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Avastin the only biologic to show overall survival benefit in some patients with colorectal cancer

New data confirms Avastin as the only biologic to demonstrate overall survival when used first-line in metastatic colorectal cancer patients with K-RAS (wild-type) gene status.

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Basel, September 16, 2008: Avastin (bevacizumab) remains the only biologic to provide overall survival (OS) benefit when used as first-line treatment in combination with chemotherapy for patients with K-Ras wi type metastatic colorectal cancer (mCRC). Avastin's strong position was confirmed today following new da from a cetuximab [Erbitux] study presented at the 33rd Congress of the European Society for Medical Oncology (ESMO). “K-Ras wild-type” describes the normal gene status seen in around 60% of colorectal cancer patients where the K-Ras oncogene has not mutated.

This confirmation of Avastin's survival benefit is important because overall survival is of key importance for patients with advanced colorectal cancer.

The data presented came from a cetuximab study called the CRYSTAL trial which showed that cetuximab combination with chemotherapy failed to deliver a significant overall survival benefit in either the general population or in patients tested for K-Ras status. In contrast, an earlier analysis of Avastin first-line in combination with chemotherapy achieved significant overall survival for over two years (27.7 months) for patients with mCRC with K-Ras wild-type. Avastin therefore remains the best treatment option for patients with mCRC, regardless of oncogene mutations (e.g. K-Ras).

"Extending the lives of my patients remains a key goal for me as a treating physician" said Dr Mark Kozloff Associate Professor, Department of Oncology, University of Chicago, School of Medicine, US. "Avastin is the only biologic in combination with chemotherapy which allows us to achieve this essential outcome and should therefore be used first-line in the majority of patients with metastatic colorectal cancer regardless o their K-Ras status".

Main findings from CRYSTAL were:

· There was no statistical difference in overall survival (OS) in the K-Ras wild-type population - the study wa negative for this secondary endpoint (24.9 vs. 21.0 months in the cetuximab and control arm respectively) (HR 0.84, p 0.22)

· There was no statistical difference in OS in the general study population - the study therefore failed to me this key secondary endpoint (19.9 vs. 18.6 months in the cetuximab and control arm respectively) (HR 0.9 p 0.30)

Main outcomes from pivotal Avastin 2107 study which demonstrated Avastin's superior K-Ras data:

· Avastin provides a statistically significant OS advantage in the K-Ras wild-type population (27.7 vs. 17.6 months in the Avastin and Control arm respectively) (HR 0.58, p 0.04)

· Avastin also provides statistically significant improvements in the time patients live without their disease

worsening for both K-Ras wild-type (PFS improved by 82%, from 7.4 to 13.5 months, hazard ratio: 0.44, p<0.0001) and K-Ras mutant patients (PFS improved by 69%, from 5.5 to 9.4 months, hazard ratio: 0.41, p=0.0008).

· Avastin provides a statistically significant gain in OS in the general population (20.3 vs. 15.6 months in the Avastin and control arm respectively) (HR 0.66, p<0.001)

· The overall survival benefit of Avastin has been confirmed in two large community-based studies (First BEAT / BRiTE), including some 4,000 patients

In January 2008, Avastin received a broad label in the EU allowing it to be used in combination with fluoropyrimidine-based chemotherapy for first and later treatment lines in patients with mCRC. This means that virtually all patients with metastatic colorectal cancer have access to Avastin's benefits.

Additional information

www.avastin-info.com
www.Roche.com
www.thenewsmarket.com (video clips about Avastin in broadcast standard, free of charge)

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