

New type of immunotherapy shows potential in advanced lung cancer

January 8 2014

(Medical Xpress)—When added to chemotherapy and antibody therapy, Imprime PGG, a type of immunotherapy, substantially improved response rates and overall survival rates in patients with late-stage, non-small cell lung cancer (NSCLC), according to the results of a phase II study presented here at the AACR-IASLC Joint Conference on the Molecular Origins of Lung Cancer, held Jan. 6-9.

"Imprime PGG is an immunotherapy that capitalizes on a natural defense mechanism in our bodies through which <u>immune cells</u> called neutrophils and monocytes recognize and kill infectious organisms," said Richard D. Huhn, M.D., medical director and senior vice president at Biothera Inc. "When combined with an antitumor monoclonal antibody, Imprime PGG redirects neutrophils and monocytes to recognize and kill antibody-targeted cancer cells.

"Imprime PGG works most effectively in people whose natural antibeta glucan antibody levels exceed a certain threshold," continued Huhn.
"The more antibodies present to bind Imprime PGG to neutrophils and monocytes, the higher the number of these immune cells that are activated to recognize and kill cancer."

Neutrophils and monocytes represent about 65 percent of all immune cells, and they are effective in killing pathogens, such as yeast and bacteria. Imprime PGG is made using a component of yeast called beta 1,3/1,6 glucan, and it binds to a specific site on the neutrophil, priming the neutrophil to become capable of killing tumor cells.



"We believe that Imprime PGG can change the way cancer is treated," said Huhn. "We have identified a subpopulation of <u>patients</u> who have sufficient levels of natural antibeta glucan antibody to enhance binding of Imprime PGG to neutrophils and monocytes. These 'biomarker-positive' patients are most likely to respond best to Imprime PGG therapy. The discovery of a biomarker-positive population may enable the enrichment of future clinical trials."

Huhn and colleagues conducted a phase II study to which they recruited 90 patients with stage 3b or stage 4 NSCLC. Thirty patients were randomly assigned to the <u>control group</u> and received the antibody drug cetuximab; 60 patients were randomly assigned to cetuximab plus Imprime PGG on days one, eight, and 15 of each three-week treatment cycle. All patients also received the chemotherapy drugs carboplatin and paclitaxel.

Of the 46 patients who received Imprime PGG and were evaluable for endpoints, 15 were biomarker-positive and 31 were biomarker-negative.

Patients in the control group and Imprime PGG group had a median overall survival of 11.2 months and 10.2 months, respectively. However, among patients who received Imprime PGG, the median overall survival for those who were biomarker-positive was 16.5 months, versus 9.1 months for those who were biomarker-negative.

While none of the patients from the control group survived for three years after treatment, 7 percent of the Imprime PGG group did. Among patients who received Imprime PGG, 17 percent of those who were biomarker-positive survived for three years after treatment, while none of the biomarker-negative patients did.

In general, important adverse events were characteristic of the chemotherapy or cetuximab, and occurred in 86 percent of the patients



in the control group and 78 percent of the patients in the Imprime PGG group.

Randomized phase III trials of Imprime PGG in combination with chemoimmunotherapy for several cancer indications are currently being planned, according to Huhn.

Provided by American Association for Cancer Research

Citation: New type of immunotherapy shows potential in advanced lung cancer (2014, January 8) retrieved 2 May 2024 from

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