large B-cell lymphoma (DLBCL). The company expects to complete our ongoing Phase 2b WM pivotal trial (NCT02952508) in the second half of 2023 and assuming an FDA Priority Review and approval, remains on target for a 2024 US product launch.

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, 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 June 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

Investors:
Monique Kosse
LifeSci Advisors
212-915-3820
monique@lifesciadvisors.com

Media:
Claire LaCagnina
Bliss Bio Health

315-765-1462
clacagnina@blissbiohealth.com

Source: Cellectar Biosciences