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PFE - Pfizer Inc to Acquire Array BioPharma Inc Call

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OVERVIEW:

On 06/17/19, Co. announced that it will acquire all outstanding shares of Array BioPharma's common stock for \$48 per share in cash for a total enterprise value of approx. \$11.4b.



CORPORATE PARTICIPANTS

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PRESENTATION

Operator

Good day, everyone, and welcome to the Pfizer Analyst and Investor Call to discuss proposed acquisition of Array BioPharma. Today's call is being recorded. At this time, I would like to turn the call over to Mr. Chuck Triano, Senior Vice President of Investor Relations. Please go ahead.

Charles E. Triano - Pfizer Inc. - SVP of IR

Thank you, operator. Good morning everyone, and thanks for joining us today on short notice to review our proposed acquisition of Array BioPharma, which we announced this morning. Today, I'm joined by Mikael Dolsten, our Head of R&D; Frank D'Amelio, our CFO; Andy Schmeltz, Global President and General Manager of Pfizer Oncology; and Chris Boshoff, our Oncology Chief Development Officer.

The slides that will be presented on the call can be viewed on our website at pfizer.com/investors.

As typical, before we start, I'd like to remind you that our discussions during the call will include forward-looking statements that are subject to risks and uncertainties that could cause the actual results to differ materially from those projected in these forward-looking statements. Additional information regarding these factors is discussed under the Disclosure Notice section in the press release we issued this morning as well as in Pfizer's 2018 annual report on Form 10-K, and Pfizer's quarterly report on Form 10-Q for the quarter ended March 31, 2019.



In addition, discussions during the call will also include certain financial measures that were not prepared in accordance with U.S. Generally Accepted Accounting Principles. Any non-GAAP measures presented are not, and should not, be viewed as substitutes for U.S. GAAP financial measures, have no standardized meaning prescribed by U.S. GAAP and may not be comparable to the calculations of similar measures at other companies.

For more information on non-GAAP financial measures, see Pfizer's 2018 financial report, which was filed as Exhibit 13 to Pfizer's 2018 annual report and Pfizer's quarterly report 10-Q for the most recent quarter ended March 31. We also urge you to read both the tender offer statement that will be filed by Pfizer with the SEC and the solicitation recommendation statement that will be filed by Array BioPharma with the SEC when they become available because they will contain important information, including terms and conditions of the tender offer, which has not yet commenced.

We'll now have prepared remarks from Andy, Frank and Mikael, and then we'll move into the Q&A session with the group. With that, I'll now turn the call over to Andy Schmeltz.

Andy Schmeltz - Pfizer Inc. - Global President, Oncology

Thanks, Chuck. Good morning, and thank you for joining us. We wanted to share with you some additional context regarding our planned acquisition of Array BioPharma, which we announced this morning. I'll begin with a few words concerning how Array aligns with our strategy and how it provides a unique value proposition for advancing Pfizer leadership in oncology.

The proposed acquisition of Array is well aligned with the strategic priorities by which we evaluate business development opportunities. Specifically, we look for opportunities to deploy capital in a disciplined way to efficiently create meaningful shareholder value. We look for opportunities to execute bolt-on deals, with the potential for mid- to long-term value creation as well as revenue and earnings growth. And we look for opportunities to strengthen individual businesses with capabilities and flagship medicines to enhance leadership positions in priority areas.

The proposed acquisition of Array meets all of these objectives. It has the potential to deliver breakthrough medicines that change patients' lives and enhances our long-term growth prospects as we look to strengthen and add durability to our growth profile for the next decade.

Now a few words about the compelling value proposition that Array brings to Pfizer. This proposed acquisition strengthens our Innovative Biopharmaceutical business and is expected to accelerate its growth trajectory, particularly in the long term. We have the rare opportunity to advance our oncology strategy and to augment our business with 3 value drivers: Value driver number one, in already-approved targeted oncology therapy, a combination of BRAFTOVI and MEKTOVI with significant long-term potential for growth through expansion into additional areas of unmet medical need; value driver two, a large portfolio of out-licensed medicines and molecules that are expected to generate significant royalties over the long term; and value driver three, a track record of a highly productive research platform with a promising preclinical portfolio. Let me talk about each of these value drivers in a bit more detail.

First, the BRAFTOVI and MEKTOVI combination. One of the most recent testaments of Array's highly productive R&D engine is the breakthrough combination of BRAF inhibitor, BRAFTOVI; and the MEK inhibitor, MEKTOVI. This combination of 2 targeted therapies is already approved for the treatment of advanced BRAF mutant metastatic melanoma and has a very attractive potential future lifecycle opportunities. BRAFTOVI and MEKTOVI are being investigated as a potential first-in-class combination for certain patients with metastatic colorectal cancer and have the opportunity to treat earlier stages of the disease.

Through the proposed acquisition of Array, Pfizer will set the stage to establish an industry-leading colorectal franchise with a potentially first and best-in-class combination that could have blockbuster revenue potential. This will further augment our existing leading positions in both breast cancer and prostate cancer.

The second value driver is royalties from out-licensed medicines. Array has an impressive track record of successfully discovering and developing small molecules and targeted therapies. Scientists from Array were responsible for the discovery of various breakthrough therapies that are now out-licensed to a number of high quality biopharmaceutical companies. Royalties from this portfolio are expected to continue to drive additional substantial value over time.



Last, but definitely not least, we are very excited by Array's strong research platform, which has generated promising -- a promising range of early stage molecule. Array's research team includes approximately 100 scientists at the research center in Boulder, Colorado. We will maintain Array's current structure and locations. Their R&D team in Boulder will be a stand-alone research unit to complement Pfizer's oncology research hubs. Now I'm going to turn it over to Frank who will take you through the financial details of the transaction.

Frank A. D'Amelio - Pfizer Inc. - CFO & EVP of Global Supply & Business Operations

Thanks, Andy. I'll provide a brief financial overview of the transaction. Under the terms of the agreement, Pfizer will acquire all of the outstanding shares of Array BioPharma's common stock for \$48 per share in cash, which represents a total enterprise value of approximately \$11.4 billion. As Andy pointed out, between the current commercial opportunity, the royalty stream and the R&D platform, there are several value drivers that supported our valuation here. In terms of financial impact, this proposed acquisition is primarily targeted to help strengthen our financial growth profile during the midterm with the potential for meaningful value creation during the mid-2020s. Given that context, we expect the deal to be approximately \$0.04 to \$0.05 dilutive to adjusted diluted EPS in each of 2019 and 2020, neutral in 2021 and accretive beginning in 2022, with increasing accretion anticipated thereafter. We expect to finance a significant majority of the deal with new debt and the remainder financed with existing balance sheet cash. And we don't see this transaction as encumbering potential future dividend increases or share repurchase activity. We will commence the tender offer shortly and the offer must remain open for at least 20 business days. The closing of the tender offer is subject to customary closing conditions, including required antitrust approvals, the tender of the majority of the fully diluted shares of Array BioPharma common stock. And we expect to close in the second half of 2019. And with that, I'll hand it over to Mikael.

Mikael Dolsten - Pfizer Inc. - Global President, Worldwide Research and Development and Medical

Thank you, Frank. I would like to take the opportunity to provide more detail about Array BioPharma's lead clinical programs BRAFTOVI and MEKTOVI. We are just about BRAFTOVI and MEKTOVI as an approved combination for the treatment of patients with BRAF mutant metastatic melanoma. And potentially a first and best-in-class medicine for the BRAF mutant metastatic colorectal cancers.

These are 2 tumors with a high prevalence and where the BRAF mutation plays an important role. In June 2018, FDA approved BRAFTOVI plus MEKTOVI for the treatment of patients with metastatic melanoma, who test positive for BRAF genetic mutation. The combination is also approved and launched in Europe and Japan. Melanoma is the third most common cancer among women and the second most common cancer in men between 20 to 39 years of age. 30,000 people are diagnosed with metastatic melanoma each year, approximately half of them harbor BRAF mutations. The initial market performance of BRAFTOVI and MEKTOVI has been strong, with the combination generating \$35 million of net sales in its third commercial quarter. We estimated, 1 in 3 new patients start the treatment on this combination.

And now, some background on BRAF mutant metastatic colorectal cancer. Colorectal cancer is the third most common cancer in the world, and the second most common cause of cancer death in the U.S. About 200,000 people are diagnosed with metastatic colorectal cancer each year, up to 15% of them harbor BRAF mutations. Metastatic colorectal cancer is a devastating disease and there are no approved targeted treatment options today for people with a BRAF mutated cancer. In late May, Array announced compelling interim results from the pivotal Phase 3 BEACON Trial for second- or third-line treatment of the BRAF mutated metastatic colorectal cancer. They intend to submit this data for regulatory review in the United States in the second half of 2019. This is truly exciting news for patients, and we believe there is also future opportunity to expand into earlier treatment settings. Please note that Array has commercial rights for BRAFTOVI and MEKTOVI product in North America and has out-licensed the rights outside of these regions to Ono for Japan and South Korea and Pierre Fabre in Europe and the rest of the world.

Now the BEACON trial. Here, you can see more detail on the compelling interim data from the pivotal Phase 3 BEACON clinical trial in patients with BRAF mutated metastatic colorectal cancer who have been unsuccessfully treated with 1 or 2 prior therapies. The study met its primary endpoint and showed statistically significant improvement in overall response rate and overall survival. The second- or third-line treatment with the BRAFTOVI triplet combination of BRAFTOVI plus MEKTOVI plus ERBITUX, the latter also known as cetuximab, reduced the risk of death by 48% compared to the current standard of care chemotherapy. These are truly encouraging results and the triplet combination could be the first chemotherapy-free targeted regimen for patients with BRAF mutant metastatic colorectal cancer. We believe that BRAFTOVI and MEKTOVI combination offer significant opportunities to expand into additional BRAF mutant solid tumors settings and expand its life cycle. The combination is being investigated in over



30 clinical trials across several solid tumor indications, and we expect to continue driving growth through the robust development plans started by Array. On the heels of the COLUMBUS trial which led to the melanoma approval and the registrational BEACON trial for the second- and third-line BRAF mutant metastatic colorectal cancer that he has mentioned, there is an ongoing single-arm ANCHOR trial for the first-line treatment of BRAF mutant metastatic colorectal cancer, which we expect to read out in the earlier 2020s. We plan to continue to look at the potential for indication expansion of BRAFTOVI and MEKTOVI in other BRAF mutated solid tumors and will pursue a tissue-agnostic approach enrolling patients across malignancies where the incidence of the BRAF mutation is more modest, including lung and pancreatic cancer.

In addition, we believe the combination has the potential to be effective in the adjuvant setting, for example, to prevent disease recurrence in patients who have undergone surgical removal of the tumors. Today, we are setting the stage to create a potentially industry-leading franchise for colorectal cancer alongside Pfizer's existing expertise in breast, prostate, lung and renal cancers. A key value driver for this proposed acquisition is Array's highly productive research engine. We are excited by the impressive track record of successfully discovering and developing innovative small molecules and targeted cancer therapies. As you can see on the right, Array has a large portfolio of attractive medicines that are licensed to leading biopharma companies. Array's research site in Boulder, Colorado includes more than 100 scientists. We will maintain the current structure, scientific talent and locations. We plan to establish Array's R&D team as a standalone research unit to complement Pfizer's leading oncology research hubs in La Jolla and Pearl River. We expect this will minimize disruptions and ensure that colleagues remain focused on the groundbreaking work.

We're enthusiastic about the promising range of early stage programs. Together with Array, we have an even more attractive opportunity to advance the most promising science, and we will be a strong force to deliver the next wave of breakthrough cancer treatment. Now I'm going to turn it back to Andy for some closing thoughts.

Andy Schmeltz - Pfizer Inc. - Global President, Oncology

Thank you, Mikael. In closing, this deal is a highly strategic fit for Pfizer. Specifically, it is consistent with our purpose to deliver breakthroughs that change patients' lives. It expands Pfizer's capabilities in oncology and brings a range of opportunities to create value. It sets the stage to establish leadership for the treatment of people with colorectal cancer. It augments Pfizer's R&D efforts in leading the next wave of targeted-cancer medicines in combinations. And finally, it enhances our long-term growth prospects.

In summary, we are creating compelling shareholder value through disciplined capital deployment, and we believe patients will benefit from this proposed acquisition for many, many years to come. Now we'll open it up to your questions.

Charles E. Triano - Pfizer Inc. - SVP of IR

Thanks, Andy. And operator, could we please poll for questions? Thank you.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Okay. Okay, your first question comes from Vamil Divan with Crédit Suisse.

Vamil Kishore Divan - Crédit Suisse AG, Research Division - Senior Analyst

So maybe just first one, you touched on this a little bit on the call, but just around the -- in your prepared remarks on the research engine and some of the steps you're taking, maybe you can just elaborate a little bit more on how you're trying to maintain that research engine within a much larger company now within Pfizer? And also specifically, is there any sort of retention packages that you've sort of set in place to maintain some of the key talent from Array? And then second question, just around -- in the slides you mentioned some potential other combination. Do you see -- are



there anything in the Pfizer pipeline right now that you see as being potentially attractive to sort of -- combine with what you're acquiring through Array?

Frank A. D'Amelio - Pfizer Inc. - CFO & EVP of Global Supply & Business Operations

We'll have Mikael answer that question.

Mikael Dolsten - Pfizer Inc. - Global President, Worldwide Research and Development and Medical

Yes. Thank you for the question. We are very impressed with the research engine that Array has. And clearly, what we think in dialogues with Array is to ensure that this productive culture and the way we are operating can continue in the most successful manner. And that's why we stated it will be an independent unit building on its process talents of today. Of course, in a company of the combined Array and Pfizer, there are encouraging deep knowledge in oncology, whether biology, chemistry and clinical regulatory, that would create a tremendous capability for the new Array to tap into as well as for Pfizer legacy to tap into Array. So we will ensure there will be one oncology enterprise but will empower unit that can execute such as the Array unit in Boulder, Colorado, supplemented with our expertise at other sites.

Clearly, one of the compelling opportunities combining oncology pipeline is to create combinations that can increase the response rate and durability. And you noted in our introduction that, that was part of Array's strategy themselves when combining BRAFTOVI and MEKTOVI. We see numerous opportunities in the Pfizer pipeline. I'll give example of compounds that may fit for this criteria given the advance of targeted therapy and its opportunity to combine with immuno-oncology agents, we are quite keen to note that our internal PD-1 RN-888 has now generated an encouraging profile in Phase 2 studies and is one example of drugs that can be combined with Array molecules. We have, in addition to that, several targeted therapies in Pfizer that will be candidates for that. Such details will be worked out together with Array scientists as this deal continue to advance. I'll ask Chris Boshoff to share some of his thoughts on the near-term opportunities in the clinical program.

Chris Boshoff - Pfizer Inc. - Chief Development Officer, Oncology

Thank you very much, Mikael. I think Mikael mentioned RN-888. This is a differentiated next-generation PD-1, currently administered subcutaneously 4 weekly, potentially up to 6 weekly. And this could be combined with a number of medicines, not only with BRAFTOVI and MEKTOVI, but also a number of medicines we've identified in Array's preclinical portfolio. Additional, although we haven't declared the preclinical portfolio from Array yet, there's other opportunities that we can see, including combinations with our CDK 4/6 franchise, including our next generation of CDK 4/6 inhibitors as well as with the next generation of HER2 ADC in our portfolio. Thank you.

Mikael Dolsten - Pfizer Inc. - Global President, Worldwide Research and Development and Medical

Thank you very much, Jason. I just wanted to say that the Array pipeline consists preclinical of a number of exciting drugs, and I know their management have indicated earlier that they expect that their pipeline can deliver about 1 IND annually, which we see as a very nice augmentation would appear to come and to grow our clinical pipeline from now and onwards.

Frank A. D'Amelio - Pfizer Inc. - CFO & EVP of Global Supply & Business Operations

And Vamil, you asked about retention. So we are taking actions in the area of retention. And obviously, retaining key talent here is a critical aspect of the deal.

Charles E. Triano - Pfizer Inc. - SVP of IR

All right. Thanks, folks. Next question, please.



Operator

Your next question comes from Chris Schott with JPMorgan.

Christopher Thomas Schott - JP Morgan Chase & Co, Research Division - Senior Analyst

All right, great. The first question I had was just elaborating a little bit more on where you see the combo positioning in CRC over time. I guess specifically, do you see the very impressive data you saw -- that second- and third-line data as de-risking the first-line opportunity? And when we think about patient sizing and commercial opportunity, can you just talk a little bit more about the opportunity in second and third line? And then if the drug was to move earlier in development, what would be the incremental, kind of, patient opportunity on that front? And then my second quick question was just a little bit more on just priorities for capital deployment post this deal. I guess specifically, as we think about business development. Just latest thoughts in terms of, should we think about the company taking a little bit of a break from M&A after this? Or is there still financial capacity to continue to look at bolt-on transactions like this going forward?

Frank A. D'Amelio - Pfizer Inc. - CFO & EVP of Global Supply & Business Operations

Thanks, Chris. I think we'll let Andy answer the first part of the question, and then I'll answer the second part. Andy?

Andy Schmeltz - Pfizer Inc. - Global President, Oncology

Sure. So the BRAFTOVI, MEKTOVI combination already approved in BRAF mutant metastatic melanoma is off to a great start, just nearing its first year of availability in the U.S. Here, there are competing BRAF, MEK agents but we see the uptake very robust based on the COLUMBUS trial results that demonstrated strong overall survival. That being said, in colorectal cancer, where the second line plus results were just disclosed in the BEACON trial, there are not other registrational trials from the other BRAF, MEK agents, combinations. And so here, we see not only the opportunity to replicate a best-in-class but certainly, a first-in-class opportunity in colorectal cancer. And with the ANCHOR trial already underway in first line, certainly strong results in the BEACON trial give us more confidence in the prospects in first line and perhaps earlier in disease. So thank you for the question.

Frank A. D'Amelio - Pfizer Inc. - CFO & EVP of Global Supply & Business Operations

And then Chris, on Biz Dev -- in the capital allocation, where you asked specifically about Biz Dev, let me bump it up a level and say from an overall capital allocation perspective, our priorities don't change. There continue to be dividends, share buybacks, investing in the business and Biz Dev. And then specific to Biz Dev, from my perspective, our priorities don't change. We've said -- and we never say never, but we've said we don't see the need to do a big deal. We continue to believe we don't have a need to do a big deal. And you'll see us continuing to do bolt-ons and these kind of early- to mid-stage deals, really talking to some of the mid-2020s when our next wave of LOEs come in. So no change in strategy on any of this.

Charles E. Triano - Pfizer Inc. - SVP of IR

All right. Thank you, Frank. Next question, please.

Operator

Your next question comes from the line of Tim Anderson, Wolfe Research.



Timothy Minton Anderson - Wolfe Research, LLC - MD of Equity Research

Can you talk about the possibility of a tumor-agnostic filing for BRAF mutation? Is that something that could realistically occur in, say, the next couple of years or is that too aggressive of an assumption? And then can you talk about loss of exclusivity in the U.S. when -- with -- when are you modeling U.S. generic entry?

Frank A. D'Amelio - Pfizer Inc. - CFO & EVP of Global Supply & Business Operations

So Tim, I'll hand it over to Mikael. Mikael, please?

Mikael Dolsten - Pfizer Inc. - Global President, Worldwide Research and Development and Medical

Yes. We clearly see an opportunity in the tumors that have low single-digit BRAF mutant genotype to use the tissue agnostic approach. And we will look together with Array into expanding existing clinical studies into that approach. And hopefully, given the strong data that have been seen in melanoma and colorectal that you will also ambition a fast pace in such a study, and in a few years, opportunities to consider data and pending registrations.

Frank A. D'Amelio - Pfizer Inc. - CFO & EVP of Global Supply & Business Operations

And on the LOE date, our assumptions are based on an LOE date of 2031, to answer your question.

Charles E. Triano - Pfizer Inc. - SVP of IR

All right, thanks. Next question please, operator.

Operator

Your next question comes from Louise Chen, Cantor Fitzgerald.

Louise Alesandra Chen - Cantor Fitzgerald & Co., Research Division - Senior Research Analyst & MD

I had a few here. So first question I had was, when you said it's the blockbuster opportunity for this type, is it just for CRC or does it include additional indications that you talked about? And when you do the enterprise value for this deal, how much did you attribute to the earlier-stage pipeline? Second question I had was what kind of share you expect to get in melanoma given some of the leadership in the PD-1 drugs and the data they've shown? And then the last question I had here was do you have any consideration to combine this product with Bavencio?

Frank A. D'Amelio - Pfizer Inc. - CFO & EVP of Global Supply & Business Operations

Andy?

Andy Schmeltz - Pfizer Inc. - Global President, Oncology

Sure. So I'll start with opportunities in metastatic melanoma. As I mentioned, the combination of BRAFTOVI, MEKTOVI has now been on the market for almost a year and has had robust uptake already. We see about 1 in 3 new patient starts for BRAF mutant metastatic melanoma to be with this BRAFTOVI-MEKTOVI combination. And you can imagine the new patient starts are a leading indicator for overall prescriptions over time. So we're confident that we'll continue to have robust uptake, recognizing that it's third-to-market combination in this category. In terms of other indications,



I think on the slide that was depicted, we do anticipate a robust lifecycle here. Possibly, additional studies in melanoma. Certainly, opportunities in colorectal cancer. And then we absolutely will engage in discussions with Array and contemplate lifecycle opportunities. We talked about tissue-agnostic opportunities, possibly different combinations and depending on those discussions, maybe move into other malignancies as well.

Frank A. D'Amelio - Pfizer Inc. - CFO & EVP of Global Supply & Business Operations

And then Louise on the value drivers, it's Frank. The nice thing about this deal from my perspective is, there are several value drivers, right? So you've got the BRAFTOVI, MEKTOVI in terms of melanoma and in terms of colorectal. Then there's royalty streams and then there is also the clinical platform. All of which contribute in a meaningful way to the value of the deal.

Charles E. Triano - Pfizer Inc. - SVP of IR

Thanks, Frank. Next question, please.

Operator

Your next question comes from Andrew Baum with Citi.

Andrew Simon Baum - Citigroup Inc, Research Division - Global Head of Healthcare Research and MD

Couple of questions, please. First, can you talk to the competitive threat from the ongoing triple combination in melanoma that's in Phase 3 from Novartis, the PD-L1b Raf/MEK, given the promising Phase 2 data that was presented recently? Second, Frank, obviously you may want to pass but whether you could attribute the value to the various components you outlined in your review so that some paid for Array. I'm assuming the bulk of it was for the BRAF, MEK but just anything you could add on that would be interesting. And then finally, one way to look at this data is obviously going along the tissue-agnostic approach leveraging BRAF but another way is looking at the potential for Pfizer to expand the colorectal cancer indication. You have some experience with CCL5. There is competitive data out there for synergy with PD-1 and that in colorectal cancer, what's your level of interest in going beyond BRAF patients population, et cetera, through cancer?

Frank A. D'Amelio - Pfizer Inc. - CFO & EVP of Global Supply & Business Operations

So Andrew, I will have Chris answer the competitive threat and then the indication expansion questions, and then I'll come back to the value question.

Chris Boshoff - Pfizer Inc. - Chief Development Officer, Oncology

Thank you, Andrew. So just to start with the data, as you know, from the COLUMBUS study showed the combination with MEKTOVI and BRAFTOVI had a median overall survival of 33.6 months. Although we can't directly compare it against the other 2 studies that was conducted and the COMBI study and the coBRIM study, numerically, that was the highest number ever recorded, the highest overall survival ever recorded for combination with the BRAF and the MEK in metastatic melanoma. We are, therefore, very confident, specifically in this BRAF medicine, we believe it's superior pharmacological properties, it's got a low dissociation from the target, a long half-life. It also inhibits BRAF, so you don't have the downstream signaling pathways you're seeing with the others. And also you -- and recorded lower incidence of premalignant or malignant skin lesions with this BRAF inhibitor. What we currently do not know yet is whether the best option for patients will be a combination upfront with a combination of BRAF-MEK plus PD-1 or the role of sequencing -- immunotherapy sequencing, with BRAF, MEK. However, having said that, there is already ongoing studies with MEKTOVI and BRAFTOVI both with Ipi/Nivo, with Nivo and with pembrolizumab. And actually there's also an ongoing study with avelumab, and we're also planning some additional studies with RN-888, our subcutaneous PD-1, I mentioned earlier.



Frank A. D'Amelio - Pfizer Inc. - CFO & EVP of Global Supply & Business Operations

And then on the value, the way to think about it is, the BRAF and the MEKTOVI in terms of melanoma and colorectal, one significant contributor; the potential royalties, another significant contributor; the platform, another significant contributor; and I'll call it some other items, less of a contributor from the value perspective.

Charles E. Triano - Pfizer Inc. - SVP of IR

Right. Thank you, folks. Next question please, operator.

Operator

Your next question comes from Jason Gerberry with Bank of America.

Jason Matthew Gerberry - BofA Merrill Lynch, Research Division - MD in US Equity Research

Just wanted to follow up on the IP question, the 2031 date. I thought from the Array 10-K, it indicated BRAFTOVI would have patent term extension to 2036. And then with MEKTOVI having shorter duration IP, would that component of the combination potentially genericize earlier than the 2031 date? That's question one. And question 2, just on the first-line collateral opportunity, how well-characterized do you think the step-up in treatment duration could be frontline versus the second line plus opportunity? I know that Array in the past has communicated, that's a big sort of uncertainty in sort of sizing the first line versus the second-line opportunities.

Frank A. D'Amelio - Pfizer Inc. - CFO & EVP of Global Supply & Business Operations

So Andy will handle the IP question and then Mikael will cover the first line versus second line question. So Andy?

Andy Schmeltz - Pfizer Inc. - Global President, Oncology

So in terms of IP, obviously this was an area that we looked at closely as part of our diligence process. Per the FDA's public Orange Book, the patents for the combination of BRAFTOVI and MEKTOVI don't expire until 2031, and that's the basis for our assumption.

Frank A. D'Amelio - Pfizer Inc. - CFO & EVP of Global Supply & Business Operations

And then Chris will handle the second part of the question.

Chris Boshoff - Pfizer Inc. - Chief Development Officer, Oncology

Just to remind you, for the triplet, the overall response rate was 26.1% in the BEACON study. However, if we only look at the second-line patients, the response rate was 34.3% for the triplet and the control, it was actually only 1.6%. And 65% of all patients recruited within the BEACON study was second-line and more or less 35% was third-line. So overall, this gives us confidence that in first-line, the overall response rate should even be higher. We are obviously looking forward to working with Array and with health authorities to understand the options for first-line CRC and if required, to enhance the current ongoing study as well as use real-world evidence, if required, as we did recently with palbociclib approval in male breast cancer and add additional studies again, if required in first-line.



Charles E. Triano - Pfizer Inc. - SVP of IR

Right. Thank you. Next question please, operator.

Operator

Your next question comes from Steve Scala with Cowen.

Stephen Michael Scala - Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

Frank, can you provide specifics on the split between cash and debt to finance the transaction? And secondly, the late-stage opportunities are clear but what do you see as the one or two most undervalued early-stage programs? Would KRAS G12V be one of them? And why wasn't a CBR used to cover some of the early-stage opportunities?

Frank A. D'Amelio - Pfizer Inc. - CFO & EVP of Global Supply & Business Operations

So Mikael will answer the early-stage question and then I'll handle the financing of the transaction. And you also asked about a CBR.

Mikael Dolsten - Pfizer Inc. - Global President, Worldwide Research and Development and Medical

Yes. So as we stated, it's a highly productive research engine, and we gave a list which was just example on the many programs that have been partnered. I think they have — we talked of 17, 17 programs partnered discovery and clinical stage. One of the partnership involves a technology developed by Array around the RAS oncogene platform, which is one of the most prominent oncogene across several tumor types. And as you can see in the slide I provided, they are partnered G12C KRAS and G12D with Mirati. And of course, that and many other of the programs contribute with a potential significant royalty stream that adds as a pillar to the BRAFTOVI MEKTOVI rights that are with Array as well as the research engine. Now we haven't disclosed, as Array hasn't disclosed, the targets in the research engine that are the substrates for the expected annual 1 IND per year. But Array has mentioned that they have benefited from working on RAS and have a significant knowledge and ambition to further develop the RAS platform beyond what's partnering with Mirati as that RAS new oncogene contains many different quotations, it offers amplitude of opportunity and value.

Frank A. D'Amelio - Pfizer Inc. - CFO & EVP of Global Supply & Business Operations

Steve, on the financing. The majority of the transaction will be financed with new debt and then the remainder will be with the existing balance sheet cash, but the strong majority will be with that new debt. And then on the CBR, quite frankly, I like the way we constructed the deal as is. And as you know, trying to value CBRs can be an extremely challenging test.

Charles E. Triano - Pfizer Inc. - SVP of IR

Thank you. Next question, please.

Operator

Your next question comes from Jim Birchenough with Wells Fargo Securities.



James William Birchenough - Wells Fargo Securities, LLC, Research Division - MD and Senior Biotechnology Analyst

There was reference earlier to PD-1 combination and there are 3 ongoing studies with MEKTOVI, BRAFTOVI and various PD-1, PD-L1 combinations. So just trying to get a sense of whether we should expect that data this year and how material it is to the acquisition? And then the second question is, Array had highlighted a new IND this year that we were eagerly anticipating and I just want you to comment on the target? And when we might expect an update on what that new IND might be in 2019?

Frank A. D'Amelio - Pfizer Inc. - CFO & EVP of Global Supply & Business Operations

Thank you. So Chris will have the first question and then Mikael will handle the second question. Chris?

Chris Boshoff - Pfizer Inc. - Chief Development Officer, Oncology

Thank you very much. We haven't disclosed yet, the date for the data to the -- shown for the combinations. But as mentioned earlier, there are combinations ongoing with nivolumab, with pembrolizumab, with Nivo and with Ipi -- as well as with avelumab. And we hope to update you on those in the near future.

Mikael Dolsten - Pfizer Inc. - Global President, Worldwide Research and Development and Medical

And the preclinical pipeline of Array is deep and very exciting but it hasn't been disclosed by the company, which will be the target for the first IND. And it contains numerous oncology targets and typically kinases is among them. In addition to that, the RAS platform. Now what is so intriguing is the opportunity to see one IND per year of cancer medicines starting possibly 2019 from Array and those medicines to be combined or standalone with many Pfizer medicines. We spoke earlier about PD-1 RN-888 for I/O. We also have relevant indication by functional antibodies from Pfizer now coming into the clinic -- in the indication colorectal cancer. We have other I/O medicine such as a TGF-beta inhibitor and we have a broad CDK franchise. So across these pipelines, there will be really added value, and that was part of the attraction, from that pillar of the research engine.

Charles E. Triano - Pfizer Inc. - SVP of IR

Great. Thank you. Next question, please.

Operator

Your next question comes from Navin Jacob with UBS.

Prakhar Agrawal - UBS Securities LLC, Research Division - Equity Research Associate

This is Prakhar Agarwal on behalf of Navin Jacob. I had two questions. So first, Array has previously said that in melanoma, they estimate a target market of about \$400 million in the U.S. and over \$1 billion globally. So how does Pfizer view the market opportunity in melanoma? And second, what are the current diagnostic rates for BRAF mutation colorectal cancer? And where does Pfizer see this reaching at peak?

Frank A. D'Amelio - Pfizer Inc. - CFO & EVP of Global Supply & Business Operations

All right. So Andy will handle the size question in terms of the \$400 million and greater than \$1 billion. And then Chris will handle the current dynamic market. Please, Andy?



Andy Schmeltz - Pfizer Inc. - Global President, Oncology

So BRAFTOVI, MEKTOVI, as I have stated, are off to a great start in metastatic melanoma. And remember here, the BRAF mutation accounts for about 45% of melanomas. So we're excited for the opportunity there. We're not in a position to affirm or contradict previous statements that Array has made. We're excited that the medicines are approved in Europe with our partner -- Array's partner, Pierre Fabre. And we look forward at the appropriate time to engaging with them and ensuring that the opportunities are maximized for patients in Europe.

Chris Boshoff - Pfizer Inc. - Chief Development Officer, Oncology

Thank you. The current rate is actually quite high in the U.S. already for BRAF testing with colorectal cancers, over 90%. But you're absolutely correct. There's significant opportunity in the rest of the world for BRAF testing in colorectal cancer. We obviously have significant experience with this, thinking of ALK and ROS testing that also more recently for EGFR testing. We're also looking forward to actually introduce potentially testing using plasma for circulating free DNA, which will make it much more -- much easier for physicians and for patients to be diagnosed with a BRAF-positive malignancy.

Charles E. Triano - Pfizer Inc. - SVP of IR

Thank you, Chris. Next question, please.

Operator

Your next question comes from Umer Raffat with Evercore ISI.

Umer Raffat - Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research

Perhaps first, what percent of the total deal consideration is for the BRAF-plus-MEK combo across melanoma and colorectal? And I apologize if this was mentioned already. And then once we sort of have a sense for that, my question really is, perhaps for Mikael, can you speak to the emerging data for the doublet versus triplet on survival in the BEACON trial? And what's your expectation for whether binimetinib gets used in colorectal setting? And then finally on 797, this might be my lack of familiarity, but can you explain why it took about 2 years from Phase 2 to Phase 3 in the cardiomyopathy indication and whether there could be possible synergy with tafamidis as well.

Frank A. D'Amelio - Pfizer Inc. - CFO & EVP of Global Supply & Business Operations

So Mikael will handle the double-versus-triple question. Chris will hand the 797 question and then I'll answer the value question. So Mikael, please? The double versus triple?

Mikael Dolsten - Pfizer Inc. - Global President, Worldwide Research and Development and Medical

Yes. We think that overall the data of the triplet was very impressive. And it had high response rate than the doublet and overall, tolerability was comparable. So we think that's the main combination going forward, both for the BEACON trial and also for first-line trials. It offers for the largest number of patients, the most positive benefit. And clearly, the combination of BRAFTOVI MEKTOVI is underpinned by the COLUMBUS trial in another indication melanoma, where it's performed superior to any other known agents. So we're very thrilled about that opportunity. Now when it comes to also our other agents like the rare disease that you asked about, we cannot comment about the previous history of Array but we think where it is now, it can also be taking benefit of our deep experience in development of our disease drug. So we look forward to combine what Array has been doing and add on our development and regulatory expertise and see if we, jointly, can accelerate things.



Frank A. D'Amelio - Pfizer Inc. - CFO & EVP of Global Supply & Business Operations

Chris, on the 797?

Chris Boshoff - Pfizer Inc. - Chief Development Officer, Oncology

Also this both will be -- triplet vs doublet. Just a reminder that current data was an early interim analysis, so less than 50% of events. And in fact, the data cut was 2 weeks after the last patient was actually dosed. We actually look at the totality of the data not only the OS but overall response rate, i.e., profile again, reminding that previously when BRAF is used with ALK or MEK inhibitor, there can be additional toxicities, especially skin toxicities. And then also looking at the progressive disease rate, which you will soon see when that is -- when the data -- when full data are disclosed. So progressive disease between the control, the doublet and the triple. So looking at the totality of the data, as Mikael has pointed out, we are confident that the drop of triplet, specifically, provides a breakthrough for patients. And on the other preclinical molecule, as mentioned, this is very highly and complementary to our cardiomyopathy franchise, specifically the laminin cardiomyopathy. And we're looking forward with our rare disease franchise to interact with the rare medicine.

Frank A. D'Amelio - Pfizer Inc. - CFO & EVP of Global Supply & Business Operations

And then Umer, on the value, I tried to answer this before, when Andrew asked me. But the way I think about it is there's the BRAF and then MEKTOVI, one meaningful contributed evaluation. So there's the royalties, which is another meaningful contributor, and by the way, related or obviously to BRAF and MEKTOVI. And then there is the platform, all 3 of which meaningfully contribute to the overall evaluation that we assigned to the transaction.

Charles E. Triano - Pfizer Inc. - SVP of IR

Thank you, Frank. Next question please, operator.

Operator

Your next question comes from Terence Flynn with Goldman Sachs.

Terence C. Flynn - Goldman Sachs Group Inc., Research Division - MD

Just was wondering if there's any possibility that the ongoing frontline Phase 2 ANCHOR trial could support registration or if you think a Phase 3 trial is going to be needed there? And then can you just remind us of your economics on the ex-U. S. rates to BRAFTOVI and MEKTOVI?

Frank A. D'Amelio - Pfizer Inc. - CFO & EVP of Global Supply & Business Operations

So Chris, will handle the Phase 2 and then I'll handle the ex-U.S.

Chris Boshoff - Pfizer Inc. - Chief Development Officer, Oncology

Thanks for the question. We are looking forward to working with Array and with health authorities to understand the options for first-line and metastatic colorectal cancer. Patients, as you know, with metastatic BRAF mutated colorectal cancer have a particularly poor prognosis and BRAFTOVI, MEKTOVI with cetuximab offers a potential chemotherapy-free regiment that could have a significant impact on this disease. And we will work with health authorities, we're looking forward to working with health authorities and with Array to see if we need to enhance any studies, as I mentioned earlier, use real-world evidence as needed and additional studies again, if required.



Frank A. D'Amelio - Pfizer Inc. - CFO & EVP of Global Supply & Business Operations

And then on the royalty arrangement. So think about Pierre Fabre has all -- has Europe and the rest of the world excluding Japan and Korea, where Ono has it. And at Pierre Fabre our royalty rates range from 20% to 35%, and with Ono they range from 22% to 25%. So we have fairly healthy royalty rates there.

Charles E. Triano - Pfizer Inc. - SVP of IR

Thanks, Frank. And if you could take our last question please, operator.

Operator

And your last question comes from Hima Inguva with Bank of America.

Hima B. Inguva - BofA Merrill Lynch - Fixed Income Research Analyst

Congrats on the deal. Frank, thanks for all the color. But maybe if you could talk about the reason behind financing the majority of the deal with debt given the strong balance sheet position and access to cash and how we should think about future financing on potential deals in the future?

Frank A. D'Amelio - Pfizer Inc. - CFO & EVP of Global Supply & Business Operations

Sure. So from my perspective, the capital markets are very favorable right now. It's a good time to go out and borrow money at, what I'll call, very, very favorable interest rates, very, very low, almost historically low. So from my perspective, we're just being opportunistic in terms of how we're trying to finance the deal. In terms of future financing, the way I think about that is market conditions will very much determine what we do or don't do in the future. That said, we continue to have a strong balance sheet and expect to continue to have a strong balance sheet going forward. Thank you.

Charles E. Triano - Pfizer Inc. - SVP of IR

Great. Thank you, everybody, for joining us this morning on short notice.

Operator

Thank you all. This does conclude today's conference call. You may all disconnect.

Editor

Forward-Looking Statements

DISCLOSURE NOTICE: This communication contains forward-looking information related to Pfizer, Array and the proposed acquisition of Array by Pfizer that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Forward-looking statements in this communication and the accompanying exhibits include, among other things, statements about the potential benefits of the proposed acquisition, anticipated royalties, earnings dilution and accretion, and growth, Pfizer's and Array's plans, objectives, expectations and intentions, the financial condition, results of operations and business of Pfizer and Array, the BRAF/MEK combination and Array's other pipeline and portfolio assets, the anticipated timing of closing of the proposed acquisition and expected plans for financing the



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A further description of risks and uncertainties relating to Pfizer can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2018 and in its subsequent Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission (the "SEC") and available at www.sec.gov and www.pfizer.com.

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20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. Pfizer's and Array's filings with the SEC are also available to the public from commercial document-retrieval services and at the website maintained by the SEC at http://www.sec.gov.

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