

**Calistoga Pharmaceuticals' CAL-101, an Oral Delta Isoform-Selective PI3 Kinase Inhibitor, Demonstrates Clinical Benefit in Patients with Relapsed or Refractory Indolent Non-Hodgkin's Lymphoma, Mantle Cell Lymphoma and Chronic Lymphocytic Leukemia**

***Interim Results From Phase 1 Study Demonstrate Single Agent Activity***

***Preclinical Data Support Induction of Cell Death and Ability to Inhibit Signaling Pathways Associated with Cancer Cell Dependence on the Tumor Microenvironment***

***Results Presented at 51<sup>st</sup> American Society of Hematology (ASH) Annual Meeting***

**Seattle, WA, December 8, 2009** – Calistoga Pharmaceuticals, Inc., the leader in the development of isoform-selective phosphatidylinositol 3 kinase (PI3K) inhibitors for the treatment of cancer and inflammatory diseases, today announced updated clinical data on CAL-101, the Company's oral, delta selective PI3K inhibitor, presented during two oral presentations at the 51<sup>st</sup> American Society of Hematology Annual Meeting in New Orleans. Interim data from an ongoing Phase 1 study evaluating CAL-101 in patients with hematologic malignancies demonstrated impressive single agent activity. In patients with relapsed or refractory indolent non-Hodgkin's lymphoma (NHL), mantle cell lymphoma, and chronic lymphocytic leukemia (CLL), overall responses rates of 60 percent, 86 percent, and 24 percent were observed, respectively. Preclinical data demonstrated that the delta isoform of PI3K is overexpressed and frequently activated in B cell malignancies. Treatment with CAL-101 induced cell death and also inhibited signaling pathways associated with cancer cell dependence on the tumor microenvironment.

Results were presented from the ongoing Phase 1 study of CAL-101, which is enrolling patients with relapsed or refractory CLL, indolent and aggressive B-cell NHL, or acute myeloid leukemia. The data are an interim evaluation of 57 patients. Of the 15 evaluable indolent NHL patients, partial responses, defined as a decrease in tumor burden of greater than 50 percent, were observed in nine patients. In the cohort of aggressive NHL patients, partial responses were observed in six of seven mantle cell lymphoma patients. Partial responses were observed in four of 17 CLL patients; however, 14 of 16 (88 percent) CLL patients' enlarged lymph nodes decreased in size by more than 50 percent.

Approximately half of the patients enrolled in the trial were refractory to their last therapy prior to entering the study, and the median number of prior treatment regimens was 4.5. The duration of response with CAL-101 is not yet established, however the longest duration of response seen to date is 9 months in a patient with follicular lymphoma,

which is longer than the response to any of the 6 prior regimens this patient received, including autologous hematopoietic stem cell transplant.

Overall, CAL-101 was generally well tolerated. A low incidence of hematological toxicity was observed. As frequently occurs in this patient population, the most common serious adverse event was infection. The dose limiting toxicity in the study was elevation of liver transaminases, which was monitorable and reversible following discontinuation of dosing. Most patients resumed CAL-101 at a reduced dose.

“These results with CAL-101 are very encouraging, with clinical responses attained in previously treated NHL and CLL patients, and provides validation for the importance of the PI3K delta pathway,” said Ian W. Flinn, M.D., Ph.D., Director of Hematologic Malignancies Research at the Sarah Cannon Research Institute who presented the clinical results at ASH.

“We are continuing to evaluate CAL-101 in this ongoing Phase 1 clinical trial, but we are pleased with the clinical benefit we have observed thus far,” said Albert Yu, M.D., Chief Medical Officer of Calistoga Pharmaceuticals. “We plan to meet with regulatory authorities in the first half of next year to discuss possible paths forward and anticipate starting registration trials in mid-2010.”

Also presented at ASH were preclinical data highlighting the role of the delta isoform of PI3K in B cell malignancies and the preclinical activity of CAL-101. These results demonstrated that selective inhibition of delta PI3K with CAL-101 decreases proliferation and causes cell death in cell lines and primary patient leukemia and lymphoma cells. Further, stimulation of malignant B cells with chemokines associated with tumor cell-microenvironment signaling could be inhibited with CAL-101. These data support the role of delta PI3K in B cell malignancies and the ability of CAL-101 to directly induce cell death and also inhibit signaling pathways associated with cancer cell dependence on the tumor microenvironment.

“We were pleased to further demonstrate the role of the delta isoform and the activity of CAL-101 in preclinical models,” said Neill Giese, Ph.D., Chief Scientific Officer of Calistoga Pharmaceuticals. “These data support a dual mechanism of CAL-101 by acting directly on constitutive signaling to cause cell death and inhibiting survival signaling that is associated with the microenvironment. The impressive clinical single agent activity of CAL-101 likely reflects both of these mechanisms at work.”

CAL-101 is a potent inhibitor of PI3K delta with greater than 200-fold selectivity in cell-based assays for the delta isoform as compared to other class 1 PI3K isoforms. These interim results are part of the cohort expansion of the ongoing Phase 1 trial of CAL-101, which is continuing enrollment with the addition of patients with multiple myeloma. Clinical response data evaluating at least 90 patients is expected to be available by the end of 2009.

## About Calistoga Pharmaceuticals

Calistoga Pharmaceuticals is dedicated to developing innovative medicines targeting selective isoforms of the PI3 kinase pathway to improve the health of patients with cancer and inflammatory diseases. Calistoga Pharmaceuticals has a portfolio of proprietary compounds selectively targeting isoforms of the PI3K pathway. The Company's most advanced compound, CAL-101, a selective PI3K delta inhibitor, is under clinical evaluation in patients with B cell malignancies. Calistoga is a private company headquartered in Seattle, Washington. For more information, visit the Company's website at: [www.calistogapharma.com](http://www.calistogapharma.com).

# # #

### Contact:

Julie Rathbun  
Rathbun Communications, Inc.  
206.769-9219  
[Julie@rathbuncomm.com](mailto:Julie@rathbuncomm.com)