

# PHARMACYCLICS INC

## FORM 8-K (Current report filing)

Filed 12/07/10 for the Period Ending 12/07/10

Address	PHARMACYCLICS INC 995 E ARQUES AVE SUNNYVALE, CA 94085-4521
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Symbol	PCYC
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	06/30

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT  
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 7, 2010

PHARMACYCLICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	000-26658	94-3148201
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)
995 E. Arques Avenue, Sunnyvale, California		4085-4521
(Address of principal executive offices)		(Zip Code)

Registrant's telephone number, including area code: (408) 774-0330

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions ( see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 7.01. Regulation FD Disclosure.**

The disclosure under Item 8.01 below is incorporated herein by reference.

**Item 8.01. Other Events.**

On December 7, 2010, Pharmacyclics, Inc. (the "Company") announced preliminary results from the Phase I A study of its novel orally administered Bruton's tyrosine kinase (Btk) inhibitor, PCI-32765, which results were presented at the 2010 Annual Meeting of the American Society of Hematology ("ASH") on December 7, 2010 in a presentation titled The Btk Inhibitor, PCI-32765, Induces Durable Responses with Minimal Toxicity In patients with Relapsed/Refractory B-Cell Malignancies: Results From a Phase I Study (the "ASH Presentation").

The Company will host a conference call to discuss the preliminary results discussed herein and in the press release attached hereto on Wednesday, December 8, 2010 at 4:30 p.m. Eastern Time.

The foregoing description is qualified in its entirety by reference to the Company's Press Release, dated December 7, 2010, the ASH Presentation and the Note Pages to the ASH Presentaion, copies of which are attached hereto as Exhibit 99.1, Exhibit 99.2 and Exhibit 99.3, respectively, and are incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

Exhibit No. Description

- |      |   |
|------|---|
| 99.1 | Pharmacyclics Reports Updated Clinical Results from its Phase IA Trial of its First in Human BTK-Inhibitor PCI-32765, dated December 7, 2010. |
| 99.2 | ASH Presentation  |
| 99.3 | Note Pages to Ash Presentation  |
-

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Current Report on Form 8-K to be signed on its behalf by the undersigned hereunto duly authorized.

December 7, 2010

PHARMACYCLICS, INC.

By: /s/ Rainer M. Erdtmann

Name: Rainer M. Erdtmann

Title: Vice President, Finance &  
Administration and Secretary



**Contact**  
**Ramses Erdtman**  
**Vice President of Finance**  
 Phone: 408-215-332

**Pharmacyclics Reports Updated Clinical Results from its Phase IA Trial of its First in Human BTK-Inhibitor PCI-32765**

*Company to Host Conference Call at 4:30 p.m. ET Wednesday, December 8, 2010 -*

**ORLANDO & SUNNYVALE**, Calif., December 7, 2010 /PRNewswire-FirstCall/ -- Pharmacyclics, Inc. (Nasdaq: PCYC) today announced results from the Phase IA study of its novel orally administered Bruton's tyrosine kinase (Btk) inhibitor, PCI-32765, in patients with relapsed or refractory B cell malignancies. The abstract titled "The Btk Inhibitor, PCI-32765, Induces Durable Responses with Minimal Toxicity in Patients with Relapsed/Refractory B-Cell Malignancies: Results from a Phase I study" is being presented by Nathan Fowler, MD at the 2010 Annual Meeting of the American Society of Hematology (ASH) today at 8:15 am in Orlando, FL.

**Data Results from the Phase IA Study of PCI-32765**

The study enrolled 56 relapsed or refractory patients with a variety of B cell malignancies to this multi-cohort dose-escalation trial. Forty-eight of these patients are evaluable for response. The response by disease is captured below in the table.

The Phase IA study enrolled patients with multiple disease histologies including CLL/SLL, follicular lymphoma, mantle cell lymphoma, DLBCL, Marginal/Malt and Waldenstrom. The progression-free survival varies by histology. We have described the time on study results by histology. Please refer to our website at <http://ir.pharmacyclics.com/events.cfm> to review the slides presented by Dr. Nathan Fowler at the 2010 Annual Meeting of the American Society of Hematology.

	N	CR	PR	SD	PD	NE*	TETE*	ORR % of ITT **	ORR % Of Eval **	ASCO 2010 ORR% Of Eval **
<b>Chronic/Small Lymphocytic Leukemia (CLL/SLL)</b>	16	1	8 **	2	0	2	1	56% ** (9/16)	69% ** (9/13)	82% ** (9/11)
<b>Follicular Lymphoma (FL)</b>	16	1	3	5	4	3		25% (4/16)	31% (4/13)	27% (3/11)
<b>Mantle Cell Lymphoma (MCL)</b>	9	3	4	1	1			78% (7/9)	78% (7/9)	75% (3/4)
<b>Diffuse Large B Cell Lymphoma (DLBCL)</b>	7		2	1	4			29% (2/7)	29% (2/7)	17% (1/6)
<b>Marginal / Malt</b>	4		1	1	1	1		25% (1/4)	33% (1/3)	33% (1/3)
<b>Waldenstrom</b>	4		2	1	0		1	50% (2/4)	67% (2/3)	N/A
<b>Total</b>	56	5	20 **	11	10	6	2	45% (25/56) **	52% (25/48) **	49% (17/35) **

\* Too Early Too Evaluate (TETE), are patients who are currently on study and have not had their tumor assessment. Not evaluable (NE) are patients who have not completed two cycles of treatment and/or had a least one tumor assessment done. Other abbreviations: Complete response (CR); Partial response (PR); Stable disease (SD); Progressive disease (PD)

\*\*2 additional evaluable patients had a nodal response with lymphocytosis and are excluded in the response categories listed in this ASH table above but were included in the totals from ASCO 2010 (far right column)

With longer-term follow-up of this Phase I trial, PCI-32765 continues to be well tolerated. As reported previously, only two patients of the enrolled 56 patients have experienced a dose limiting toxicity (DLT) on this trial (drug hypersensitivity and delay in dosing due to neutropenia for 7 days). The overall rate of grade  $\geq 3$  adverse events continues to be low, and significant hematologic toxicities have been uncommon (<5% incidence of grade  $\geq 3$  neutropenia or thrombocytopenia). No adverse events related to liver or renal function have been reported. To date, there appears to be no dose-toxicity relationship, and there is no evidence of cumulative toxicity in patients receiving treatment for  $\geq 6$  months. There have been only three serious adverse events that were considered drug related to the study treatment.

In addition the company announced the presentation of its poster titled "The Histone Deacetylase (HDAC) Inhibitor PCI-24781 decreases pro-inflammatory cytokine secretion in *vitro* and *in vivo* and protects against endotoxemia in a sepsis model" at the American Society of Hematology in Orlando on Monday December 6, 2010. The poster by Balasubramanian et al focuses on the anti-inflammatory properties of our HDAC inhibitor, PCI-24781. Through modulation of the NF- $\kappa$ B pathway, PCI-24781 potently inhibits the transcription and secretion of pro-inflammatory cytokines and other mediators produced by myeloid cells. As a result, PCI-24781 is effective in treating inflammatory disorders, as demonstrated by the potent inhibition of LPS-induced endotoxemia in a mouse model of sepsis.

### **ASH Conference Call and Webcast Details:**

Date: Wednesday, December 8, 2010

Time: 4:30 pm ET

Slides used in Presentation: <http://ir.pharmacyclics.com/events.cfm>

Listen via Internet: <http://ir.pharmacyclics.com/events.cfm>

Live Participant Dial In (Toll Free): 877-407-8133

Live Participant Dial In (International): 201-689-8040

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 Web site at [www.pharmacyclics.com](http://www.pharmacyclics.com).

### **About this trial**

The Phase IA is a multicenter study being conducted in collaboration with investigators at leading lymphoma centers including Stanford University, MD Anderson Cancer Center, the University of Chicago, the University of Vermont, Weill Medical College of Cornell University, and the US Oncology Group. The trial is an open-label, dose-escalation study of PCI-32765 in recurrent B cell malignancies treating a minimum of 6 patients per cohort. Fifty six patients were enrolled between March 2009 and September 2010.

In the Phase IA five dose levels are being explored—1.25, 2.5, 5.0, 8.3 and 12.5 mg/kg/day. Each cycle of treatment consists of 28 consecutive days of once daily dosing followed by a 7-day rest period. Additionally two dose groups at 8.3 mg/kg/day and 560mg have also been explored using a 35-day cycle with no rest period ("continuous dosing" or "CD1 and CD2"). Dose limiting toxicities were evaluated at the end of the first cycle and drug efficacy is evaluated every 2 cycles. Safety is being monitored throughout the trial.

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The Phase IB/II is a multicenter study being conducted in collaboration with investigators at leading lymphoma and leukemia centers including the University of Texas, MD Anderson Cancer Center, Stanford University, Sarah Cannon Research Institute, the University of Vermont, Weill Medical College of Cornell University, the Ohio State University and the US Oncology Group. This open-label, fixed dose study was designed to evaluate safety and preliminary efficacy in patients with CLL/SLL who received a continuous dose of PCI-32765. The study is evaluating two patient populations, relapsed refractory and elderly patients (naïve to therapy). The first cohort of relapsed/refractory patients have been dosed at 420 mg (27 patients, fully enrolled) and a second cohort is being dosed at 840mg (20 patients enrolled out of 24 total planned). The elderly patients, naïve to therapy, are being dosed at 420 mg daily and 16 patients out of a planned 24 have been enrolled. The enrollment numbers for the Ib/II study were as of November 30, 2010 and the study continues to enroll rapidly.

#### **About Bruton's Tyrosine Kinase Inhibitor PCI- 32765**

PCI-32765 is an orally active small molecule inhibitor of Bruton's tyrosine kinase (Btk) that is being developed by Pharmacyclics for the treatment of patients with B-cell lymphoma or leukemia. Btk plays a prominent role in B-cell lymphocyte maturation by mediating B-cell receptor (BCR) signal transduction. Recent studies indicate that some B-cell lymphomas have kinases that are activated downstream of the BCR and that suppression of this signaling by a Btk inhibitor can induce apoptosis in these cells. BCR signaling is also thought to promote malignant cell expansion and survival in chronic lymphocytic leukemia (CLL).

**About Non-Hodgkin's Lymphoma** Non-Hodgkin's lymphoma (NHL) is a type of malignant disease that occurs within the lymphatic system and the fifth most common form of cancer. It is caused by the abnormal proliferation of white blood cells, which spreads through the lymphatic system. NHL can occur at any age and is often marked by lymph nodes that are larger than normal, fever, and weight loss. NHL can be broadly classified into two main clinical categories: indolent lymphomas, mainly characterized as follicular lymphomas, which tend to grow relatively slowly; and aggressive lymphomas, mainly typified as diffuse large B-cell lymphomas (DLBCL), which grow much more rapidly. According to the National Cancer Institute's SEER database the incidence of NHL (all types including indolent and aggressive) is projected at nearly 66,000 in the United States for 2009 and approximately 19,500 patients are expected to die from this disease. According to the Leukemia & Lymphoma Society (LLS), there are approximately 452,723 people in the United States living with NHL (with active disease or in remission).

#### **About Pharmacyclics**

Pharmacyclics<sup>®</sup> 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 exceptional scientific development expertise, develop our products in a rapid, cost-efficient manner and pursue commercialization and/or development partners when and where appropriate. We exist to make a difference for the better and these are important times to do just that.

Presently, Pharmacyclics has four product candidates in clinical development, a clinical development candidate in late stage pre clinical evaluation 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>.

**NOTE:** This announcement may contain forward-looking statements made in reliance upon the safe harbor provisions Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding our expectations and beliefs regarding our future results or performance. Because these statements apply to future events, they are subject to risks and uncertainties. When used in this announcement, the words "anticipate", "believe", "estimate", "expect", "expectation", "should", "would", "project", "plan", "predict", "intend" or similar expressions are intended to identify such forward-looking statements. Our actual results could differ materially from those projected in the forward-looking statements. Additionally, you should not consider past results to be an indication of our future performance. For a discussion of the risk factors and other factors that may affect our results, please see the Risk Factors section of our filings with the Securities and Exchange Commission, including our annual report on Form 10-K and quarterly reports on Form 10-Q. We do not intend to update any of the forward-looking statements after the date of this announcement to conform these statements to actual results, to changes in management's expectations or otherwise, except as may be required by law.

#### **Contact:**

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**Vice President of Finance**  
Phone: 408-215-3325

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## THE BTK INHIBITOR, PCI-32765, INDUCES DURABLE RESPONSES WITH MINIMAL TOXICITY IN PATIENTS WITH RELAPSED/REFRACTORY B-CELL MALIGNANCIES: RESULTS FROM A PHASE I STUDY

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*NATHAN FOWLER, MD<sup>1</sup>, JEFF PORTE SHARMAN, MD<sup>2</sup>, SONALI M SMITH, MD<sup>3</sup>, THOMAS BOYD, MD<sup>4</sup>, BARBARA GRANT, MD<sup>5</sup>, KATHRYN S. KOLIBABA, MD<sup>6</sup>, RICHARD R. FURMAN, MD<sup>7</sup>, JOSEPH BUGGY, PHD<sup>8</sup>, DAVID LOURY, PHD<sup>8</sup>, AHMED HAMDY, MD<sup>8</sup> AND RANJANA ADVANI, MD<sup>9</sup>*

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<sup>7</sup>Weill Medical College of Cornell University, New York, NY

<sup>8</sup>Pharmacyclics, Inc., Sunnyvale, CA

<sup>9</sup>Dept. of Medicine/Oncology, Stanford University, Stanford, CA

# Disclosures

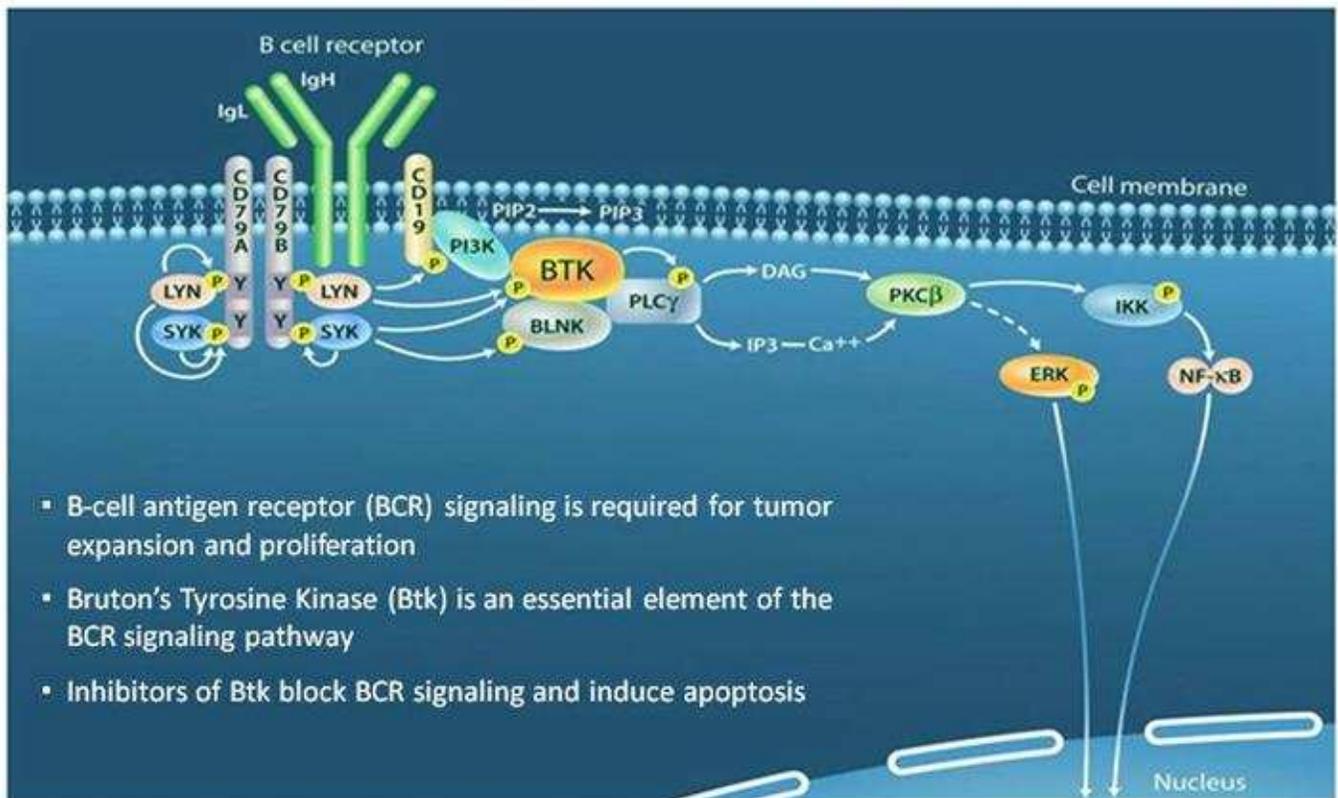
## Nathan Fowler MD

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- RESEARCH FUNDING/PI: Pharmacyclics
- EMPLOYEE: N/A
- STOCKHOLDER: N/A
- CONSULTANT: Pharmacyclics
- SCIENTIFIC ADVISORY BOARD: Pharmacyclics

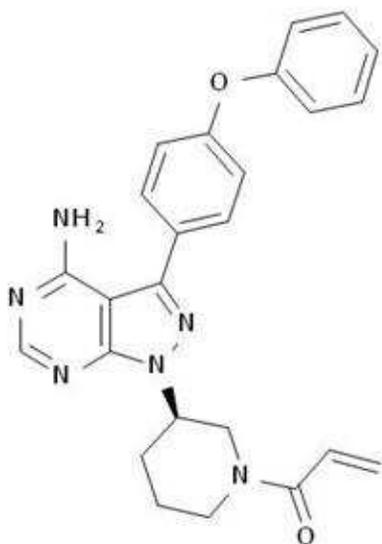
# Bruton's Tyrosine Kinase (Btk)

## A Critical B-Cell Signaling Kinase



# PCI-32765

## Novel Small Molecule Btk Inhibitor



- Forms a specific and irreversible bond with cysteine-481 in Btk
- Potent Btk inhibition
  - IC<sub>50</sub> = 0.5 nM
- Orally available
- Once daily dosing results in 24-hr sustained target inhibition

# Study Design

- Dose-Escalation Study
  - Cohorts  $n \geq 6$  patients
  - Escalate to MTD or 3 dose levels above complete active site occupancy
  - Tumor assessment performed every 2 cycles

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- Dosing
  - 1.25, 2.5, 5.0, 8.3, 12.5 mg/kg/d PO (Cycle=28 days + 7-days rest)
  - 2 continuous dosing cohorts (Cycle=35 days)
    - 8.3 mg/kg/day PO
    - 560 mg/day (fixed dose) PO

# Key Inclusion / Exclusion Criteria

- Recurrent B-cell malignancies
- ECOG  $\leq 1$
- Prior treatment:  $\geq 1$  and  $\leq 4$  (except for CLL)
- Measurable disease
  - $\geq 2$  cm diameter for NHL or  $\geq 5000$  leukemia cells/mm<sup>3</sup> for CLL or IgM level  $\geq 1000$  mg/dL + BM infiltration for WM
- No known CNS involvement or uncontrolled infection
- Laboratory:
  - Platelets count  $\geq 75,000/\mu\text{L}$  and ANC  $\geq 1500/\mu\text{L}$  (unless CLL with BM involvement)
  - Adequate renal /hepatic function

# Objectives

- **Primary Objectives**
  - **Establish the safety and the MTD**
  - Determine the pharmacokinetics of study drug
  - Measure pharmacodynamic parameters, including drug occupancy of Btk

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- **Secondary Objective**
  - **Evaluate tumor response**

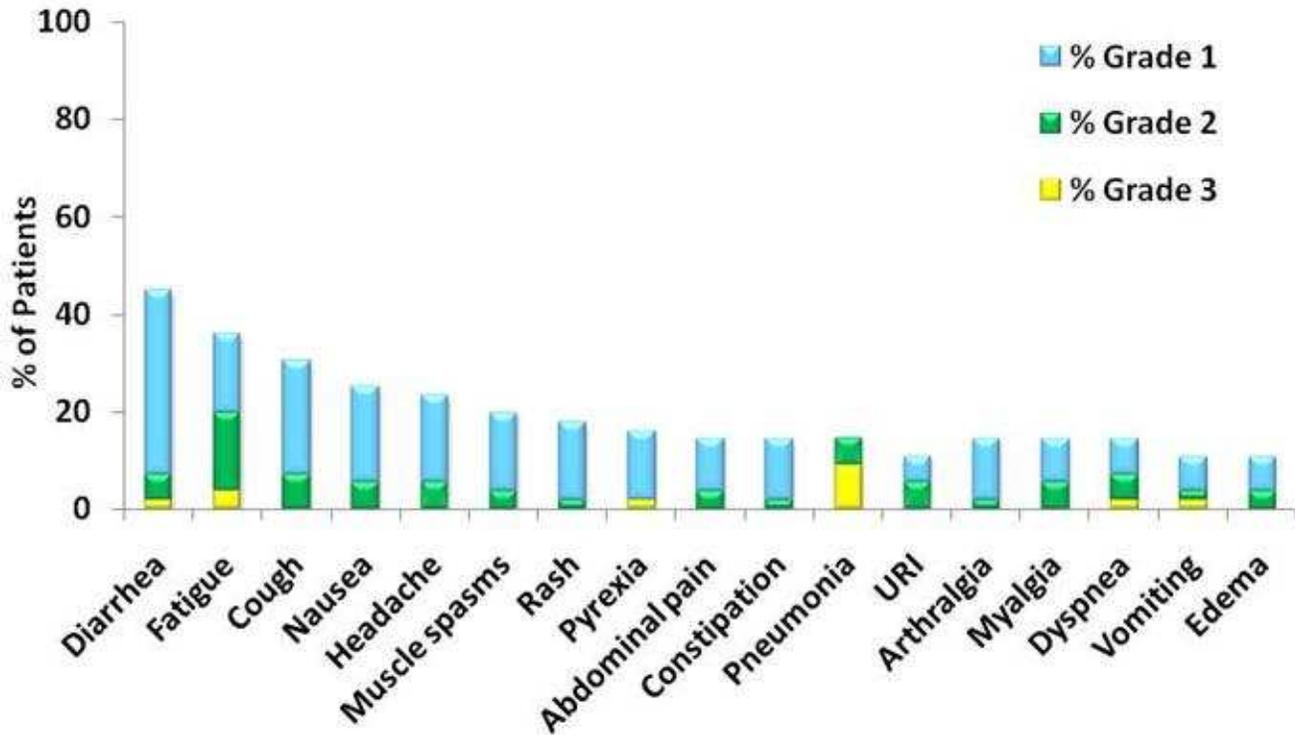
## Baseline Characteristics (N=56)

<b>Median age, years (range)</b>	65 (41-82)
<b>M/ F, n (%)</b>	38 (68) / 18 (32)
<b>Histology, n (%)</b>	
FL	16 (29)
CLL/SLL	16 (29)
MCL	9 (16)
DLBCL	7 (13)
MZL / MALT	4 (7)
WM	4 (7)
<b>Median prior therapies, number (range)</b>	3 (1-10)

# Disposition

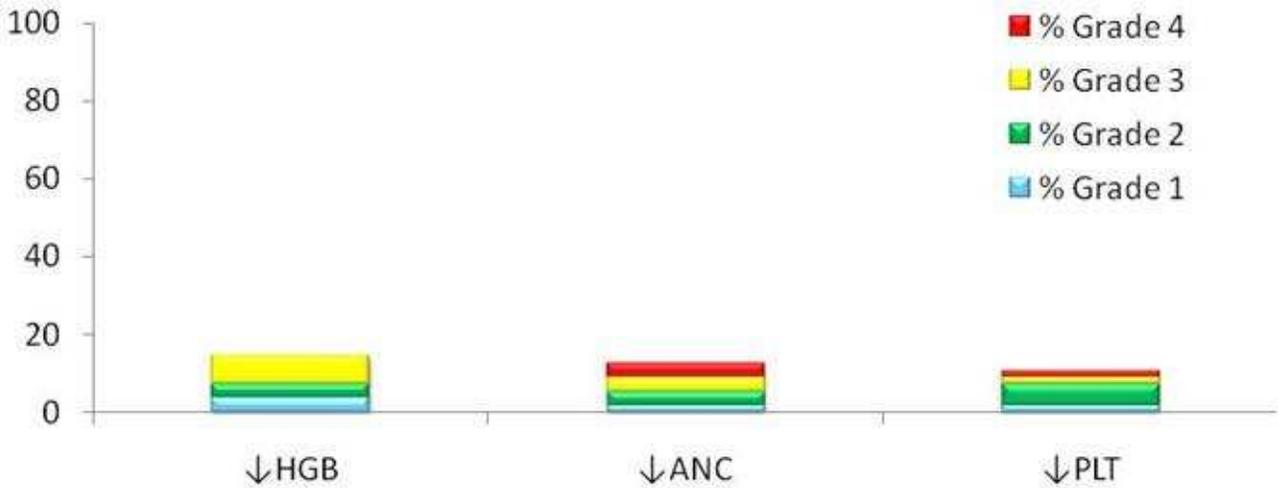


## Adverse Events ( $\geq 10\%$ Incidence)

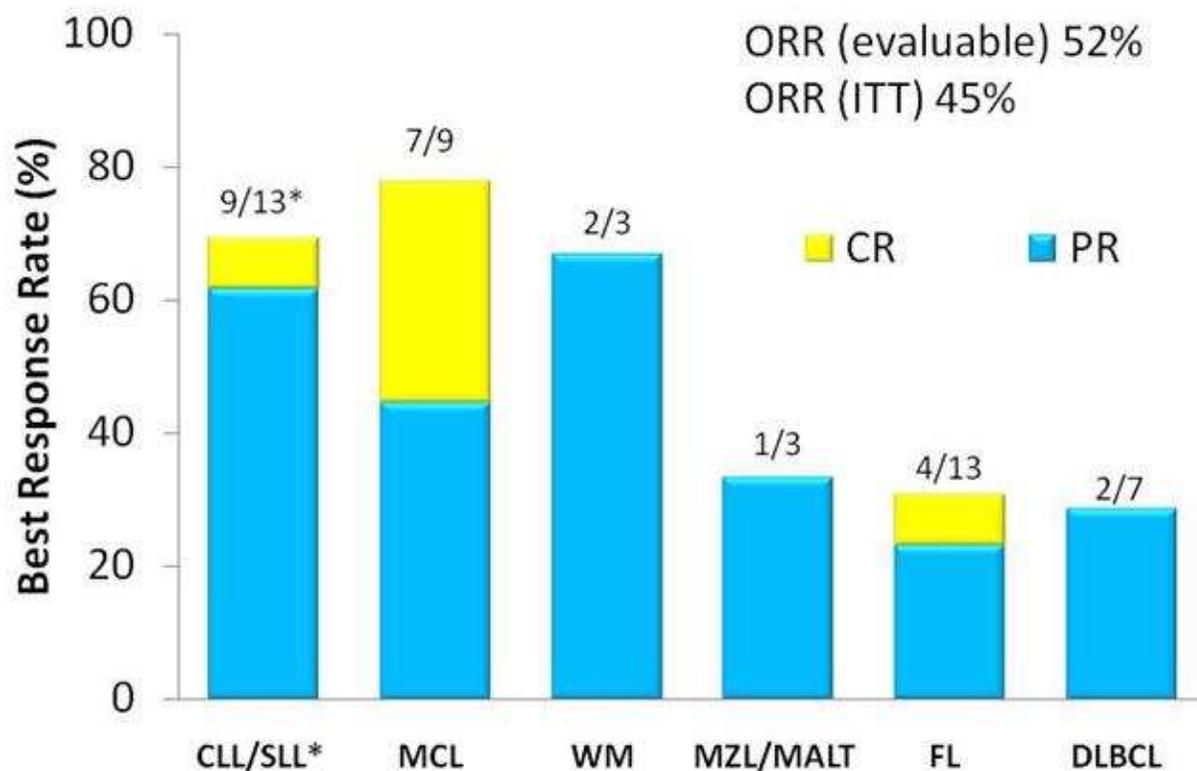


# Laboratory Adverse Events (N=56)

- No hepatic or renal toxicities
- No evidence of cumulative hematologic toxicity

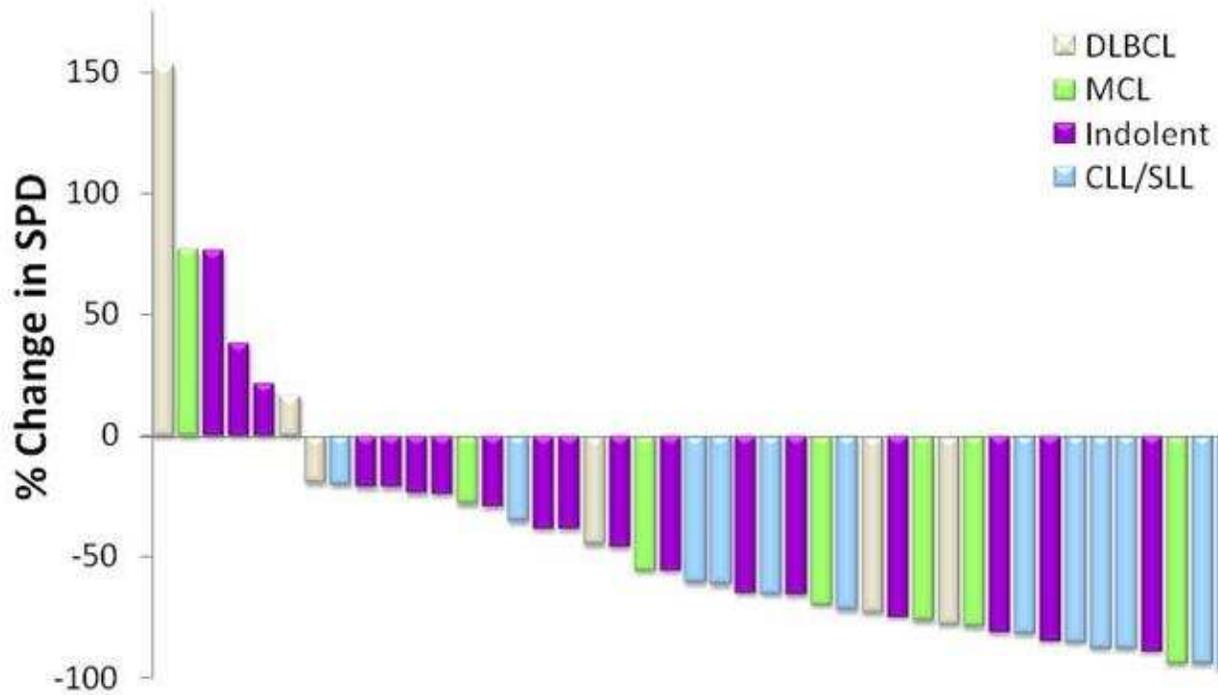


# Objective Response in Evaluable Patients (N=48)

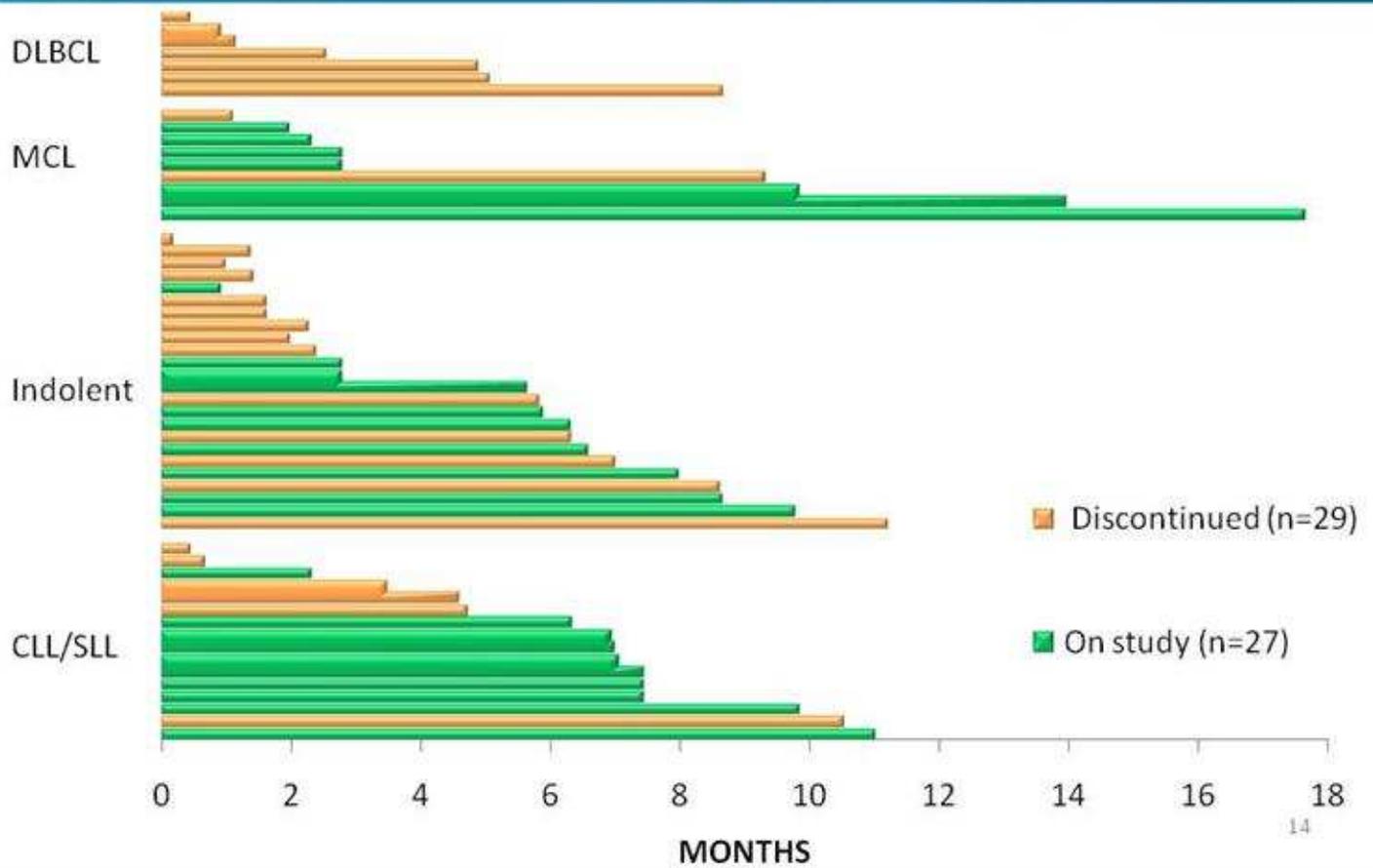


\*2 CLL pts had nodal response with lymphocytosis

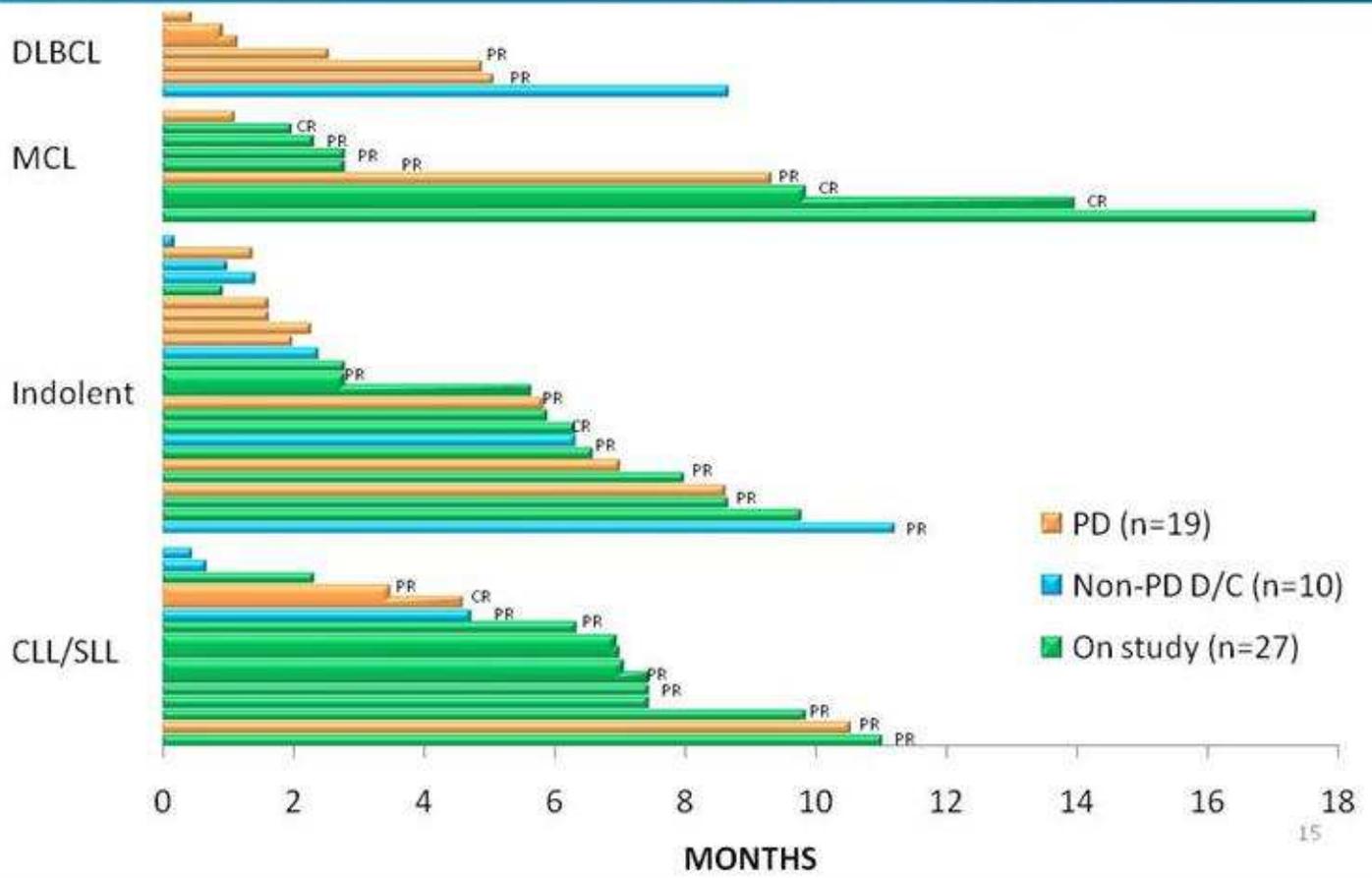
# Max % Change in Tumor Burden (N=45)



# Time on Study (N=56)



# Time on Study (N=56)

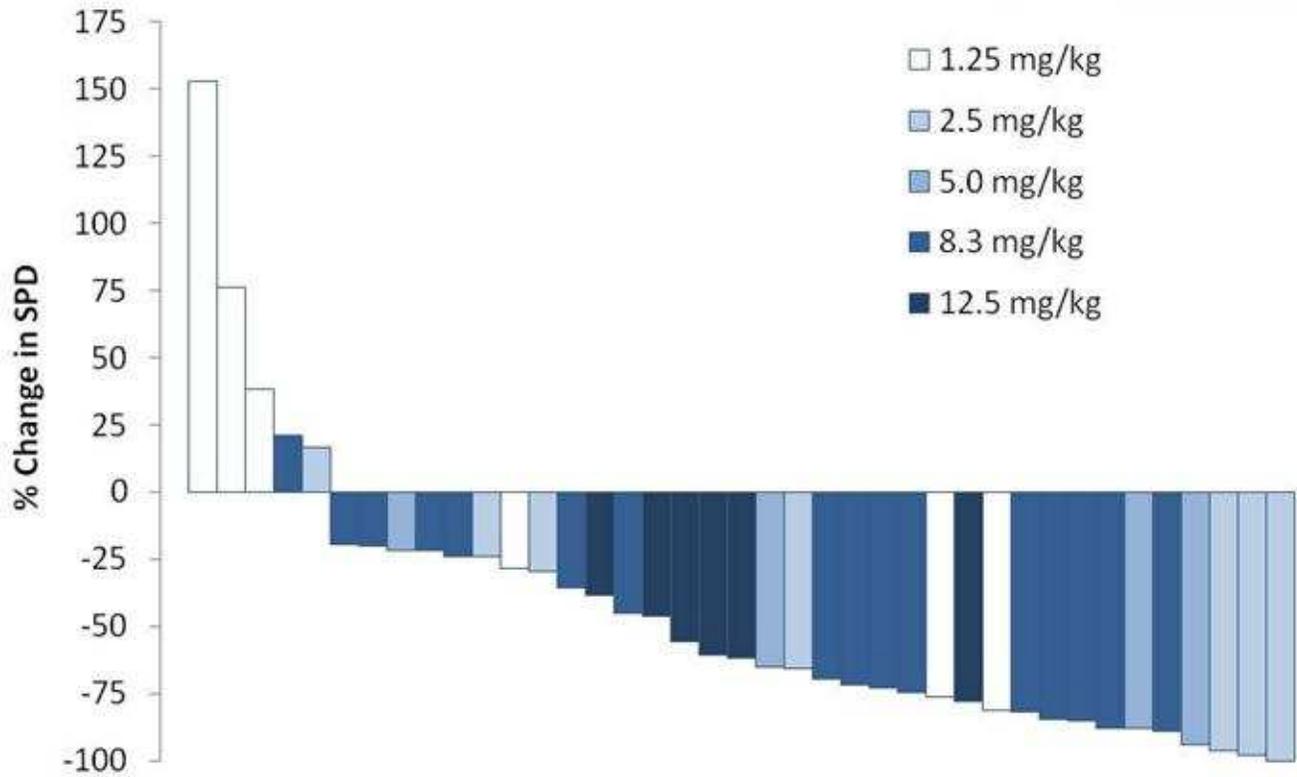


## Conclusions

- In this phase 1 trial, PCI-32765, an oral Btk inhibitor, was tolerable, safe, and active in B-cell malignancies
  - No cumulative toxicity with treatment durations > 6 months
  - Myelosuppression is minimal
  - Durable responses observed in multiple histologies
- Data strongly support continued clinical evaluation in various B-cell malignancies

# Back up slides

# Maximum Change in Tumor Burden (by Dose)



# Best Response According To Histology (N=56)

	N	CR	PR	SD	PD	NE*	TETE*	ORR % ITT	ORR % Eval
CLL/SLL	16	1	8**	2		2	1	56%**	69%**
FL	16	1	3	5	4	3		25%	31%
MCL	9	3	4	1	1			78%	78%
DLBCL	7		2	1	4			29%	29%
MZL/MALT	4		1	1	1	1		25%	33%
WM	4		2	1			1	50%	67%
<b>TOTAL</b>	<b>56</b>	<b>5</b>	<b>20**</b>	<b>11</b>	<b>10</b>	<b>6</b>	<b>2</b>	<b>45%**</b>	<b>52%**</b>

\*TETE = too early to evaluate; NE = not evaluable

\*\*2 additional evaluable patients had a nodal response with lymphocytosis and are excluded from the response rate

Please note that the notes contained herein should be read in conjunction with and correspond to the specific slides in Exhibit 99.2, the ASH Presentation.

NOTE PAGES

Prepared for the 2010 Annual Meeting of the American Society of Hematology. For the oral presentation titled "The Btk Inhibitor, PCI-32765, Induces Durable Responses with Minimal Toxicity in Patients with Relapsed/Refractory B-Cell Malignancies: Results from a Phase I study" presented by Nathan Fowler, MD.  
December 7, 2010

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Slide 1: Introduction

Slide 2: Investigator Disclosures

Slide 3: Btk is a Tec family kinase that is required for B-cell activation mediated by BCR signaling. The essential role of Btk in normal B-cell development is evidenced by the clinical syndrome X-linked agammaglobulinemia, in which BCR signaling is abrogated by mutations in Btk. Signaling from the BCR is also believed to be required for the maintenance of cell division and survival in B cell malignancies, presumably via downstream phosphorylation of PLC-gamma by Btk, ultimately leading to the activation of the anti-apoptotic transcription factor NF-kB and the kinase ERK. Additionally, Btk may also play a role in the pathogenesis of B-cell malignancies by regulating integrin-mediated migration and adhesion, through regulation of malignant cell response to lymph node-derived chemotactic factors, such as CXCL12 and CXCL 13.

Slide 4: PCI-32765 is a small-molecule that irreversibly binds Btk, through covalent binding to the cysteine-481 residue. As previously reported at ASCO 2010, once-daily oral administration, at doses equivalent to or greater than 2.5 mg/kg, results in sustained full occupancy of Btk in peripheral blood mononuclear cells, and predictably achieves serum levels associated with inhibition of B-cell activation in vitro.

Slide 5: Study PCYC-04753 is a multi-cohort, dose-escalation Phase I study, in which two schedules of daily oral PCI-32765 were evaluated, a 28-day-on/ 7-day-off schedule, and a continuous dosing schedule. Dose escalation was designed to continue until MTD or, in the absence of a MTD, to three dose levels above the level in which continuous Btk occupancy, as measured by a fluorescent probe assay in peripheral blood mononuclear cells, was achieved. In this trial, patients were also evaluated for tumor response every two cycles by the principal investigators.

Slide 6: The key inclusion and exclusion criteria are noted in this slide. Patients with relapsed or refractory B-cell malignancies following 1 to 4 prior therapies were eligible. There was no limit on prior therapies in patients with chronic lymphocytic leukemia. Patients must have had good performance status, measurable disease, and adequate bone marrow, hepatic, and renal function.

Slide 7: The objectives of the trial are listed here. As the preliminary findings of this trial have been previously reported, with a detailed description of pharmacokinetic and pharmacodynamic data, this presentation will largely focus on updated safety and efficacy data.

Slide 8: A total of 56 patients were enrolled between March 2009 and September 2010. The median age was 65 years, with a roughly 2 to 1 male to female ratio. The median number of prior therapies was 3, and the histologies represented, in order of frequency, were follicular lymphoma, chronic lymphocytic leukemia or small lymphocytic lymphoma, mantle cell lymphoma, and diffuse large B-cell lymphoma, Malt/marginal lymphoma, and Waldenstrom's.

Slide 9: In this slide we note the current disposition of the 56 patients enrolled to this trial. The majority of patients (47) were enrolled more than 6 months ago. In July 2010, the study was amended to include a second continuous dosing cohort; the 9 patients enrolled to this cohort have a significantly shorter follow-up time and are considered separately on the left-hand side of this slide. Of the 47 patients with longer follow-up, 19 remain free-from-progression and on study treatment. Of those patients who discontinued study treatment, 18 did so for progressive disease, 6 did so for either a protocol-defined dose-limiting toxicity or adverse event, and an additional 4 patients either withdrew consent or discontinued on the basis of investigator discretion.

Of the 9 patients with shorter follow-up, 8 remain on study, and 1 patient discontinued due to progressive disease.

Slide 10: Depicted in this slide are all events occurring in at least 10% of patients on study. Of note, all of the more frequently reported events are non-hematologic events. The severity is represented in the different colors of the bars, with grade 3 events represented in yellow. Overall, grade 3 events were very uncommon; the vast majority of events have been of mild severity. Grade 1-2 diarrhea and fatigue were the most frequently reported events.

Slide 11: As noted in the previous slide, significant myelotoxicity was uncommon; there were only 4 reports of grade 3 or greater neutropenia and 2 reports of grade 3 or greater thrombocytopenia. Additionally, there were no reports of renal insufficiency or transaminase elevation of any grade.

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Slide 12: Moving to efficacy, this slide reflects best response to date across various histologies, according to standard response criteria. Evaluable patients had at least 1 on-study tumor assessment. SD=23%; PD=21%

Of note, amongst patients with CLL or SLL, the response rate is 69%. In follicular lymphoma, the response rate is 31%. In 9 patients with mantle cell lymphoma, there have been seven objective responses (78%), including 3 patients who achieved a complete response, and in diffuse large B-cell lymphoma, two of seven (29%) patients achieved a partial response.

Also of note, only 10 of the 56 patients receiving PCI-32765 had progressive disease on initial assessment.

Slide 13: Most patients had an impressive and rapid decrease in their nodal disease reflected here as the sum of the perpendicular diameters. Eleven patients were not included due to lack of tumor measurements (2 clinical PD, 1 WM pt had non-measurable disease at baseline, 3 WD, 1 SAE, 2 DLT, 2 TETE)

Slide 14: This slide describes the current status of the 56 patients enrolled with respect to time on study treatment. Overall, 27 of the 56 patients remain on study treatment. Of the patients achieving an objective response, only 7 have subsequently progressed. Particularly notable is the high proportion of continuing responses in CLL and MCL, ranging from 2 to nearly 18 months from study entry.

Slide 15: See slide 14

Slide 16: Conclusions

Slide 17: Transition to back up slides

Slide 18: Maximum change in tumor burden by dose

Slide 19: Best response according to histology

Slide 20: Progression-free survival by histology

NOTE:

This presentation may contain forward-looking statements made in reliance upon the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding our expectations and beliefs regarding our future results or performance. Because these statements apply to future events, they are subject to risks and uncertainties. When used in this announcement, the words "anticipate", "believe", "estimate", "expect", "expectation", "should", "would", "project", "plan", "predict", "intend" and similar expressions are intended to identify such forward-looking statements. Our actual results could differ materially from those projected in the forward-looking statements. Additionally, you should not consider past results to be an indication of our future performance. For a discussion of the risk factors and other factors that may affect our results, please see the Risk Factors section of our filings with the Securities and Exchange Commission, including our annual report on Form 10-K and quarterly reports on Form 10-Q. We do not intend to update any of the forward-looking statements after the date of this presentation to conform these statements to actual results, to changes in management's expectations or otherwise, except as may be required by law.