Your abstract submission has been received

Click here **to print this page now.**

You have submitted the following abstract to 58th Annual Meeting and Exposition (December 3-6, 2016). Receipt of this notice does not guarantee that your submission was complete, free of errors, or accepted for presentation.

Plinabulin, a Novel Small Molecule That Ameliorates Chemotherapy-Induced Neutropenia, Is Administered on the Same Day of Chemotherapy and Has Anticancer Efficacy

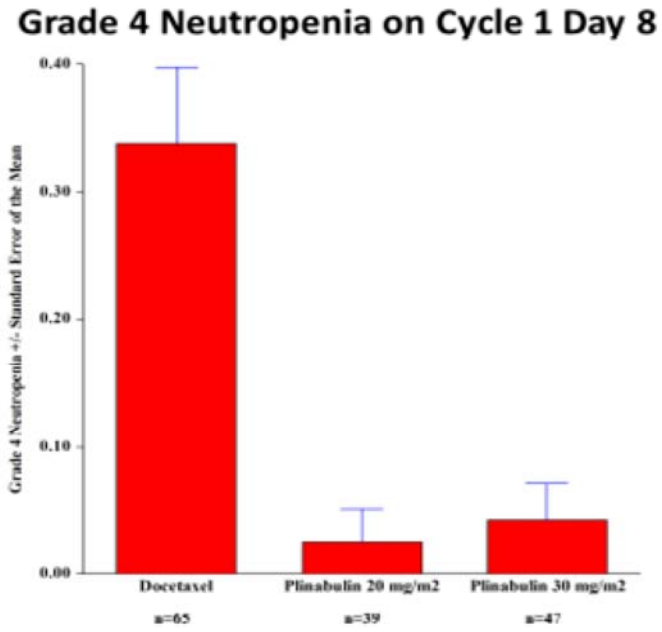
Douglas W Blayney, MD[1*], Lyudmila Bazhenova, MD[2*], G. Kenneth Lloyd, PhD[3*], Lan Huang, PhD[3*] and Ramon Mohanlal, MD, PhD[3*]

[1]Stanford Cancer Institute, Stanford University, Stanford, CA; [2]University of California, San Diego, La Jolla, CA; [3]BeyondSpring Pharmaceuticals Inc., New York, NY

Plinabulin is a small molecule with tumor-inhibiting and immune-enhancing effects. Plinabulin induces dendritic cell maturation and cytokines interleukin-1β (IL-1β), IL-6, and IL-12 production, all of which are important in neutrophil survival. In preclinical studies, plinabulin prevented docetaxel- or cyclophosphamide-induced neutropenia via a mechanism of action different from that of granulocyte colony-stimulating factor (G-CSF) analogues. In phase 1 and 2 solid tumor trials of plinabulin, which included >140 patients, routine safety laboratory assessments revealed an unexpected protective effect against neutropenia.

In the phase 2 clinical trial, patients were randomized to receive docetaxel 75 mg/m^2 alone (n=73) or docetaxel 75 mg/m^2 followed by plinabulin (NPI-2358-101) at 30 mg/m^2 (n=50) or at 20 mg/m^2 (n=40), repeated every 3 weeks (clinicaltrials.gov NCT00630110). Plinabulin was given by a 30-minute intravenous (IV) infusion, starting 1 hour after administration of docetaxel. The primary efficacy endpoint was median overall survival. Secondary endpoints included safety assessments, such as complete blood count measurements, on Days 1, 8, and 15 of each cycle.

Compared to docetaxel treatment alone, the addition of plinabulin to docetaxel significantly ($p<0.0003$) reduced the proportion of patients with grade 4 neutropenia from 33.3% to 4.6% in Cycle 1. The figure shows the proportions of patients with grade 4 neutropenia (absolute neutrophil count [ANC] <0.5x10^9/L) on Day 8, the approximate day after docetaxel administration corresponding to the largest reduction in neutrophil count (Blackwell Ann Oncol 2015). Plinabulin also reduced the clinical sequelae associated with docetaxel-induced neutropenia (sepsis, infections, hospitalizations, need for docetaxel dose reduction, and G-CSF use). Bone pain was reported in 4% of patients receiving plinabulin. Plinabulin had a favorable safety profile; the most prominent finding was grade 3 transient hypertension in 20% and 5% of patients receiving 30 mg/m^2 and 20 mg/m^2 plinabulin, respectively.



Docetaxel (n=65) vs plinabulin 20 mg/m^2 (n=39): p = 0.00026

Docetaxel (n=65) vs plinabulin 30 mg/m^2 (n=47): p = 0.00018

Plinabulin 20 mg/m^2 (n=39) vs plinabulin 30 mg/m^2 (n=47): p = 0.68

Plinabulin is a novel small molecule that is being developed for the mitigation of chemotherapy-induced neutropenia. Administered by IV infusion on the same day of (approximately 1 h after) chemotherapy, plinabulin will be given in a single dose of 20 mg/m^2 per cycle. Plinabulin has the potential to be an effective, safe (with much less bone pain), cost-effective, and convenient alternative to G-CSF for the prevention of chemotherapy-induced neutropenia.

Abstract ID#: 91348
Password: 224685
Title: Plinabulin, a Novel Small Molecule That Ameliorates Chemotherapy-Induced Neutropenia, Is Administered on the Same Day of Chemotherapy and Has Anticancer Efficacy
Review Category Selection: 201. 201. Granulocytes, Monocytes and Macrophages
Preferred Presentation Format: Oral
Submitter's E-mail Address: dblayney@stanford.edu
Publish only on the Blood Abstracts site: Yes
First submission to an ASH Annual Meeting: No
Compliance with the Declaration of Helsinki for Studies Involving Human Subjects: Agree
Is the first author/presenter of this abstract a hematologist in training?: No
Interim Analysis of Clinical Trial: No
Special Consideration: We are reporting the neutropenia ameliorating effects of plinabulin. The anticancer effects have been previously reported.
Hematologist in training: No
Keywords: Chemotherapy Toxicity, Neutropenia

First Author

Presenter
Corresponding
Douglas W Blayney, MD
Stanford University
Stanford Cancer Institute
Stanford, CA
Phone Number: 650-725-6704
Email: dblayney@stanford.edu

I have relevant financial relationship(s) to disclose. Yes

Name of Organization	Type of relationship
BeyondSpring	Other: Travel and lodging to develop clinical trial protocol

Signed on 07/28/2016 by *Douglas W Blayney, MD*

Second Author

Lyudmila Bazhenova, MD
University of California, San Diego
3855 Health Services Dr.
Mail Code 0987
La Jolla, CA 92093
Phone Number: (858) 554-8116
Email: ludo@salk.edu -- Will not be published

I have relevant financial relationship(s) to disclose. No
Signed on 07/28/2016 by *Lyudmila Bazhenova, MD*

Third Author

G. Kenneth Lloyd, PhD
BeyondSpring Pharmaceuticals Inc.
New York, NY
Phone Number: 858-748-1485
Email: Ken.lloyd@Beyondspringpharma.com -- Will not be published

I have relevant financial relationship(s) to disclose. Yes

Name of Organization	Type of relationship
BeyondSpring	Consultancy

Signed on 07/28/2016 by *G. Kenneth Lloyd, PhD*

Fourth Author

Lan Huang, PhD
BeyondSpring Pharmaceuticals Inc.
New York, NY
Email: lan.huang@beyondspringpharma.com -- Will not be published

I have relevant financial relationship(s) to disclose. Yes

Name of Organization	Type of relationship
BeyondSpring	Employment

Signed on 07/29/2016 by *Lan Huang, PhD*

Fifth Author

Ramon Mohanlal, MD, PhD
BeyondSpring Pharmaceuticals Inc.
New York, NY
Phone Number: 917-526-1956
Email: rmohanlal@beyondspringpharma.com -- Will not be published

I have relevant financial relationship(s) to disclose. Yes

Name of Organization	Type of relationship
BeyondSpring	Employment

Signed on 07/29/2016 by *Ramon Mohanlal, MD*

If necessary, you can make changes to your abstract between now and the deadline of Thursday, August 4, 2016

- To access your submission in the future, use the direct link to your abstract submission from one of the automatic confirmation emails that were sent to you during the submission.
- *Or* point your browser to /ash/reminder.cgi to have that URL mailed to you again. Your username/password are 91348/224685.

Any changes that you make will be reflected instantly in what is seen by the reviewers. You DO NOT need to go through all of the submission steps in order to change one thing. If you want to change the title, for example, just click "Title" in the abstract control panel and submit the new title.

When you have completed your submission, you may close this browser window.

Tell us what you think of the abstract submittal

Home Page