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Gilead to halt phase III study of leukemia drug

October 10, 2013 | News | By BioSpectrum Bureau

Singapore: Gilead Sciences plans to halt phase III study evaluating idelalisib in previously-treated chronic lymphocytic leukemia (CLL) patients who are not fit for chemotherapy.

Idelalisib is an investigational, highly selective and potent oral inhibitor of phosphoinositide 3-kinase (PI3K) delta. PI3K delta signaling is critical for the activation, proliferation, survival and trafficking of B lymphocytes and is hyperactive in many B-cell malignancies.

The recommendation is based on a predefined interim analysis showing highly statistically significant efficacy for the primary endpoint of progression-free survival in patients receiving idelalisib plus rituximab compared to those receiving rituximab alone.

Gilead has informed the US FDA of the plan to end the study and will engage in a dialogue with the FDA regarding a regulatory filing in CLL. Ã?Â¢Ã¢â??Â¬Ã â??Given the significant unmet medical need in CLL, particularly in this population of patients who are not fit for chemotherapy, we are pleased that idelalisib has shown a clinically meaningful benefit for patients,Ã?Â¢Ã¢â??Â¬Ã?Â• said Dr Norbert W Bischofberger, executive VP, R&D and chief scientific officer, Gilead.

Ã?Â¢Ã¢â??Â¬Ã â??This is the first phase III study to report positive results for a new class of targeted therapies that inhibit B-cell receptor signaling as a major component of their mechanism of action, an important area of focus in the development of chemotherapy-free regimens in CLL and other B-cell malignancies. We extend thanks to the investigative sites and to the other research collaborators participating in this study, as well as to the patients who volunteered, and we look forward to sharing these data with the hematology community,Ã?Â¢Ã¢â??Â¬Ã?Â• said Dr Bischofberger