Anti-interleukin-1 alpha antibody MABp1 improves outcomes significantly over placebo

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A novel anti-interleukin 1-alpha antibody has shown a significant impact on symptoms, and a high level of safety and tolerability in patients with advanced colorectal cancer, according to phase III data presented at the European Society for Medical Oncology's 18th World Congress of Gastrointestinal Cancer in Barcelona, Spain.

Xilonix is the first monoclonal antibody immunotherapy to specifically target and neutralize interleukin-1 alpha (IL-1α), one of the most potent inflammatory substances manufactured by the body or tumour cells.

"IL-1α in tumours promotes angiogenesis, helping to provide crucial blood supply for tumour growth, and it can also send the body's metabolism out of control, causing it to burn muscle and lose weight," said lead investigator Dr Tamas Hickish. At the same time, IL-1α effects on the brain can cause the fatigue, anxiety and anorexia associated with advanced cancer.

The study enrolled 309 patients with metastatic colorectal cancer whose disease had not responded to standard chemotherapy with oxaliplatin and irinotecan and who showed a high degree of symptoms, functional impairment, weight loss or elevated systemic inflammation.

In addition to trialing the new agent, researchers also implemented new criteria for objective response based on control of symptoms, which were developed in collaboration with the European Medicines Agency' Scientific Advice Working Group. These criteria were applied in

conjunction with dual-energy X-ray absorptiometry and EORTC-QLQC30 to assess disease control.

Patients were randomized them in a 2:1 ratio to MABp1 with best supportive care, or placebo and the same.

Treatment with MABp1 was associated with a significant 76% relative increase in clinical response rate. Patients who showed a clinical response lived almost three times as long as those who did not respond (11.5 months vs. 4.2 months).

Researchers also found that measures of improved health status correlated with improvement in almost all other self-reported and laboratory-based measures of health, including with improved control of tumor-related white blood cell activity and reduced systemic inflammation.

There were also one-quarter fewer serious adverse events in the treatment arm of the study compared to placebo.

"These data suggest Xilonix is very well tolerated, and has the potential to meet the real and urgent need for more effective, less toxic therapies for patients with advanced colorectal cancer," Dr Hickish said.

"This study also provides the first evidence that health status can actually be used to measure efficacy of anti-tumour therapy in advanced, refractory colorectal cancer, and that clinical responses based on health status can be a predictor of overall survival benefit."

More information: Abstract O-027 - 'A pivotal phase 3 Trial of MABp1 in advanced colorectal cancer' will be presented by Dr. Tamas Hickish during Session XIX: Colorectal Cancer, on Saturday, 2 July 2016, 11:15 AM (CEST).

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