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# Study shows use of Herceptin in treatment of stomach cancer prolongs life

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(PhysOrg.com) -- A study involving a University of Glasgow cancer specialist has found that using Herceptin increases survival rates among those with stomach cancer.

Final findings from ToGA, the largest ever randomised study of an agreesive form of stomach cancer, have shown that adding Herceptin - the breast cancer drug - to standard chemotherapy prolongs the lives of patients with aggressive gastric cancer by over four months to 16 months. This represents a 35% increase in survival compared to chemotherapy alone.

The study involved Jeff Evans, Professor of Translational Cancer Research at the university. Drug manufacturers hope the findings will mean patients suffering from the advanced gastric cancer will be able to receive Herceptin as part of their treatment. Herceptin, also known by the chemical name of Trastuzumab, is currently not licensed for the treatment of gastric or stomach cancer.

Based on the findings, Herceptin manufacturer Roche have submitted a label extension with the EU Health Authorities for the drug to be used in HER2-positive advanced gastric cancer and a decision is expected by early 2010.

“Trastuzumab’s impressive efficacy in improving patient survival represents a significant advance in how we treat patients with this aggressive type of advanced gastric cancer,” said UK investigator

Professor Evans. He added: “The results of the study mean that we need to establish accurate HER2 testing of all patients with advanced gastric cancer.”

The results were presented today (Friday 25 September) at the joint 15th congress of the European CanCer Organisation (ECCO) and the 34th Congress of the European Society for Medical Oncology (ESMO) in Berlin, Germany.

To date HER2 testing for gastric cancer patients in the UK is not routine and would need to be instigated prior to prescription of Herceptin in this patient group.

The sub-analysis of the international phase III study is among the group of patients whose tumours express higher levels of HER2, the same criteria currently recommended to define those patients with breast cancer as having HER2-positive disease.

Herceptin was the focus of intense media attention in 2005 when Patricia Hewitt, the then Health Secretary, called for women with early stage HER2-positive breast cancer to be granted access to the treatment and to early HER2 testing following data presented at the American Society for Clinical Oncology (ASCO) meeting showing that it offered women unprecedented survival benefits.

The drug’s efficacy in patients with gastric cancer demonstrates the important opportunity that a targeted medicine may offer patients and reinforces the principle that targeting HER2-positive tumours is not restricted to breast cancer.

Gastric cancer is the seventh most common cause of cancer-related death in the UK with nearly 8000 new cases diagnosed each year. It is associated with poor prognosis and early diagnosis is challenging because

most patients do not show symptoms in the early stage. Nearly 17% of stomach tumours express higher levels of HER2 based on the ToGA study, the largest prospective study to assess HER2 status in patients with advanced gastric cancer using a validated methodology.

“We are pleased to see the impressive benefit that the targeted therapy trastuzumab provides for patients with HER2-positive stomach cancer,” added William Burns, CEO of Roche’s Pharmaceuticals Division. “Trastuzumab will become the new standard of care and will make an important contribution to helping these patients.”

In the ToGA study, no new or unexpected side effects were observed. The most common side effects were diarrhoea (4.8%) and febrile neutropenia (3.4%).

Trastuzumab is already well established as the foundation of care for patients with HER2-positive breast cancer and now, based on the ToGA results, Roche has filed in Europe for use in treatment of HER2-positive gastric cancer.

The ToGA study is the first randomised Phase III trial investigating the use of trastuzumab in patients with inoperable locally advanced, recurrent and/or metastatic HER2-positive gastric cancer. Approximately 3,800 patients were tested for HER2-positive tumours and 594 patients with HER2-positive disease were enrolled into the study.

The rationale for conducting this trial was based on the knowledge that the targeted therapy trastuzumab has demonstrated unprecedented efficacy in the treatment of HER2-positive breast cancer. In addition, the overexpression of HER2 was also observed in stomach cancer. Targeted cancer therapies are drugs or other substances that block the growth and spread of cancer by interfering with specific molecules

involved in tumor growth and progression.

In the ToGA study, patients were randomised to receive one of the following regimens as their first line of treatment:

• A fluoropyrimidine (capecitabine or intravenous 5-FU) and cisplatin every 3 weeks for 6 cycles. Most patients were receiving capecitabine and cisplatin as chemotherapy

• Trastuzumab 6mg/kg every 3 weeks until disease progression in combination with a fluoropyrimidine and cisplatin which was stopped after a maximum of for 6 cycles

The primary objective of the study was to demonstrate superiority in overall survival of the trastuzumab-containing treatment arm compared to the chemotherapy alone arm. The pre-planned interim analysis was triggered by the occurrence of 347 events. Secondary endpoints for the study included progression-free survival, overall response rate, duration of response, safety and quality of life. In the ToGA study, no new or unexpected side effects were observed.

Provided by University of Glasgow