Lion Biotechnologies Announces Allowance of IND Application to Begin New Phase 2 Study in Metastatic Melanoma

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LOS ANGELES, Feb. 2, 2015 (GLOBE NEWSWIRE) -- Lion Biotechnologies, Inc. (LBIO), a biotechnology company that is developing novel cancer immunotherapies based on tumor-infiltrating lymphocytes (TIL), today announced that the US Food and Drug Administration (FDA) has allowed its investigational new drug (IND) application to initiate a Phase 2 study of its lead product candidate, LN-144, in the treatment of refractory metastatic melanoma.

The single-arm clinical trial will be conducted at up to five sites in a total of 20 evaluable patients with stage 4 metastatic melanoma, who have previously progressed following systemic treatment. The objectives of the study are to assess safety, feasibility and anti-tumor activity, as well as various other indicators of efficacy.

"We are pleased to have received FDA clearance to begin a new Phase 2 study of LN-144 in patients with refractory metastatic melanoma, who urgently need new treatment options," said Elma Hawkins, PhD, Lion's president and chief executive officer. "In previous studies, TIL therapy has demonstrated impressive objective response rates, including in patients who had previously failed treatment with various biologic treatments. We look forward to further investigating the safety and efficacy of LN-144 in this new study."

About Lion Biotechnologies

Lion Biotechnologies, Inc. is engaged in the development of T cells and engineered T cells for the treatment of various cancers. The company's lead product candidate, LN-144, is a ready-to-infuse, autologous T-cell therapy utilizing tumor-infiltrating lymphocytes (TIL) for the treatment of patients with 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 the H. Lee Moffitt Cancer Center & Research Institute. 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 the risks relating to the Company's ability to conduct its Phase 2 clinical trial in metastatic melanoma, the timing and conduct of the trial, and to further successfully develop or commercialize the Company's TIL technologies. Additional risks and uncertainties are 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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