Pharmacyclics Reports Fourth Quarter and Full Year 2014 Financial Results and Provides Business Updates

-- Reaffirms 2015 U.S. Product Revenue Guidance --

SUNNYVALE, Calif., Feb. 18, 2015 /PRNewswire/ -- Pharmacyclics, Inc. (the "Company") (NASDAQ: PCYC (http://studio-5.financialcontent.com/prnews?Page=Quote&Ticker=PCYC)) today reported financial results for the quarter and year ended December 31, 2014, as well as commercial, regulatory and clinical updates.

Key Highlights

- In the first full year of IMBRUVICA® (ibrutinib) sales, the Company recorded total revenue of $730 million, driven by U.S. net product revenue of $492 million for the year ended December 31, 2014, compared to U.S. net product revenue of $14 million for the prior year.
- Worldwide IMBRUVICA net product revenue of $548 million was recorded for the year ended December 31, 2014, including net product revenue of $56 million from outside of the U.S. as reported by our collaboration partner Janssen Biotech, Inc. and its affiliates (Janssen).
- Strong fourth quarter U.S. net product revenue of $185 million was reported, representing 31% quarter over quarter growth.
- The fourth quarter represents the second profitable quarter under the worldwide collaboration and license agreement (Agreement) with Janssen.
- IMBRUVICA received regular (full) U.S. Food and Drug Administration (FDA) approval on January 29, 2015, as the first and only treatment for patients with Waldenstrom's Macroglobulinemia (WM), and it is approved in all lines of therapy. This is the fourth indication for IMBRUVICA in less than 15 months. In the United States, approximately 1,500 people are diagnosed each year with WM, the prevalence is approximately 12,000 (G7 incidence estimated at 6,000 and prevalence at 23,000).
- 25 IMBRUVICA trials commenced in 2014 across a variety of hematologic histologies.
- Research expansion with trials in several solid tumor types will begin in the first half of 2015.

"2014 was a year of significant progress across many fronts for IMBRUVICA and for Pharmacyclics. The high clinical adoption rate by prescribers, steady regulatory advancement inside and outside of the U.S. generation of important clinical data, and quarter-over-quarter increase in product revenue and demand have been important elements in our success to date," commented Bob Duggan, Chairman & CEO of Pharmacyclics. "With the elevation of IMBRUVICA to Category 1 status within NCCN guidelines, continued growing demand within our approved indications, and market expansion in support of our new FDA label/fourth indication, we anticipate IMBRUVICA 2015 U.S. net product revenue of approximately $1 billion. Simultaneous with robust commercial expansion in 2015, we will continue to advance our understanding of the use of IMBRUVICA as a single agent and in combination with other therapies of high drug value. We will not pause in our purpose to make a difference for the betterment of patients until they achieve a cure and we return them to normal living."

Financial Results for the Quarter and Year Ended December 31, 2014

Total Revenue

For the year ended December 31, 2014, total revenue increased to $730 million, compared to $260 million for the prior year, primarily due to $479 million increase in IMBRUVICA net product revenue, as the year ended December 31, 2014 was our first full year of IMBRUVICA product sales.

Total revenue for the quarter ended December 31, 2014 increased to $290 million from $124 million in the same period in the prior year, primarily due to a $172 million increase in IMBRUVICA net product revenue year over year.

Milestone Revenue

In connection with the Agreement, we recognized $100 million of milestone revenue during the quarter ended December 31, 2014, compared to $110 million for the same period a year ago.

Milestone revenue for the quarter ended December 31, 2014 of $100 million was based on two events: 1) the EC's approval of IMBRUVICA for mantle cell lymphoma (MCL) and chronic lymphocytic leukemia (CLL) on October 17, 2014 which triggered milestone payments to us of $80 million under the Agreement and 2) the EMA's acceptance of a Type II variation application for IMBRUVICA for the treatment of adult patients with WM on December 1, 2014 which triggered a milestone payment to us of $20 million under the Agreement.

To date, in addition to the upfront payment of $150 million, milestone payments of $605 million have been earned under the Agreement and the Company maintains the potential to receive up to an additional $220 million in development ($50 million), regulatory ($50 million) and approval ($120 million) milestone payments from Janssen, assuming specific targets are achieved.

GAAP and Non-GAAP net income

Non-GAAP net income for the quarter ended December 31, 2014 was $75 million, or $0.96 per diluted share, compared to non-GAAP net income of $24 million, or $0.30 per diluted share for the quarter ended December 31, 2013.

Non-GAAP net income for the year ended December 31, 2014 was $140 million, or $1.80 per diluted share, compared to non-GAAP net income of $1 million or $0.01 per diluted share for the year ended December 31, 2013. See "Use of Non-GAAP Financial Measures" below for a description of the Company's Non-GAAP

Financial Measures. Reconciliation between certain GAAP and Non-GAAP measures is provided at the end of this press release.

GAAP net income for the quarter ended December 31, 2014 was $63 million, or $0.81 per diluted share, compared to GAAP net income of $64 million or $0.82 per diluted share for the quarter ended December 31, 2013.

GAAP net income for the year ended December 31, 2014 was $86 million, or $1.10 per diluted share, compared to GAAP net income of $67 million or $0.87 per diluted share for the year ended December 31, 2013.

Worldwide Collaboration and License Agreement with Janssen

Under the Agreement, the repayment of Excess Amounts is contingent and would become payable, with interest, to Janssen from the Company's quarterly share of pre-tax commercial profits, commencing after the third profitable quarter for the collaboration until the total Excess Amounts have been repaid from the Company's earned pre-tax collaboration net profit in subsequent quarters. As of December 31, 2014, total Excess Amounts were $138 million which was comprised of the cumulative amount funded by Janssen to-date of $134 million and interest of $4 million.

The quarter ended December 31, 2014 represented the second profitable quarter for the collaboration, calculated as follows (in thousands):

	Three Months Ended Dec. 31, 2014
50% of Pharmacyclics' U.S. product revenue, net	$ 92,568
Less: 50% of Pharmacyclics' U.S. cost of goods sold	(6,687)
Pharmacyclics' 50% share of U.S. net product revenue, less cost of goods sold	85,881
Less: Pharmacyclics' share of U.S. commercial expenses under the Agreement	(20,695)
Pharmacyclics' share of U.S. pre-tax profits from the commercialization of IMBRUVICA under the Agreement	65,186
Less: Pharmacyclics' share of outside-U.S. pre-tax commercial loss under the Agreement	(7,741)
Pharmacyclics' share of worldwide pre-tax profits from the commercialization of IMBRUVICA under the Agreement	57,445
Less: Pharmacyclics' share of world-wide research and development expenses under the Agreement	(31,748)
Pharmacyclics' share of IMBRUVICA related pre-tax net profit under the Agreement	$ 25,697

As of December 31, 2014, the Company has achieved two profitable quarters for the collaboration and expects that the three months ending March 31, 2015 will represent the third profitable quarter for the collaboration. Accordingly, the Company will begin to pay Excess Amounts from its quarterly share of pre-tax commercial profits to Janssen beginning in the fourth profitable quarter for the collaboration and until Excess Amounts have been fully paid.

GAAP and Non-GAAP costs and expenses

Non-GAAP R&D expenses of $44 million for the quarter ended December 31, 2014 increased by $3 million, compared to $41 million for the quarter ended December 31, 2013. Non-GAAP SG&A expenses of $43 million for the quarter ended December 31, 2014 increased by $8 million, compared to $35 million for the quarter ended December 31, 2013. Reconciliation between certain GAAP and Non-GAAP measures is provided at the end of this press release.

GAAP R&D expenses of $48 million for the quarter ended December 31, 2014 increased by $37 million, compared to $11 million for the quarter ended December 31, 2013. GAAP SG&A expenses of $50 million increased by $26 million, compared to $24 million for the quarter ended December 31, 2013.

The Company recorded no Excess Amounts for the quarter ended December 31, 2014.

Company Update

During the fourth quarter, Pharmacyclics was the recipient of two prestigious awards. The 2014 Society for Medicines (SMR) Research Award for Drug Discovery was awarded to the Company at the U.K.-based organization's bi-annual award lecture in London for the Company's discovery of ibrutinib. This prestigious independent research award recognizes outstanding development in the multidisciplinary field of drug discovery and is bestowed upon compounds which demonstrate a novel mechanism of action, a novel molecular interaction principle, a high degree of clinical benefit, and a significant ability to address an unmet medical need. In addition to accepting the award, Betty Y. Chang, Ph.D., Vice President of Research at Pharmacyclics who has studied the Bruton's tyrosine kinase (BTK) pathway and leads the Company's research of BTK inhibitors, presented the SMR Award Guest Lecture entitled, *"Bench to Bedside: From PCI-32765 to ibrutinib to IMBRUVICA.Dav"* Past recipients of this award include Vertex Pharmaceuticals for its work in hepatitis C, Genentech on behalf of Avastin, and Novartis for its development of Glivec, among others.

In addition, the Company received BayBio's 2014 Pantheon DiNA™ Award for Outstanding Company for its rapid development and commercialization of IMBRUVICA. BayBio, the Northern California affiliate of the Biotechnology Industry Association (BIO), represents 1,000 life sciences companies and institutions in Northern California. The Outstanding Company Award is given through an independent nomination and selection process to one company each year that has made the greatest advancement in and/or the greatest overall contribution to the Northern California life sciences industry in the prior year. Past recipients of this award include BioMarin Pharmaceuticals, Medivation, and Onyx Pharmaceuticals, among other companies.

Commercial and Medical Affairs Update

In January 2015, the National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology (NCCN Guidelines® Non-Hodgkin's Lymphomas, Version 1.2014) for relapsed/refractory (R/R) CLL updated its guidelines to elevate use of IMBRUVICA to a Category 1 designation.

In the fourth quarter of 2014, the Company announced the launch of informCLL™, a large, observational, prospective registry that will explore the natural history of CLL, examine how IMBRUVICA and other approved targeted therapies are being used to treat patients with CLL, and provide a comparison to treatments using conventional chemoimmunotherapy. The CLL registry will enroll more than 1,000 patients with CLL or small lymphocytic lymphoma (SLL) from community and academic institutions across the U.S. Registry enrollment is planned to begin in the first half of 2015.

Regulatory Update

On January 29, 2015, the U.S. FDA granted full approval for the use of IMBRUVICA (across all lines of treatment) for patients with WM, a rare, indolent form of blood cancer. This is the fourth FDA label approval for IMBRUVICA in less than 15 months and represents a significant milestone for WM patients as it now is the first and only drug approved for this rare blood cancer. IMBRUVICA received FDA Breakthrough Therapy Designation for this indication in February 2013. The FDA application was filed on October 20, 2014 and was approved more than two months ahead of the April 17, 2015 Prescription Drug User Fee Act (PDUFA) target date.

Previously, the Company announced that the EMA accepted a Type II variation application for IMBRUVICA to be used as a treatment for patients with WM. This triggered a milestone payment to the Company of $20 million.

Clinical Update

In November 2014, the Company announced a clinical trial collaboration agreement with AstraZeneca to evaluate the efficacy and safety of its investigational anti-PD-L1 immune checkpoint inhibitor, MEDI4736, in combination with IMBRUVICA as a treatment for hematologic cancers including diffuse large B-cell lymphoma (DLBCL) and follicular lymphoma (FL). A separate agreement will also study this investigational combination in solid tumors. In addition, a clinical trial collaboration agreement was also signed to explore separate combinations of two different AstraZeneca investigational products including a PI3 kinase pathway inhibitor and an mTOR inhibitor in combination with IMBRUVICA for the treatment of R/R DLBCL.

This follows two earlier collaborations that were announced in October 2014. One was for a clinical trial collaboration to evaluate the safety, tolerability and preliminary efficacy of Bristol-Myers Squibb's investigational PD-1 immune checkpoint inhibitor, nivolumab, in combination with IMBRUVICA as a potential treatment option for patients with non-Hodgkin Lymphoma (NHL), including DLBCL, FL and CLL. The other one was for a master clinical drug supply agreement with Roche to evaluate the safety, tolerability and preliminary efficacy of IMBRUVICA in combination with obinutuzumab, in patients with NHL and CLL/SLL.

During the fourth quarter, 52 clinical, non-clinical and pre-clinical abstracts on IMBRUVICA data were presented at the 56th Annual American Society of Hematology (ASH) Meeting in San Francisco from December 5-9, 2014. Of these abstracts, nine were oral presentations. Key data from select studies evaluating IMBRUVICA's use as a single agent and in combination included:

- New longer term data from the Phase III RESONATE™ (PCYC-1112) in IMBRUVICA patients with relapsed/refractory CLL, including high-risk CLL patients with del 17p demonstrated at 12 months an 84% progression-free survival rate (PFS) in all patients with previously treated CLL or SLL who received IMBRUVICA and at 12 months a 94% PFS rate in patients who received only one prior therapy. One hundred twenty-two patients (62%) randomized to ofatumumab crossed over to IMBRUVICA; the best ORR for single-agent IMBRUVICA was 90% versus 25% for ofatumumab, with 74% of IMBRUVICA patients achieving a partial response (PR), 8% partial responses with lymphocytosis (PR-L) and 4% complete responses (CR). The most frequent Grade 3 or 4 adverse events (AEs) in the RESONATE trial analysis occurring in IMBRUVICA patients were: neutropenia (18%); pneumonia (9%); thrombocytopenia (6%); anemia (6%); and, hypertension (6%).
- Results were presented from Phase II RESONATE™-17 (PCYC-1117), the largest prospective trial dedicated to studying CLL or SLL patients with del 17p (n=114) showing that IMBRUVICA was associated with an 83% overall response rate (ORR). Seventy-nine percent of patients were alive and had not

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