Calithera Biosciences Presents Data for CB-839 in Triple-Negative Breast Cancer Models at the 2013 San Antonio Breast Cancer Symposium

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For Immediate Release

Calithera Identifies Potential Biomarkers for Selecting Breast Cancer Tumors with High Sensitivity to CB-839 Glutaminase Inhibition

South San Francisco, CA; December 12, 2013 â€“ Calithera Biosciences, a biotechnology company focused on the development of novel cancer therapeutics, today announced the presentation of preclinical data for its lead anti-cancer therapeutic candidate, CB-839, at the 2013 San Antonio Breast Cancer Symposium. CB-839 is a potent, selective, orally available glutaminase inhibitor that interferes with tumor metabolism and blocks cancer cell growth and survival.

â€œTriple-negative breast cancer, which represents 10-20% of all breast cancers, can be aggressive and difficult to treat due to the fact that the current hormonal and HER-2 directed therapies do not work against these tumors. Recent data indicate that triple-negative tumor growth is driven in part by high glutaminase expression and a reliance on the conversion of glutamine into glutamate to provide fuel for growth. CB-839 demonstrates potent inhibition of glutaminase and significant anti-tumor activity in triple-negative breast cancer models, both as a single agent and in combination with the standard-of-care drug paclitaxel,â€ said Susan Molineaux, Ph.D., President and Chief Executive Officer of Calithera Biosciences. â€œThis research also highlights the potential for use of biomarkers to identify patients whose breast cancer is most likely to respond to CB-839 treatment. We look forward to advancing CB-839 into Phase 1 clinical studies in patients with advanced triple-negative breast cancer and other solid tumors early next year.â€

The anti-tumor activity of CB-839 was evaluated in a panel of breast tumor cell lines that included both triple-negative breast cancer and hormone receptor-positive subtypes. Triple-negative breast cancers displayed higher sensitivity to CB-839 treatment, and this sensitivity was correlated with high glutaminase expression relative to tumor cells that were estrogen receptor positive. In vitro treatment with CB-839 reduced cell viability and induced apoptosis in the majority of triple negative breast cancer cell lines. CB-839 treatment also resulted in significant anti-tumor activity in two triple-negative breast cancer xenograft models: as a single agent in a patient-derived tumor with a metabolite and expression profile suggestive of high glutamine utilization, and in a second cell line model in which CB-839 demonstrated robust anti-cancer activity both as a single agent and in combination with paclitaxel.

To verify biomarker indicators for CB-839 sensitivity, Calithera researchers studied the Cancer Genome Atlas mRNA expression dataset (n=756) of primary human breast cancers and confirmed a pattern of significantly increased markers of glutaminase in triple-negative breast cancers relative to hormone-receptor driven tumors. Similar observations were made at the metabolite level in 262 primary breast tumors, suggesting that biomarkers of glutamine utilization and high glutaminase expression may be useful in identifying patients most likely to benefit from CB-839.

Calithera presented these data today during the Tumor Cell and Molecular Biology session in a poster titled: Antitumor Activity of the Glutaminase Inhibitor, CB-839, in Triple-Negative Breast Cancer (# P2-09-03).

About Calithera Biosciences
Calithera is discovering and developing novel small molecule oncology therapeutics that inhibit pathways critical to tumor growth and survival. The Calithera team has the experience and the ability needed to discover novel therapeutics and advance these discoveries through clinical development. The company is applying this expertise to build a pipeline of anti-cancer compounds that are distinct from other oncology therapeutics. Calithera’s lead clinical candidate, CB-839, blocks glutaminase, an enzyme critical to tumor metabolism, and is poised to enter Phase 1 clinical testing. Calithera Biosciences is a privately held company located in South San Francisco, CA. For more information, please visit www.calithera.com.