Premier Insight 258

Glioblastoma Drug Study Yields ‘Unexpectedly Huge’ Advance

A three-nation study of a treatment for recurring glioblastoma showed the therapy more than five times as effective as the typical protocol, an unexpectedly large advance in fighting these aggressive brain tumors. But it was a long road, and the drug’s efficacy was a big factor in extending the trial to five years — nearly twice its expected duration.

Yes, recruiting was time consuming — it took 21 months to find the 84 patients who were ultimately randomized and treated in this Phase II evaluation of an antibody-like human fusion protein. And it took extra effort to ensure that devices used across more than two dozen study sites were accurately calibrated.

Arresting tumor growth

But no factor was more significant than the drug’s own effectiveness. While 3.8 percent of patients treated with radiotherapy alone survived six months with no tumor progression, a remarkable 20.7 percent of those receiving the new compound plus radiation saw no tumor growth.

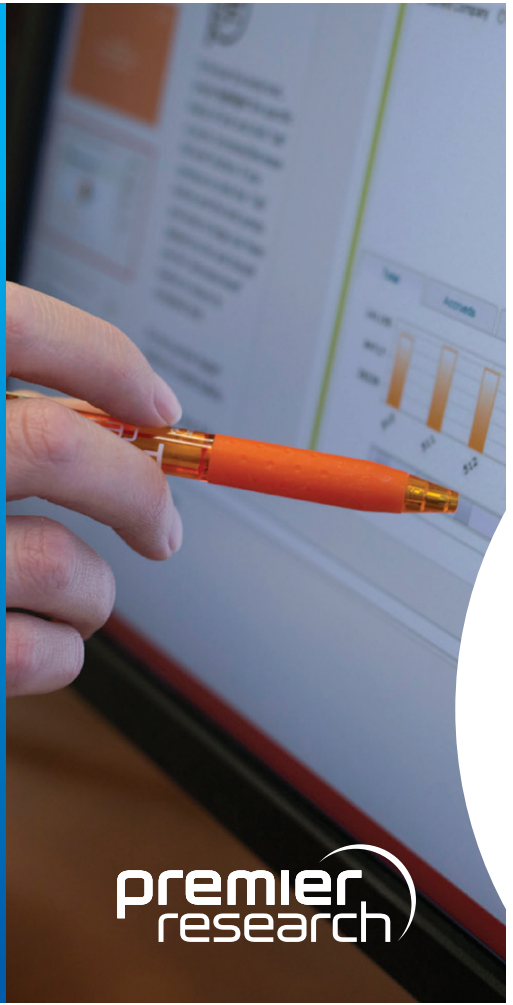
Quality of life was better, too: Two-thirds of patients getting the combined therapy said theirs maintained or improved, while the same percentage of the other group said it got worse.

What’s more, half of the combined-therapy patients were able to reduce or stop use of corticosteroids, compared to 28 percent of those who received just radiation. The sponsor, a European biotech company, called the results “an unexpectedly huge step forward” in overcoming the limited efficacy of current treatments and invited Premier Research to continue its work and bid for the pending Phase III study.

Uncommon depth of experience

We have worked with thousands of patients and have experience with just about every type of cancer. With strong ties to leading cancer centers and specialists in the U.S. and Europe and an extensive database of feasibility and study metrics, we have the expertise to guide your oncology research.

ONCOLOGY



Tumor Drug Shows Five Times the Effectiveness of Typical Therapy

Study Description:
Phase II randomized, open-label, multi-center study of weekly compound dosage (antibody-like fusion protein) + reirradiation vs. reirradiation in the treatment of patients with first or second progression of primary glioblastoma multiforme.

Therapeutic Area:
Oncology.

Indication:
Primary glioblastoma multiforme.

Geographic Scope:
33 sites across Germany, Russia, Austria.

Patient Population:
107 patients screened, 91 enrolled and randomized, 84 treated.

Enrollment Period:
21 months.

Outcome:
Sponsor is pleased with the results and has invited Premier Research to continue its work and bid for the pending Phase III study.

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