Galecto Completes Strategic Review to Focus on Oncology and Liver Disease and Acquires Acute Myeloid Leukemia Preclinical Asset from Bridge Medicines

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- *Galecto will focus on cancer and liver disease, leveraging existing clinical stage asset GB1211*
- *Bolsters pipeline by obtaining global rights to BRM-1420, a novel dual ENL-YEATS and FLT3 inhibitor for multiple genetic subsets of acute myeloid leukemia (AML)*
- *BRM-1420 has the potential for enhanced clinical effectiveness compared to FLT3 inhibitors alone and has shown synergistic effects with SOC in preclinical models*

BOSTON, Oct. 07, 2024 (GLOBE NEWSWIRE) -- Galecto, Inc. (NASDAQ: GLTO), a clinical-stage biotechnology company focused on the development of novel treatments for cancer and fibrosis, today announced that, following an intensive strategic review process, Galecto has determined to focus on cancer and liver disease, leveraging its existing clinical stage asset GB1211, which has shown positive results in non-small cell lung cancer (NSCLC) and decompensated cirrhosis clinical studies. Galecto further announced that it has bolstered its pipeline with the acquisition of the global rights to BRM-1420, a novel, first-in-class asset developed by Bridge Medicines, a company co-founded by Takeda.

“Our strategic review process concluded that our best opportunity for building value and changing the lives for patients with severe diseases was to focus on our existing clinical stage compound GB1211 and increase our chance for success by acquiring complementary assets. The addition of BRM-1420 represents a significant advancement in our mission to develop and deliver breakthrough treatments for oncology and liver conditions,” said Dr. Hans Schambye, CEO of Galecto. “We are particularly optimistic about BRM-1420's potential to address challenging genetic subsets of AML and its observed synergistic effects with standard-of-care therapies and menin inhibitors.”

“AML is the most common acute leukemia in adults, yet despite available treatments, patient prognosis remains poor with significant unmet needs,” said Miles Gerson, Head of Takeda Ventures and Takeda’s Representative to Bridge Medicines. “Bridge Medicines has made considerable progress in recent years developing this new class of drugs and Galecto’s team is well positioned to continue advancing BRM-1420.”

As consideration for the acquisition of the global rights of BRM-1420, Galecto issued 62,594 shares of common stock to Bridge Medicines, representing 4.99% of the outstanding shares of Galecto’s common stock as of the date of the asset purchase, and 160.562 shares of a newly-issued Series A preferred stock convertible into 160,562 shares of common stock, or approximately 12.8% of Galecto’s common stock, upon receipt of stockholder approval.

Matthew Kronmiller, Bridge Medicine’s Chief Executive Officer, will be joining Galecto’s management team as the Executive Vice President of Strategy and Chief Business Officer. The transaction was approved by the Boards of Directors of both companies.

Leerink Partners served as the exclusive financial advisor to Galecto and Lazard served as exclusive financial advisor to Bridge Medicines. Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. is serving as legal counsel to Galecto. Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP is serving as legal counsel to Bridge Medicines.

About BRM-1420
BRM-1420 is a potent and selective ENL-YEATS and FLT3 inhibitor of multiple genetic subsets of AML. It disrupts key oncogenic pathways by inhibiting these domains, showing potent activity in MLLr and NPM1c cell lines. Promising preclinical and *in vivo* results highlight its efficacy in inhibiting leukemia cell growth and extending survival in AML models. In animal models, BRM-1420 exhibited superior efficacy to both FLT3 and menin inhibitors and was shown to inhibit cell proliferation in primary AML patient samples across multiple genotypes, including MLL-r, NPM1m, cKIT+, FLT3+, TET2+, and TP53+. These mutations are often seen in AML and, in total, could account for greater than 30% of the AML patient population. Many of these mutations have proven difficult to treat with currently available regimens and therefore represent a significant unmet medical need. The Company believes, based on preclinical data, that BRM-1420 could be additive or synergistic when used in combination with the current standard of care (azacitidine, venetoclax, cytarabine, gilteritinib), as well as current therapies under development, such as menin inhibitors.

Galecto plans to file an IND for BRM-1420 in the US in late 2025 or early 2026 and initiate clinical studies in patients with AML thereafter. Exclusive global rights to the program were assigned by Bridge Medicines to Galecto through a license with The Rockefeller University. The pioneering discoveries were a result of collaboration between the Rockefeller University and the Tri-Institutional Therapeutics Discovery Institute (Tri-I TDI), followed by licensing by Bridge Medicines.

About Galecto’s Pipeline
Galecto continues to develop GB1211, its first-in-class, oral small molecule, galectin-3 inhibitor for the treatment of oncology and severe liver cirrhosis. GB1211 is currently being studied in an investigator-initiated Phase 2 trial at Providence Portland Medical Center’s Earle A. Chiles Research Institute (EACRI). GB1211 is being administered in combination with the standard therapeutic dose of pembrolizumab (Keytruda®) in patients with unresectable or metastatic melanoma or recurrent or metastatic HNSCC progressing during or after platinum-containing chemotherapy. This trial is designed to evaluate the safety and efficacy of GB1211 in combination with pembrolizumab and determine whether the addition of GB1211 increases the response rate of pembrolizumab in metastatic melanoma and HNSCC patients. This trial was initiated and enrolled its first patient in the second quarter of 2024.

In addition, during the second half of 2023, Galecto concluded its Phase 1b/2a trial examining GB1211 in combination with atezolizumab, a PD-L1 checkpoint inhibitor, for the treatment of first-line non-small cell lung cancer (NSCLC). Four patients in this trial showed a partial response according to RECIST criteria (version 1.1), and two of these four patients continue to receive treatment in the extension phase of the trial.

As part of the strategic alternative review process, Galecto has determined not to further advance GB2064, its LOXL-2 inhibitor candidate, at this time.

About Galecto
Galecto is a clinical-stage biopharmaceutical company committed to realizing the promise of novel treatments for cancer and liver diseases. The Company's pipeline consists of first-in-class small molecule drug candidates that target cancer and fibrosis signaling pathways, including (i) an orally active galectin-3 inhibitor (GB1211) for the treatment of liver cirrhosis; (ii) an orally active galectin-3 inhibitor (GB1211) in combination with a checkpoint inhibitor for various oncology indications; and (iii) a preclinical dual inhibitor of ENL-YEATS and FLT3 (BRM-1420) for multiple genetic subsets of AML. Galecto intends to use its website as a means of disclosing material non-public information. For regular updates about Galecto, visit www.galecto.com.

Forward-Looking Statements
Certain statements in this press release are forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements include statements about Galecto's preclinical and clinical development plans for BRM-1420; BRM-1420's potential to address challenging genetic subsets of AML and its observed synergistic effects with standard-of-care therapies and menin inhibitors; that BRM-1420 has the potential to transform the treatment of AML; that the MLL-r, NPM1m, cKIT+, FLT3+, TET2+, and TP53+ mutations could account for greater than 30% of the AML patient population; and that BRM-1420 could be additive or synergistic when used in combination with current standard of care as well as current therapies under development. Such forward-looking statements include statements about Galecto's focus and plans for preclinical and clinical development of its product candidates and pipeline. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. For such statements, Galecto claims the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from Galecto's expectations. Factors that could cause actual results to differ materially from the forward-looking statements include risks and uncertainties related to the development of Galecto's product candidates and their therapeutic potential, having adequate funds and their use, and those disclosed in Galecto's filings with the Securities and Exchange Commission (SEC), including, but not limited to, Galecto's Annual Report on Form 10-K, as filed with the SEC on March 8, 2024. These forward-looking statements represent Galecto's judgment as of the time of this release. Galecto disclaims any intent or obligation to update these forward-looking statements, other than as may be required under applicable law.

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