Lion Biotechnologies Opens Enrollment in Phase 2 Study of LN-144 for the Treatment of Refractory Metastatic Melanoma

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NEW YORK, Sept. 14, 2015 (GLOBE NEWSWIRE) -- Lion Biotechnologies, Inc. (Nasdaq:LBIO) a biotechnology company that is developing novel cancer immunotherapies based on tumor-infiltrating lymphocytes (TIL), today announced that it has opened enrollment in a Phase 2 clinical trial of its lead product candidate, LN-144, for the treatment of refractory metastatic melanoma.

The single-arm study is expected to enroll approximately 20 evaluable patients with metastatic melanoma whose disease has progressed following treatment with at least one systemic therapy. The trial will be conducted at up to five sites.

The purpose of the study is to evaluate the safety, efficacy and feasibility of autologous TIL infusion (LN-144). The trial's primary endpoints include safety, and feasibility of LN-144 production using Lion's central manufacturing process. Secondary outcome measures include an additional feasibility measure of number of patients successfully infused with LN-144 and best overall response rate.

LN-144 is an autologous cell therapy of tumor-infiltrating lymphocytes (TIL) derived from the patient's own tumor and is based on TIL therapy regimens developed at the National Cancer Institute (NCI). Following a lymphocyte-depleting preparative regimen, patients are treated with a single infusion of LN-144 followed by IL-2. In this study, patients will be evaluated for response 12 weeks after LN-144 infusion. Additionally, patients with stable disease and responders will be evaluated for progression-free survival (PFS), and overall survival (OS) for up to 24 months.

Elma Hawkins, PhD, Lion's president and chief executive officer, added, "We are encouraged by the consistently robust data from previous studies of TIL therapy in melanoma treatment at leading cancer centers. As we continue to evaluate the safety and efficacy of LN-144 in this study, we also look forward to assessing the feasibility of manufacturing TIL on a commercial scale, with the goal of ensuring that this promising therapy can be available for many patients who may benefit from it."

Manufacturing for LN-144 will take place at a central cGMP manufacturing facility according to established protocols that are similar to those in use at NCI. The company expects to present initial trial data in 2016 in a scientific forum. For more information on the study, please see ClinicalTrials.gov (Identifier: NCT02360579).

About Lion Biotechnologies

Lion Biotechnologies, Inc. is a clinical-stage biotechnology company focused on the development of cancer immunotherapy products for the treatment of various cancers. The company's lead product candidate is an adoptive cell therapy using tumor-infiltrating lymphocytes (TIL) for the treatment of patients with refractory metastatic melanoma, and is based on a clinical Cooperative Research and Development Agreement with the National Cancer Institute. TIL therapy is also being evaluated in physician-sponsored clinical trials at MD Anderson Cancer Center and Moffitt Cancer Center. For more information, please visit http://www.lionbio.com.

Forward Looking Statements

This press release contains certain forward-looking statements that are subject to a number of risks and uncertainties, including risks associated with the enrollment of patients, the conduct of the study, the results of the study, and the other risks described in the Company's most recently filed quarterly report on Form 10-Q and annual report on Form 10-K. Except as permitted by law, the Company undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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