CANCER RESEARCH UK

Cancer Research UK response to the National Institute for Health and Clinical Excellence's Appraisal Consultation Document:
Trastuzumab for the treatment of HER2-positive metastatic gastric cancer

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At Cancer Research UK we are very disappointed that trastuzumab will not be available to patients with metastatic gastric cancer in England and Wales. This treatment offers a significant and meaningful improvement for patients and is a real step forward in the systemic treatment of stomach cancer.

Results from the ToGA study, included in NICE's deliberations, clearly demonstrated a clinically significant survival advantage for the addition of trastuzumab to chemotherapy in HER2 positive gastric cancer. Trastuzumab is now globally accepted as standard care for this disease.

Every year around 7,900 people are diagnosed with stomach cancer in the UK. Stomach cancer has an incidence rate of 8.9 per 100,000 and a mortality rate of 5.5 per 100,000 population in the UK. Currently prognosis is poor.

Trastuzumab is indicated for use in patients with metastatic gastric cancer who have not previously received treatment for metastatic disease and whose tumours have HER-2 overexpression. It is administered intravenously three weekly until disease progression providing it is well tolerated. It is the first biological drug for use in gastric cancer.

We would like to raise objection with NICE's decision on three grounds.

Firstly, NICE has accepted the efficacy of the treatment. The quality of the evidence submitted was accepted by the committee. This showed that trastuzumab in addition to chemotherapy offered a 4.2 month improvement in survival (16 months in trastuzumab plus chemotherapy compared to 11.8 months in chemotherapy alone group). Trastuzumab also improved secondary outcome measures. Progression-free survival increased from 5.2 months to 6.7 months and overall response rate increased from 34.5% to 47%. These are both clinically and statistically significant.

Secondly we do not believe that Epirubicin can be used as an alternative to trastuzumab. Epirubicin is greatly more toxic than the antibody, especially in terms of mucositis and myelosuppression. Even if the trial results had not shown additional benefit from trastuzumab treatment the antibody would still be greatly preferable.

Finally we believe it is inappropriate of NICE not to apply the end of life criteria to this treatment. The small number of patients with gastric cancer brings this clearly inside the limit for the end of life criteria. The short life expectancy of these patients coupled with the extension of life offered by trastuzumab over other treatments should make this drug a good candidate for inclusion.

We are deeply disappointed with this decision in the face of the first real step forward in the systemic treatment of stomach cancer for more than a decade. We hope that NICE will now work with the manufacturer to reach an agreement that will make this drug available to patients on the NHS, so that the UK isn't left behind while the rest of the world benefits from this advance in treatment for gastric cancer.

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