

Company Name: Array Biopharma Inc. (ARRY)
Event: Jefferies 2018 Global Healthcare Conference
Date: June 6, 2018

<<Eun Yang, Analyst, Jefferies & Company>>

Okay, I think we can start. Thanks for joining us today. This is Eun Yang, a Biotech Analyst with Jefferies. Joining me today is Array management team, Ron Squarer, CEO of the company; and Andrew Robbins, Chief Operating Officer. So this is going to be a fireside chat format. And so if you have any questions during the discussion, please raise your hand because there is not going to be a breakout session at the end of this.

So before we start the discussion, Ron is going to give us a brief overview of the company.

<<Ron Squarer, Chief Executive Officer>>

Yeah. Thank you, Eun, and thanks for everyone who is here. All right, so don't – we just have a corporate slide up here, but I will give just a brief overview where we are as a company. And first just to mention that I will be making forward-looking statements and that we encourage investors to take a look at our recent Ks and Qs for a full discussion of risk.

So we are waiting patiently for the approval of our two products that we plan to commercialize in BRAF melanoma. We have a PDUFA date at the end of this month, certainly ready to go earlier. Our entire commercial organization is in place and ready to go. We did have a great ASCO, where we've just come from a couple of days ago, a highlight of course was that we did share the overall survival data for the COLUMBUS trial.

And while we didn't think that it was remarkable given that we'd already announced the overall survival results by press release a few weeks earlier. We do know that there were a number of investors that were interested in what's their anything anomalous, anything concerning about the patient populations of our study or the treatment before or after the study. And the good news is that there was not. So one of the questions people would naturally ask is, Array's combination with studies a little bit later than their competition with their more post-treatment I/O that might explain what was a remarkable OS result.

So the result came in over 30 months at 33.6 or almost three years in median overall survival, the highest ever observed with the use of MEK and RAF combination. And the use of I/O agents after the study was similar to prior Phase 3 trials run with other MEK and RAF. Perhaps the other a bit of information for what it's worth, the trial included an arm of encorafenib or RAF inhibitor alone have its single agent maximum tolerated dose of 300 milligrams, we can't give more unless we add the MEK.

And we'd already shown that it beat vemurafenib, the historic standard of care RAF inhibitor statistically or with a very low P value in terms of PFS and that we're able to show that regarding OS as well with a very low P value. We had a head-to-head direct comparison between

ENCO300 and vemurafenib suggesting in the minds of some KOLs that it is – it has very special properties. Now you may know by now that we increase the dose of encorafenib in combination with the MEK 50% to 450 that is our treatment regimen.

And so, we're trying to put together all of the rationale for why these results are legitimate, are consistent and explainable. So we have the highest ever reported progression free survival at 15 months, the highest ever reported overall survival at almost three years. And then a tolerability profile, which we think leads to a very high dose intensity and a better patient experience versus other option.

So we have a slide up here now. And so, I'm referring here to the COLUMBUS Trial readouts and the fact that the next step is regulatory approval assuming everything goes well and we're not aware of any serious issues and then a commercialization soon after. And we do have Andy here, who can talk about our commercial preparedness there.

Now in just a couple of weeks, we will be providing an update on the Phase 3 study of the same two drugs in BRAF colorectal. In the BRAF colorectal, the percent of colorectal, that's driven by the BRAF-mutation is lower than in melanoma, in melanoma its 50%, in colorectal its 10% to 15%, but there are more colorectal patients. And so, there're actually more BRAF-colorectal patients for us to treat than melanoma.

And we've already shown a remarkable overall response rates using the combination of our MEK or RAF cetuximab. We've already shown that coming in at almost 50% response rate in the second-line at over 60%. These are remarkable when you consider that the current approved standards of care are single digit response rates. We also showed PFS earlier this year coming in at eight months, which is remarkable when you consider the current available standards of – approved standards of care come in at only two months. But we haven't talked about OS. We did schedule the ESMO GI meeting, because it is the last big meeting till much later in the year, we will take a look at the data that we have and present what we can in terms of an update, which may include a discussion of overall survival.

That study is recruiting well. We're still expecting it to complete recruiting around the end of this year. We do expect to introduce an interim analysis of response rate, a durable response rates or PFS that we would have around when the study is fully recruited or well recruited to pursue an accelerated approval, while the primary endpoint of OS continues to mature.

So beyond a BRAF melanoma launch, which is pending, we're already getting close to the end of the BEACON CRC Phase 3 trial. There's a lot going on at Array, but the last thing I'm going to mention is that we continue to pursue three partnerships examining the potential utility of MEK inhibitor in combination with immunotherapy.

Most important and most advance is collaboration with Merck and BMS, looking at their PD-1s. Now I think folks are probably well aware that IMblaze did not have a successful study and we're hoping to learn more about the IMblaze result. This is Roche cobicicicel in MSS colorectal, which is almost all of colorectal. We want to learn more about it, but our approach with the Merck and BMS partnerships are very different in a number of ways. First, we are combining

with PD-1s in the form of pembro and nivo. And there are some who believe that PD-1 is a preferred approach. These are certainly the leading checkpoint inhibitors in the market today.

Next, we are studying earlier lines of therapy than Roche. Roche was in late line to even salvage populations. With Merck it is a first and second line study. With BMS it's the second and third line study. Next, we are combining with a third agent regimen, in the case of Merck in order to treat first and second line patients; they are using FOLFOX or FOLFIRI respectively. In the case of BMS, we are adding ipilimumab. And then finally, with the BMS study, we are also selecting for rash patients it is about half of the MSS CRC patients based on a scientific rationale that there maybe greater activity there, we can also expand the population latter if it's worthwhile. But, those are the multiple sort of layers of differentiation in our approach.

The Merck study is sponsored and conducted by Merck and paid for by them. They are moving very quickly, I've been impressed with the pace of the study given how much is going on at Merck. And we are co-funding with BMS but we are running actually sponsoring and conducting the BMS collaboration. They are moving forward on a similar timeframe and that means that as we look forward to maybe around the end of the year, beginning in next year, next year we'll begin to consider whether we're seeing something important.

Now we caution because response rates may not be very high, PFS may not be very high. It may be more of an OS story. So, we won't want to make judgments about it too early but we're very excited to be moving in that direction with a very different approach than IMblaze.

Finally and more recently, we entered into a collaboration with Pfizer not in MSS colorectal but instead in pancreatic and lung. And there, we are looking at binimetinib our MEK inhibitor with their PARP based on the thought that MEK may potentate PARP. But also with their checkpoint inhibitor because of the hypothesis that MEK potentates PD1 and there will be an opportunity to even study these together but we're not able to discuss the details until Pfizer places this on clinicaltrials.gov, which we think is coming soon.

So they are paying for and conducting this trial. So for the most part we have very important research going on that could enable substantial upside and benefit to patients that is mostly being paid for and conducted by other companies, in the BMS case it's a joint effort.

So next step is ESMO GI in a couple weeks with some updated BRAF colorectal data. Then hopefully we'll hit our PDUFA and hopefully will be off to the races. And then over the year we – over the coming months we would expect to have perhaps an interim analysis on our BEACON CRC trial to begin to learn about MEK and PARP potentiation.

And then the cherry on top I would say is that sometime next year hopefully early next year you can look forward to a new Array invented IND in oncology we'll be discussing that product as we get closer to preparing to enter human trials. And you can expect us to – we're targeting one new IND in oncology a year using the incredibly productive research platform that we have maintained for many years now.

So that's a introduction and now I'm going to turn it over to Eun, who may have a question or two. And I'm sure we can take questions from the audience as well.

<<Eun Yang, Analyst, Jefferies & Company>>

Sure. So now I mean, big event for the company the PDUFA date for binimetinib and encorafenib BRAF melanoma by end of this year and it's widely expected that they are going to be approved. And you, Ron you mentioned that a whole commercial team is in place. So maybe I can ask you Andy. How – the clinical data is very impressive. This is the third entrant to the market in BRAF melanoma. So can you talk about how you expect the launch will go?

<<Andrew Robbins, Chief Operating Officer>>

Thanks, Eun. So first of all we see over the last 12 to 18 months that Roche [indiscernible] (0:12:02) have essentially withdrawn much of their promotional effort on their doublet. So we really see this in the United States, in BRAF melanoma as essential in Novartis and then assuming, we're approved Array as the two main choices from MEK BRAF therapy.

Based on the differentiation that I think we've demonstrated via our COLUMBUS trial both on efficacy benchmarks, as well as our tolerability advantage. I do think, we are bringing an offering to melanoma healthcare providers and patients, that they will see as attractive and potentially better than what is currently available.

So we as, you mentioned, have our entire commercial infrastructure in place including over 60 customer facing employees, across sales and medical and market access, who are ready to go as soon as they're given the green light. We also believe that in addition to our product profile and our therapeutic index, we have in place plans to put forward a very attractive, what we see is best-in-class patient assistance programs, which should help uptake of these products.

During the second half of 2018, certainly one of our big focuses will be on sharing with the payers, the approval, the label, the data from our trial, getting our drugs on policy and positions that's not disadvantage to the current available therapies, so we will be focused on trial with physicians, primarily in the early going. And then once, we climb the hurdle of getting on policy with payers then we will start focusing on market – total market share, total prescriptions in sales, probably in early 2019. So I think, we're well positioned, where cautiously optimistic and we're looking forward very much to FDA action.

<<Eun Yang, Analyst, Jefferies & Company>>

So how long do you think it will take to for those two products to get on to reimbursement policy on the payers?

<<Ron Squarer, Chief Executive Officer>>

Sure. So two things, it differs by payer. So certainly, there are some payers that are willing to meet rapidly and put you on policy within 45 to 90 days, while there are other larger players that

have more established meaning cadence or new product launch cadence closer to six months. So, we think it will be a stage process, depending on the size and who the payer actually is. But because of our patient population, the size of the population and the expected knowledge that MEK plus BRAF therapy works quite well in BRAF melanoma patients. We don't believe that it will be a significant challenge, even on payers that don't have us on policy, to actually get patients started on our combination.

So it is a joint effort, we're going to continue to go and promote. What we believe is a differentiated combo to all melanoma treaters in the U.S. starting day one, and then parallel, our market access team will do their best to get us coverage with the payers as rapidly as possible.

<<Eun Yang, Analyst, Jefferies & Company>>

So based on although it's cross study comparison based on the data, binimetinib and encorafenib data is quite impressive, as looks a superior to currently marketed doublets. But based on your discussion with the physicians, do they think that, bini and encore in fact superior drug is compared to others on the market. How they view the drug.

<<Ron Squarer, Chief Executive Officer>>

Yes, so perhaps I will start and Andy, you can weigh in as well. So I think a lot of this has depends on whether you're talking to thought leaders in KOL, at academic centers or community physicians. From the point of view of KOLs, I'll give you one example, following our ASCO presentation of OS. We did have Dr. Keith Flaherty from Harvard, present a webcast, which is on our website and we can make available. Now Keith is particularly relevant because he has been involved in all the MEK/RAF developments in history.

And so, he very clearly views, and he is very comfortable stating that he views this is a next generation offering and that it is in his words best-in-class. And so, I think that for those types of thought leaders, they're comfortable making these types of inclusions. And the exam centers are going to be very important not just from where scripts or prescriptions originate, but also in terms of influencing the community. So maybe I'll ask Andy to comment on the research we've done in the community setting and our messages there.

<<Andrew Robbins, Chief Operating Officer>>

Yeah, I'll just point out two other things to keep in mind. First, we're the only clinical experience where a single agent BRAF inhibitor has been tested against another single agent BRAF inhibitor, and in our case of encorafenib versus vemurafenib, we showed with a p-value less than 0.05, both on progression free survival, and now again at ASCO on overall survival that encorafenib looks superior to vemurafenib. So I think that is starting to raise eyebrows in the overall melanoma community as potentially the reason why our combination appears to be more efficacious.

To Ron's point, when we talk to the general community, while I would say that physicians are less aggressive about making cross trial comparisons on efficacy endpoints, they are very willing

to look across trials for tolerability differences. And it's hard to miss things like the Novartis combination with nearly 60% incidence of pyrexia or febrile syndrome, when we will have something in the teens, where the Roche combination having nearly 50% incidence of photosensitivity and skin toxicity, while we have 4% or 5% incidence of that adverse event.

They are not willing to chalk that up to anomalous data populations they do see that as a real differentiation. So again both on efficacy and tolerability without head to head data and of course, we won't be able to promote head to head, I do think there is a growing perception in the melanoma community that we have a superior offering.

<<Eun Yang, Analyst, Jefferies & Company>>

Any questions on melanoma site?

<<Ron Squarer, Chief Executive Officer>>

Maybe, I'll just mention that the current – since the market has dominated by Novartis. And Novartis continues to report sales that current run rate for Novartis, MEK/RAF is \$400 million annual run rate and then globally including the U.S. is \$1 billion. We do anticipate the continued growth, and we do think with our longer PFS at 15 months and our excellent tolerability profile, there may be growth with people using the Array combination for longer and higher doses that could grow that even further, just to give you a sense of what we are competing for out of the gate.

<<Eun Yang, Analyst, Jefferies & Company>>

Do you know what's kind of median duration for Novartis dabrafenib and BRAF melanoma?

<<Andrew Robbins, Chief Operating Officer>>

You're talking in sort of real world experience. Yes. We have seen data presented at quality of life conferences or other floor where world experience have been presented on mechanism of Tafinlar and it appears as though they're looking more on the order of five months plus or minus for median or mean duration of therapy in the community setting. That's substantially less than their reported median progression-free survival from their Phase 3 pivotal trials of around 11.5 months.

And so that knock down from the clinical trial setting to the community setting. We acknowledge, it will be interesting to see what that translates into for Array, clearly with what we believe is an improved tolerability profile. We'll be looking for a longer real world experience on median duration, which in addition to penetrating the market and capturing share, we have an opportunity, as I think Ron mentioned to grow the overall size of this market with longer durations of therapy.

<<Eun Yang, Analyst, Jefferies & Company>>

So we have about five minutes or so and I'd talk to you about the pipeline products. So, out of ASCO, you have a great presentation but also your partners have a great presentation and one that I want to highlight is AstraZeneca's data on selumetinib, another MEK inhibitor for NF1 orphan disease indication. So, first question to you, Ron is, are you planning to run a clinical trial for NF1 with binimetinib. And secondly, when you look at NF1 market size, I mean could it be potentially quite big and data is quite impressive. So can you talk about how your financial agreement with AstraZeneca?

<<Ron Squarer, Chief Executive Officer>>

Yeah. So, you're right that at ASCO, where there wasn't a whole lot of breakthrough data across cancer unfortunately. Array was quite pleased, because beyond our BRAF melanoma OS data, we were pleased to see a great data coming out of the Loxo partnership products from AstraZeneca and even in AKT at Genentech in triple-negative breast cancer and they're in two pivotal trials now. So, there is this in – the company's value was driven by successful launch in BRAF melanoma.

And I think the expectations are a bit low right now. I'm talking about peak, not first year, but peak. Getting BRAF colorectal right, which could be worth more than melanoma and then seeing these MEK, PD-1/PARP combos through. But royalties and milestones really help. And so I think the first one and most likely is going to be the track at Loxo because they have a PDUFA in November, milestone related to that potential royalties afterwards.

And then I would guess the next one's probably going to be selumetinib. And the results were amazing because the initial results from an earlier trial that only focus in tumor shrinkage had a 70% response rates in a disease that has responded to no other treatment for which a surgery is often not relevant other than tragically to amputate limbs.

And so they repeated that over 70% response rates. But now they were able to show powerfully statistically significant improvements in function. Specifically, they were focused on pain and on range of motion. And so we believe that is what it takes to get a rare disease approval. They are continuing to finalize their data to analyze it and clean it. And then we would hope they would pursue an indication and also it is our hope that they pursue value based pricing meaning a rare disease pricing.

This is a transformative treatment for these kids that changes potentially the course of their life, and it could be a multi-year intervention. So it could be quite valuable. All we're able to say is that the AstraZeneca collaboration pays up to double-digit royalties assuming commercial success, which could be relevant in this case.

And so we're very excited and look forward to them reaching the market. We have a dispute with them about neurofibromatosis, but it is in no way, it is not intended there to impede their ability to get this product to patients. It's really about a value discussion and if we're owed anything for it, we certainly aren't looking to regain the rights to selumetinib.

So, finally with binimetinib, because we expect to be on the market very, very soon again, in the coming weeks, we are studying binimetinib in – not in combination, in neurofibromatosis, there is a possibility that bini will be out there and available earlier. And so at least to give these kids an option is something that we would look forward to, trametinib presented some data at ASCO as well. It did look like their numbers were quite a bit lower; it was not a pivotal trial. So we think that ultimately selumetinib is going to be the leader in this really important field.

<<Eun Yang, Analyst, Jefferies & Company>>

So if you actually pursue binimetinib in NF, how the pricing will be differentiated between melanoma and NF1 market?

<<Ron Squarer, Chief Executive Officer>>

There's really not an opportunity most likely to differentiate pricing. We will be pricing for cancer. But again, our focus is going to be on cancer and we are assuming that AstraZeneca is going to focus potentially the entire product and franchise on NF1. We're just generating data in order, in the event that binimetinib is available to patients sooner that at least some of them will have access to the products, not something we would be able to promote. And then of course, it's just differential economics we get a royalty or some small direct sales. The real objective there is patient health.

<<Eun Yang, Analyst, Jefferies & Company>>

We have 10 seconds. Any questions?

<<Ron Squarer, Chief Executive Officer>>

Any 10-second questions?

<<Eun Yang, Analyst, Jefferies & Company>>

Okay. Thank you very much.

<<Ron Squarer, Chief Executive Officer>>

Great, thank you.