Medical Xpress

Will pembrolizumab improve recurrence-free survival for patients with high-risk melanoma?

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A recently opened double- blind phase III EORTC trial 1325 will prospectively assess whether post-operative adjuvant therapy with pembrolizumab, an anti-PD-1 monoclonal antibody, improves recurrence-free survival as compared to placebo in patients with high-risk stage III melanoma.

A unique feature of the study is that in case of relapse all patients will have guaranteed access to pembrolizumab. This allows the study to assess a second question: is there a difference in benefit between early or late access to pembrolizumab.

Prof Alexander M.M. Eggermont of Institut de Cancérologie Gustave Roussy Villejuif, Paris, France and Chair of this study says, "The current thinking in treating melanoma is to inhibit the inhibitor and thereby break tolerance rather than to pursue immune-activating strategies. For instance, Ipilimumab, a monoclonal antibody, works by inhibiting CTLA-4, a protein receptor that down regulates the body's immune system. The body needs cytotoxic T lymphocytes (CTLs) to attack cancer cells, so using this approach, tumor control is now possible. Most patients with durable responses seem to have obtained a state of tumor control rather than one of complete tumor eradication. Now, with EORTC trial 1325, we want to improve this level of response."

Prof Caroline Robert, Institut de Cancérologie Gustave Roussy Villejuif,

Paris, France and coordinator of this study adds, "Pembrolizumab blocks the programmed death receptor 1 (PD-1), another receptor that tumors activate to suppress immune control. Anti-PD1 monoclonal antibodies have higher response rates as compared with ipilimumab, and most of the responses are durable."

"Bringing forward true advances that change survival outcomes for patients with cancer requires us to ask challenging scientific questions across many treatment settings," said Dr. Roger Dansey, therapeutic area head and senior vice president, oncology late stage development, Merck Research Laboratories. "We are pleased to continue our important partnership with EORTC—an organization very much aligned with Merck's commitment to the field of immuno-oncology—on the initiation of this large phase III trial in order to help more patients with advanced melanoma."

"EORTC trial 1325 is an example of a successful partnership between the EORTC as an academic clinical research organization and pharma to set up large trials where we complement each other's strengths," points out Dr. Denis Lacombe, EORTC Director General. "As an organization, the EORTC is committed to unifying stakeholders towards common goals so that we can realize our mission of improving treatments for patients with cancer."

EORTC trial 1325 is coordinated by the EORTC Melanoma Group and will accrue 900 patients at 132 sites located in 25 countries: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Japan, Israel, Italy, New Zeeland, Norway, Poland, Portugal, Russia, Serbia, Singapore, Slovenia, Spain, Sweden, Switzerland, The Netherlands, the United Kingdom, and the United States of America. This trial is sponsored by Merck Sharp & Dohme Corp.