Galecto Announces First Patient Treated in Phase 2a Trial of the Oral LOXL2 Inhibitor GB2064 in Myelofibrosis (the MYLOX-1 Trial)

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BOSTON, Aug. 18, 2021 (GLOBE NEWSWIRE) -- Galecto, Inc. (NASDAQ: GLTO), a biotechnology company focused on the development of novel treatments for fibrosis and cancer, today announced the treatment of the first patient in a Phase 2a trial of its oral LOXL2 inhibitor GB2064 in myelofibrosis. Myelofibrosis, a form of chronic leukemia, is a rare type of blood cancer in which the normal bone marrow is destroyed by fibrous scar tissue that does not produce blood cells.

The open label MYLOX-1 trial is designed to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of orally administered GB2064 in 16 patients over 9 months. The trial will also assess impact on fibrosis and quantification of the tissue targeting of GB2064, as well as other aspects of clinical response in myelofibrosis.

“We are very pleased to start this Phase 2a trial with GB2064 in myelofibrosis, which marks a further important milestone in the development of Galecto’s exciting clinical pipeline. There is a significant unmet need in myelofibrosis, with very few therapeutic alternatives. Fibrosis in the tumor micro-environment remains unaddressed and LOXL2 inhibition could be disease modifying,” said Dr. Hans Schambye, CEO of Galecto.

The current standard of care for myelofibrosis is JAK inhibitors, but questions remain regarding side effects caused by the mechanism of action. LOXL-2 is an attractive target, as it is upregulated in myelofibrosis fibrotic tissue and plays a key role in fibrosis and disease progression in the tumor micro-environment. Focused inhibition of LOXL-2 is believed to be inherently safer than pan-inhibition of all LOX enzymes because some of the iso-enzymes potentially carry important liabilities. Galecto successfully completed the Phase 1 SAD/MAD study of GB2064 in healthy volunteers without observing any safety issues.

Professor Srdan Verstovsek, MD, PhD of the University of Texas MD Anderson Cancer Center, and the principal investigator of the MYLOX-1 trial, added: “I have long been excited about the prospect of LOXL2 inhibitors in myelofibrosis, and with GB2064 we have a novel and elegant method of inhibiting the enzyme which plays a key fibrotic role. There are a significant number of patients who are in desperate need of novel treatment options and I look forward to further investigating the potential of GB2064 to address this.”

About Galecto
Galecto is a clinical stage biotechnology company incorporated in the U.S. that is developing small molecule-based galectin inhibitors and the collagen cross-linking enzyme, LOXL2, inhibitors. Galecto has multiple clinical programs in fibrosis and cancer focused on galectin-3 and LOXL2, including an inhaled galectin-3 modulator (GB0139) currently in a phase 2b trial for the potential treatment of idiopathic pulmonary fibrosis. The company’s pipeline also includes an orally active galectin-3 inhibitor (GB1211) that is expected to be part of (i) a phase 2 trial for the potential treatment of NSCLC in combination with an anti-PD1/-L1 product and (ii) a phase 1b/2 trial in liver cirrhosis, as well as an orally active LOXL2 inhibitor (GB2064) that is expected to part of a phase 2 trial (the MYLOX-1 trial) for the potential treatment of myelofibrosis.

Galecto intends to use its website as a means of disclosing material non-public information. For regular updates about Galecto, visit www.galecto.com.

The MYLOX-1 Trial
The MYLOX-1 trial is an open label trial focusing on safety in patients who are intolerant to or ineligible for JAK1 inhibitor therapy. The trial will include safety measures as per the state of the art MRI for spleen size and bone marrow sampling for measurement of fibrosis and of drug presence.

https://www.clinicaltrials.gov/ct2/show/NCT04679870

About GB2064
GB2064 is a pseudo-irreversible inhibitor of the LOXL2 enzyme, which means that high plasma concentrations will cancel the enzyme for a disproportionately longer time than the presence of the drug in plasma. This may mean that the risk of potential side effects due to drug remaining in the system could be avoided. GB2064 has been tested in healthy volunteers without finding dose limiting or dose-related tolerability issues.

About LOXL2
LOXL2 is an extracellular enzyme, which carries out cross-linking of collagen and elastin fibrils and thus contributes to building and strengthening of the fibrous matrix that is exaggerated in fibrotic disease.

About Myelofibrosis
Myelofibrosis is a blood cancer where the normal bone marrow loses its ability to produce life preserving blood cells like erythrocytes, platelets and white blood cells. The bone marrow is destroyed by fibrotic tissue and hence the name Myelofibrosis (myelo- means marrow). Bone marrow transplantation may be possible, but these patients are older and the risks of non-success is high. Therefore, medicines which can help patients to become transfusion free and live longer are needed.

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 the planned design of the MYLOX-1 trial, the future myelofibrosis market and Galecto’s focus, plans for clinical development, 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 its most recent Annual Report on Form 10-K filed with the SEC on March 29, 2021. 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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