ASHER CHANAN-KHAN: My name is Asher Chanan-Khan, and I'm the Chair of Hematology and Oncology and Associate Director of Center for Individualized Medicine at Mayo Clinic in Florida.

The HELIOS study is a landmark study that was conducted to evaluate the value of ibrutinib, a new and novel drug recently approved by the FDA for patients with relapse and refractory CLL or chronic lymphocytic leukemia. The investigators in the HELIOS group sought out to answer whether this particular drug could be combined with chemotherapy and whether that would have an impact in overall response rate, as well as durability of remission in these patients, who otherwise have limited treatment options.

It is very exciting to know that while ibrutinib by itself was an effective treatment, when combined with chemotherapy in relapse and refractory patient population, it made a huge impact in the outcomes of patient with relapse CLL. This study was so successful that it had to be stopped earlier on because those patients who were not randomized to receive the investigational drug, or ibrutinib, were noted to have an adverse outcome. Addition of ibrutinib to the BR regimen actually demonstrated that more than 80% of the patients would go into remission versus about 60-plus percent in those who did not receive it. Not only that, the risk of progression and death from the disease was significantly decreased if patient received ibrutinib in combination with their chemoimmunotherapy. This is an amazingly pivotal study that is poised to change the outcome of how we treat patients with CLL.

Although it is important to know that CLL remains an incurable disease, the excitement brought forward by this particular clinical trial demonstrate one more time that ibrutinib is an effective treatment and as an addition, another new way to treat and control disease for a longer period of time. For patients who require chemoimmunotherapy as part of their therapy for relapse CLL, this study proves that they should concurrently receive ibrutinib, because that combination is far more potent and result in more durable remission and perhaps decrease in the incidence of death from this disease.

It's very exciting to note that on the interim analysis of the study, patients who had received ibrutinib as part of their chemotherapy regimen did significantly better, prompting us to evaluate that this study should be stopped earlier on and the patients who were randomized not to receive the drug should be extended the opportunity to have this drug. This seldom happens in cancer, and when it does happen, as a cancer researcher, it is extremely rewarding and exciting. This study is poised to make a difference in how we treat patients with relapse CLL.

Over the last two years, we have already learned that ibrutinib is a very effective drug for patients who have relapse chronic lymphocytic leukemia. What we had not known today but that can it be effectively, safely combined with chemotherapy? And if so, would it be more meaningful for patients to get such a combination? It's been so rewarding to see the results of this study, because for the first time, in a large, randomized placebo controlled trial, this point has been proven that ibrutinib, while given alone or also given in combination with chemotherapy can be highly effective for patients with chronic lymphocytic leukemia.