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Adding Plinabulin To Chemotherapy Reduces Toxicity, Improves Efficacy

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MedicalResearch.com Interview with:



Dr. Lan Huang

Dr. Lan Huang PhD

Co-founder and Chief Executive Officer

[BeyondSpring Pharmaceuticals, Inc.](http://BeyondSpring.com)

MedicalResearch.com: What is the background for this study? What are the main findings?

Response: The background for this study is the toxicity of Docetaxel chemotherapy causes inadequate dosing with Docetaxel due to dose delay, reduction or discontinuation, thus leaving the patient with inadequate chemotherapy treatment.

A main finding is a statistically significant p value of 0.002 in lower rates of grade 3 and 4 Neutropenia for patients dosed with a combination of BeyondSpring's Plinabulin and Docetaxel compared to those patients dosed with Docetaxel alone. As a result, approximately 14 percent more patients stayed on the adequate (dense) dose of Docetaxel in the Docetaxel + Plinabulin arm as compared to Docetaxel alone.

MedicalResearch.com: What should readers take away from your report?

Response: The take away for readers is that with the addition of Plinabulin to Docetaxel, we would expect not only a better safety profile (less grade 3 and 4 Neutropenia frequency), but also a better efficacy profile since approximately 14 percent more patients will stay on the dense Docetaxel dose, and added to that, Plinabulin's vascular and immune mechanisms are expected to have additional efficacy benefit.

MedicalResearch.com: What recommendations do you have for future research as a result of this study?

Response: Our recommendations for further research are: BeyondSpring will pursue a stand-alone program for the indication of prevention of chemotherapy-induced Neutropenia, with the intention to have this indication authorized for marketing worldwide in 2018. In addition, the Company will continue to initiate programs with chemotherapy regimens that are known to cause severe Neutropenia in a high frequency of patients, with the intent to demonstrate that the addition of Plinabulin to these chemo regimens will not only improve safety profile (less Neutropenia), but also to improve efficacy (overall survival).

MedicalResearch.com: Is there anything else you would like to add?

Response: Our assessment of Plinabulin's effects would suggest that Plinabulin is a more effective, safe, convenient and cost-effective alternative to G-CSFs (including PEGylated G-CSF and G-CSF biosimilars). G-CSFs are known to cause bone pain in a large number of patients (estimated 30 percent of patients), whereas only in 4 percent of patients receiving Plinabulin. Furthermore, per product label, G-CSFs have to be administered 24 hours after chemotherapy (thus the next day after chemo), whereas Plinabulin is administered 1 hour after chemotherapy (on the same day of chemo).

Plinabulin is an inexpensive small molecule, whereas G-CSFs are expensive biologics. Combined with the benefit on hospitalization rates observed with Plinabulin, we believe that Plinabulin could represent a cost-effective alternative to G-CSF.

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Citation: Abstract presented at the 2016 ASCO meeting

The Plinabulin/Docetaxel combination to mitigate the known safety concerns of Docetaxel
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