



Pharmacyclics® Reports Interim Phase II Trial Results for BTK Inhibitor PCI-32765 in Mantle Cell Lymphoma at American Society of Hematology (ASH) Annual Meeting

Investigational agent PCI-32765 achieves overall response rate (ORR) of 69% as a single agent in previously treated patients with mantle cell lymphoma (MCL)

SAN DIEGO, Dec. 12, 2011 /PRNewswire/ -- Pharmacyclics, Inc. (Nasdaq: PCYC), a biopharmaceutical company focused on developing and commercializing innovative small molecule drugs for the treatment of cancer and immune mediated diseases, announced today interim results from an ongoing Phase II trial of the selective irreversible Bruton's tyrosine kinase (BTK) inhibitor PCI-32765 in MCL. Dr. Michael Wang, Director of Mantle Cell Lymphoma Program at the University of Texas MD Anderson Cancer Center, presented these data at the ASH Annual Meeting in San Diego, CA. In this interim report, the investigational agent PCI-32765 demonstrated a high rate of overall response as a single therapy in patients with relapsed or refractory MCL, including patients that had been previously treated with the FDA-approved agent bortezomib (Velcade®). MCL is a B-cell lymphoma that is relatively rare, with about 16,000 people living with the disease in the U.S.

This interim analysis included a total of 68 patients accrued to this Phase II trial. PCI-32765 was administered orally at 560 mg daily until disease progression. 51 patients (31 patients had bortezomib-naive disease, 20 patients had previously received bortezomib) had post-baseline tumor assessments and were thus evaluable for response. The ORR, according to the 2007 Non-Hodgkin's Lymphoma International Working Group criteria, was 69% (35/51 patients). ORR was similar in bortezomib-naive and bortezomib-exposed patients (71% and 65%, respectively). At the time of this analysis 31 of 35 (89%) responding patients have ongoing responses with the median follow-up of 3.7 months. Consistent with previous trials of PCI-32765, the most common adverse events reported in this trial were Grade 1 (mild) or 2 (moderate) fatigue, diarrhea and nausea. Three patients discontinued the study due to adverse events regardless of causality. Overall, these data support Phase III evaluation of PCI-32765 as a single agent in patients previously treated MCL.

"The trial results suggest that PCI-32765 is a highly active and well tolerated single agent treatment in previously treated MCL patients," said Dr. Michael Wang, Director of Mantle Cell Lymphoma Program, of the University of Texas MD Anderson Cancer Center in Houston, who presented the study results. "We are very hopeful that, with longer follow-up, these encouraging results will support Phase III studies of PCI-32765 in Mantle Cell Lymphoma."

Conference Call Details

The Company will be holding a conference call on Wednesday, December 14, 2011 at 4.30 p.m. ET. To participate in the conference call, please dial 1-877-407-8133 for domestic callers and 1-201-689-8040 for international callers. To access the live audio broadcast or the subsequent archived recording, log on to <http://ir.pharmacyclics.com/events.cfm>. The archived version of the webcast will be available for 30 days on the Investor Relations section of the company's website at www.pharmacyclics.com.

About PCI-32765

PCI-32765 is a first-in-class, oral, selective irreversible Bruton's tyrosine kinase (BTK) inhibitor that is being investigated in clinical trials for its potential in treating patients with B-cell malignancies.

As of December 1st, 2011, 370 patients have been enrolled into clinical trials evaluating PCI-32765. Pharmacyclics' ongoing clinical development program includes the following trials:

- PCYC-04753: A Phase I of PCI-32765 in patients with recurrent B cell malignancies. This study is designed to assess the safety and tolerability of PCI-32765. Patient enrollment is completed with 66 patients enrolled in the main portion of the study. Enrollment into the diffuse large B-cell lymphoma (DLBCL) activated B-cell (ABC) investigator-led cohort is still ongoing.
- PCYC-1102-CA: A multicenter, open-label, single agent Phase IB/II study of PCI-32765 in subjects with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). This study is designed to assess safety, tolerability, and efficacy of PCI-32765. Patient enrollment is complete, with 117 patients enrolled.
- PCYC-1104-CA: A Phase II, international, multicenter, single agent study of PCI-32765 evaluating efficacy, safety, and tolerability into patient populations with relapsed or refractory mantle cell lymphoma (MCL). This trial is active in several US and EU sites and has enrolled 82 patients. The company expects to complete enrollment from this study in Q1 2012.
- PCYC-1106-CA: A multicenter, open-label, Phase II study of PCI 32765 in subjects with relapsed or refractory DLBCL.

This study is designed to assess the activity of PCI-32765 in two genetically distinct subtypes of DLBCL, the ABC subtype and the germinal center (GC) subtype. This trial is active in several US sites and has enrolled 27 patients. The company expects to complete enrollment by calendar Q1 2012.

- PCYC-1108-CA: A Phase IB, multicenter, open-label study of PCI-32765, in combination with intensive immune chemotherapy (FCR = fludarabine, cyclophosphamide and rituximab; or BR = bendamustine and rituximab) in subjects with CLL/SLL. This trial is active in several US sites and enrollment is completed with 33 patients.
- PCYC-1109-CA: A Phase IB/II study of PCI-32765 in combination with ofatumumab in subjects with relapsed or refractory CLL /SLL is ongoing and has enrolled 47 patients between two scheduled cohorts of the combination.
- PCYC-1111-CA: A Phase II study of PCI-32765 in subjects with relapsed or relapsed/refractory multiple myeloma (MM). Pre-clinical studies, both internally as well as through external collaborations, have suggested a potentially vital role for BTK in both malignant plasma cells and osteoclasts, which are involved in the bone complications of this disease. This Phase II trial of PCI-32765 is on track to start in Q1 2012.

About Pharmacyclics

Pharmacyclics® is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative small-molecule drugs for the treatment of cancer and immune mediated diseases. Our mission and goal is to build a viable biopharmaceutical company that designs, develops and commercializes novel therapies intended to improve quality of life, increase duration of life and resolve serious unmet medical healthcare needs; and to identify promising product candidates based on scientific development expertise, develop our products in a rapid, cost-efficient manner and pursue commercialization and/or development partners when and where appropriate.

Presently, Pharmacyclics has three product candidates in clinical development and several preclinical molecules in lead optimization. We are committed to high standards of ethics, scientific rigor, and operational efficiency as we move each of these programs to viable commercialization.

The Company is headquartered in Sunnyvale, California and is listed on NASDAQ under the symbol PCYC. To learn more about how Pharmacyclics advances science to improve human healthcare visit us at <http://www.pharmacyclics.com>.

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