Ibrutinib continues strong showing against mantle cell lymphoma

June 19 2013

In a major international study led by researchers at The University of Texas MD Anderson Cancer Center, the targeted therapy ibrutinib continues to show remarkable promise for the treatment of relapsed or refractory mantle cell lymphoma (MCL).

The most recent interim findings of the 18-center Phase 2 study were published today in the *New England Journal of Medicine*. Previous interim findings were presented in December 2012 at the 54th American Society of Hematology Annual Meeting and Exposition.

Unprecedented results, fewer side effects

"This oral inhibitor of the Bruton's tyrosine kinase in the B-cell receptor pathway is the most important breakthrough to date in the treatment of mantle cell lymphoma," said Michael Wang, M.D., associate professor in MD Anderson's Departments of Lymphoma and Myeloma and Stem Cell Transplantation and Cellular Therapy. Wang is lead author of the trial.

"It is an oral drug, taken once a day, and its side effects are not severe. Yet it can achieve more than previous combination chemotherapy approaches. Our results constitute excellent news for our patients and patients around the world."

The ongoing trial of oral ibrutinib in patients with heavily treated

relapsed or refractory MCL has maintained a response rate as high as 70 percent - better than any other single agent ever tested in the challenging disease – with milder side effects than other treatments.

Targeted approach to dangerous disease

MCL is a rare and aggressive B-cell subtype of non-Hodgkin lymphoma that, according to the Leukemia and Lymphoma Society, accounts for 6 percent of non-Hodgkin cases. Despite high response rates to initial highly toxic combination-drug chemotherapy, patients often relapse.

The B-cell receptor pathway is critical in B-cell lymphoma, and Bruton's tyrosine kinase (BTK) is an essential component of this pathway. Ibrutinib targets the BTK molecule, causing cell death and decreasing cellular migration and adhesion in malignant B-cells.

In this study, patients were given 560 mg daily ibrutinib in continuous 28-day cycles until disease progressed or side effects became intolerable. To date, 111 patients have participated in the study.

Seventy-seven percent had stage 4 disease, and the median number of prior treatments was three.

Ongoing results continue to show promise

In the past six months, ibrutinib has continued to show excellent results. With a median follow-up period of 15 months:

- Overall response rate was 68 percent
- Complete response rate was 21 percent
- Partial response rate 47 percent

Response and complete remission rates improved with longer duration of treatment.

Among the 75 patients who responded, median:

- Response duration was 18 months
- Time to response was two months
- Progression-free survival was 14 months

Most side effects were minor and included diarrhea, fatigue, upper respiratory tract infections, nausea and rash. Grade 3 or higher effects included low white cell blood counts, anemia and diarrhea.

Next steps

Wang believes further investigation of ibrutinib as a first line therapy and in combination with other targeted therapies and traditional cytotoxic agents is essential.

"This drug, which is the safest option we have for MCL, shows unprecedented durable single agent activity," he said. "The favorable toxicity profile also implies that ibrutinib provides the opportunity for less intense and more effective regimens. The long-term impact of ibrutinib definitely warrants further clinical testing."

Provided by University of Texas M. D. Anderson Cancer Center

Citation: Ibrutinib continues strong showing against mantle cell lymphoma (2013, June 19) retrieved 27 April 2024 from https://medicalxpress.com/news/2013-06-ibrutinib-strong-mantle-cell-lymphoma.html

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