Efficacy by consolidation administration site: Subgroup analysis of a phase III study of CPX-351 versus 7+3 in older adults with newly diagnosed, high-risk AML

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Hi, I am Dr. Stuart Goldberg. I am a member of the Division of Leukemia at the John Theurer Cancer Center in Hackensack, New Jersey, and I am here at ASCO 2017. Our group had the honor of being part of the group that has studied a novel agent known as CPX-351. At this meeting, we are presenting additional findings from the registration trial on **CPX versus 7 and 3 conventional chemotherapy in older adults with acute myeloid leukemia**.

We are focusing at this meeting on a subgroup analysis and looking at the site of care for consolidation. CPX is a novel agent. For many years, we have used standard cytarabine in combination with either daunorubicin or idarubicin in a combination known as 7 and 3 to treat most of our patients with AML. CPX is a liposomal form of cytarabine and daunorubicin. One of the advantages of CPX by putting it into liposome is it every little droplet will have a 5:1 molar ratio of cytarabine to daunorubicin, so that the optimal concentration is delivered to every cancer cell, and this hopefully increases the effectiveness of the agents. It is a new drug delivery system of two conventional agents we have looked at for many years and used as treatment for patients with AML.

At last year's meeting, we showed in a randomized trial in older adults with secondary AML (AML developing out of myelodysplasia, AML with high-risk cytogenetics) that the combination of the drug CPX beat the combination of 7 and 3. Specifically, at 1 year, 42% of the patients treated with CPX were still alive, compared to only 28% for the patients treated with conventional 7 and 3. At 2 years, three times more patients with CPX are still alive. At this year's ASCO meeting, we are showing that in the CPX arm, patients would receive consolidation as a 90-minute infusion in the office, as opposed to standard 5 and 2 consolidation which required hospitalizations. We could cut down the number of hospitalizations for patients treated with CPX, and yet, the outcomes – even in the patients who received outpatient therapy – were maintained. The site of administration did not change the outcomes, and therefore, our patients do not need to go through hospitalization, and it will hopefully reduce costs. CPX is hopefully going to the FDA this year, and we may see a new agent for us in the treatment of AML this year.