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Jazz Pharma advances recombinant crisantaspase development program

08 August 2019 | News

Pivotal Phase 2/3 study expected to initiate later this year in collaboration with Children's Oncology Group

Ireland based Jazz Pharmaceuticals plc has announced that the Phase 1 study of its recombinant crisantaspase molecule, JZP-458, met its efficacy and safety objectives. The company plans to initiate a single-arm, pivotal Phase 2/3 study evaluating JZP-458 as a potential treatment option for patients with acute lymphoblastic leukemia (ALL) or lymphoblastic lymphoma (LBL) who are hypersensitive to *E. coli*-derived asparaginase products.

"Jazz is committed to the ALL patient community, and we are pleased to advance this development program with the goal of bringing a new treatment option to ALL and LBL patients who are hypersensitive to *E. coli*-derived asparaginase products as soon as possible," said Robert Iannone, M.D., M.S.C.E., executive vice president, research and development of Jazz Pharmaceuticals. "Following a meeting with the U.S. Food and Drug Administration, we are finalizing the Phase 2/3 study protocol in collaboration with the Children's Oncology Group and plan to initiate the study later this year."

A recombinant crisantaspase Phase 1 study in healthy volunteers in the U.S. met safety and efficacy objectives with efficacy based on measurement of serum asparaginase activity levels. Results of this Phase 1 study will be submitted for presentation at an upcoming medical meeting.