



ASH 2017 Atlanta: Dr. Matthew Davids on the Amazing Results of Ibrutinib in Combination with FCR for Frontline CLL -Transcription

Dr. Brian Koffman – Hi. I'm Dr. Brian Koffman. I'm a family doctor and a CLL patient, myself. I'm here at the first day of ASH 2017 in snowy Atlanta.

Dr. Matthew Davids – I'm Matt Davids. I'm a CLL specialist at Dana Farber Cancer Institute and Harvard Medical School in Boston.

BK – Dr. Davids, you've been involved in the research of using some traditional chemo-immunotherapies with a novel agent... FCR and ibrutinib specifically. Can you tell us about your research in that regard?

MD – Yeah. So, at this meeting we're presenting data on our ibrutinib plus FCR study for young, fit CLL patients. So, this is a fairly small group of CLL patients. They're under age 65, and they tend to be very fit and able to tolerate aggressive therapies. And the idea here was to put together our most powerful chemo-immunotherapy regimen, FCR, with a very promising drug, ibrutinib, which is very active, even for high-risk patients, even patients with un-mutated IGHV, and to try to really maximize the response in terms of depth of response and durability of response. And we've seen some pretty striking results so far.

BK – Can you share some of those with us?

MD – Sure. So, I think the most striking result we've had is the rate of bone marrow MRD negativity on our study. We've achieved an 83% rate of bone marrow MRD negativity.

BK – Oh, my gosh.

MD – To our knowledge, that's the highest rate for any regimen ever in CLL. And our study includes both mutated and un-mutated IGHV patients, and the rate is a little bit lower in the unmutated patients, but it's still 71%. And so, we think these are going to be very durable responses. Obviously, we don't know if these are going to be curative responses, but it may be for a subset of patients.

BK – And any unexpected toxicities putting these two medications together?

MD – Fortunately, not. So, we've seen some of the usual toxicities you'd expect from ibrutinib and from FCR, but certainly no additive or synergistic toxicities. This regimen has been well-tolerated. Nearly all the patients have been able to get the full six cycles of FCR. And I think that does speak to the young, fit patient population, and also to the mandatory use of growth factor support and antimicrobial prophylaxis.

BK – So, you're aggressively managing the potential adverse events and side effects with these patients by being ahead of the curve in terms of infections, and ahead of the curve if their blood counts get low... the red blood cells or the neutrophils get low.

MD – Exactly.



BK – So, let me just push on one point on this. What do you say to the argument of people who say, “Well you know chemo is dead in CLL, and you're adding a chemo regimen to a non-chemo drug”? How do you respond to that? And from your colleagues and from patients, I'm sure you get feedback.

MD – Sure. So, I think where we need to look is for the long-term data. And right now, we don't have long-term data for novel agents. We have up to about five years of follow-up for some patients. But with FCR, now we have patients fifteen years from their original six months of FCR, and they remain in complete remission. So presumably some of those patients are cured. So, I certainly also advocate performing studies of novel agents only without the use of chemotherapy, but I can't imagine how we could throw out the only curative therapy we know for CLL. So, I think also trying to add novel agents to chemotherapy makes sense. We need to pursue both in clinical trials, and then eventually, hopefully, we can compare them head-to-head to really find out what's the better strategy.

BK – Dr. Davids, thanks so much for what you're doing.

MD – My pleasure.

BK – Thanks.