

GSK

Investor and analyst call

Friday, 18 December 2015

David Redfern, Chief Strategy Officer and Chairman of ViiV Healthcare

Good afternoon everyone. We very much appreciate you joining us on the last Friday before Christmas after what has obviously been a very busy year in the healthcare space to discuss the two transactions that we announced this morning with Bristol-Myers Squibb to acquire their late-stage HIV pipeline assets and also their pre-clinical and discovery stage research assets.

I am joined today here in London with Dominique Limet, who is the CEO of ViiV Healthcare and we also have on the phone Dr John Pottage from North Carolina, who is the Chief Scientific and Medical Officer for ViiV.

I will make a few reasonably brief introductory comments, much of which is covered in the press releases that GSK and ViiV issued today, but I will highlight some of the key points and then we will open it up to Q&A.

First of all why are we doing these transactions? Taken together, these acquisitions offer a unique opportunity to strengthen our leadership and innovation in HIV, one of our core areas of scientific research. They enhance the breadth and depth of our pipeline with innovative potentially first-in-class assets that complement our current portfolio but also broaden the opportunities for further combination therapies.

As you know our HIV business at ViiV is growing very strongly this year, driven primarily by *Tivicay* and, more recently *Triumeq*, our recently launched integrase inhibitor medicines.

These transactions have the potential to significantly improve the long term outlook and sustainability of the HIV business. We believe it is testament to the success and expertise of ViiV, a company of course 100% dedicated to HIV that BMS has selected us to take forward the late-stage experimental medicines and early scientific projects that they have been working on and which hold potential for further innovative treatments.

In terms of the specifics of what is being acquired, first of all the late-stage assets: the late-stage are indeed programmes being acquired in two potentially first-in-class assets. First of all fostemsavir, in Phase III, for heavily treatment experienced patients in a new class of antiretrovirals with the potential to treat multiclass resistant HIV infections due to its lack of

cross-resistance with any existing class of antiretroviral agents. These types of patients are an area of high unmet medical need that we at ViiV are very keen to try and do something more for.

The second asset, a maturation inhibitor in Phase IIb for treatment naïve and treatment experienced patients also has potential to be the first in the new class of antiretrovirals with no cross resistance.

If these products are successful there is also the potential for the development of combinations with other products in our portfolio, including our integrase inhibitors. In particular we are already looking at the potential combination of dolutegravir with the BMS maturation inhibitor and are quite excited by the potential of that combination.

In the second transaction the preclinical and discovery assets, which we are acquiring, these will deepen our current R&D portfolio in HIV and offer the potential to bring further innovative new treatment options to HIV patients.

Assets in the preclinical and discovery phases of development include a biologic with potential to be a single, weekly subcutaneous injection for home administration and others include a further backup maturation inhibitor, an allosteric integrase inhibitor and a capsid inhibitor. This transaction also includes a number of highly talented BMS drug discovery employees being offered the opportunity to transfer to ViiV Healthcare.

Finally, in relation to the deal financials, the late-stage clinical assets purchase comprises an up-front payment of US\$317 million, followed by development and first commercial sales milestones of up to \$518 million. ViiV Healthcare will also pay tiered royalties on sales of acquired assets. This transaction will be accounted for as an asset deal as we are not really taking any permanent activity from BMS.

The acquisition of BMS's HIV R&D Discovery Unit comprises an up-front payment of \$33 million followed by development and first commercial sales milestones of up to \$587 million and further considerations contingent on future sales performance.

This transaction will be accounted for as a business acquisition as it is more of a platform deal involving the transfer of people and capabilities as well as of course assets.

We expect both transactions to complete independently during the first half of 2016, subject of course to the usual anti-trust and regulatory clearances.

With that I will pause and we are very happy to open the line to any questions that any of you may have.

Questions & Answers

Jo Walton (Credit Suisse): A question on the timing, please for the combination drugs, the dolutegravir and the maturation inhibitor. How much further do you have to get with the maturation inhibitor, perhaps as a monotherapy before you can actually initiate some combination?

Dominique Limet: This is Dominique speaking, but John, I think you are the best to respond to that question.

John Pottage: Okay, that's a good question and actually we are already starting a clinical trial with dolutegravir combined with the maturation inhibitor, so the maturation inhibitor it's in Phase IIb clinical trials. There is one trial which is in treatment-naïve patients and so it's a dose-ranging study and that's fully enrolled and moving along and it is in combination with nucleosides.

The second trial is for experienced patients and that has started and it is actively enrolling at this time. There are a number of combinations of the maturation inhibitor, including a couple of different doses, but it is in combination with dolutegravir and so I think when we see the data from that study we will have some good information on the efficacy of those two drugs together and then there are plans ultimately to think about trying to put together a fixed dose combination with them.

But I think we are well underway in answering the question that you raised.

Jo Walton: Can you also tell us please, if there is any Phase II data that has been published on your Phase III asset and a final one from me would be just to confirm, and I think I understood this perhaps incorrectly, why the two parts of the deal are being accounted for differently, so why the second half is accounted for completely differently from the first half.

David Redfern: Maybe I'll deal with the second question first Jo, and then we'll go back to John.

As I said, the Discovery part of the deal is being accounted for as a business acquisition and that's really because it involves not just the transfer of assets but also people capability and know-how, so in a sense it is a business, certainly under the accounting standards whereas the clinical part of the deal we are really just taking the assets and we will transfer them to ViiV and there will be some short-term transitional services with BMS, but essentially the ViiV Development organisation will pick them up. That's why they are accounted for separately.

John, do you want to talk about some of the Phase II data you've seen?

John Pottage: Yes, in terms of the attachment inhibitor or fostemsavir, there was a publication in *The Lancet HIV* in October of this year, so just a couple of months ago reporting the 24-week data from their Phase IIb study and so the data there looks quite encouraging, it's for treatment of people who have treatment experience, but actually do still have a few options, so it is the attachment inhibitor with raltegravir and tenofovir, obviously in the phase III programme which is a study we have up running now it is for people with more advanced disease, and so that is beginning but *The Lancet HIV* paper is there, there is an accompanying editorial with it.

Jo Walton: Thank you.

James Gordon (JP Morgan): Hello, thanks for taking my questions, a couple of questions please. One was on combos with dolutegravir, for the attachment inhibitor, the studies so far look like that is twice daily, does that mean it will be difficult to make that into a combination with dolutegravir or might that be possible, was the first question? One question was just on accounting, are the assets owned by GSK or ViiV, so do you get 79% of the economics and pay 79% of the costs or is GSK fully owning it and then can sell it into ViiV and will the BMS royalties go through the P&L or will there be a similar arrangement to dolutegravir? And then just a final question was in terms of why BMS are selling and, you know, they have products already on the market for HIV, but they are selling their pipeline, could that be because they think post the mid-20s, something like *Triumeq* is such a good drug, it is convenient and works well that it is going to be hard to make anything much better and so it is not worth doing lots more development in HIV beyond that, or why else would they want to leave these assets if they are so good and Bristol has already got assets on the market?

David Redfern: Well, I think on the accounting, so as we said the clinical stage will be accounted as an asset deal, so the royalties will go through the P&L as normal. The Discovery part of it is accounted for as business acquisition, so deferred consideration goes on the balance sheet. I think it is really a question for BMS in terms of why they are selling, I think it is all about prioritising what they are really focused on, which is increasingly Oncology and clearly their marketed assets are really in decline now, so I think they are doubling down on Oncology and keen to focus their R&D spend there.

John, do you want to talk about potential combinations of the attachment inhibitor?

John Pottage: Yes, sure. I think with the attachment inhibitor you are correct, it is a BID or twice a day dose, and it is also being directed to people with limited options, so the accompanying drugs that a physician would choose will be whatever the patient is – whatever the patient’s virus is sensitive to, so there is not a natural fit of a fixed dose combination to them. That said, however, I think as the data develops from the phase III study we will take a look at it, it won’t be simple, but it is something we are thinking about, but I think in terms of the fixed dose combinations with dolutegravir it is really more centred on the maturation inhibitor than the attachment inhibitor.

David Redfern: James, sorry, I should have said, just to be absolutely clear this is a ViiV transaction, so everything will be booked through ViiV, it will be paid for by ViiV and then the economics passed through ViiV and through the ViiV P&L and balance sheet.

James Gordon: That means no change in –

David Redfern: Correct, there is no change in the shareholdings, and all three shareholders therefore are very supportive of the transaction.

Okay, next question.

Nicolas Guyon-Gellin (Morgan Stanley): Yes, thanks for taking my questions, I have two actually. The first one is about the positioning and the commercial potential for the attachment inhibitor, so in that situation that it is more of a niche product for multiple treatment failures and just as a follow-up, what proportion of HIV patients could it address and how big of a sales opportunity do you foresee? And the second question is more of a financial one, could you please elaborate on the financial impact of the transaction on both Group earnings, I mean is it slightly dilutive and the Global R&D budget as well? Thank you.

David Redfern: Okay, I might ask Dominique to comment on the positioning of the attachment inhibitor.

Dominique Limet: Yes, you are absolutely right, these attachment inhibitors, as John alluded to, are dedicated to people who are heavily treatment experienced patients. We know that there is a significant unmet medical need and I would say we can characterise that population as representing around 5% of the current HIV population in the developed world. In that it is clear that if the product delivers its promise we should have a significant share of that sub-segment of the total HIV patient population.

David Redfern: Nicolas, on the dilution it is very marginally dilutive at the ViiV level next year, principally because we are picking up the Phase III costs for the attachment inhibitor programme, but it is not material at a group level and clearly it won't have any impact on guidance or anything like that.

Nicolas Guyon-Gellin (Morgan Stanley): Many thanks.

Richard Parkes (Deutsche Bank): Hi, thanks for taking my questions; I just have two or three. The first one, I just wondered whether you could talk about whether you see an opportunity for some of these new mechanism drugs in the first-line setting, given the expected availability of generics over the next decade or so? It sounds like you feel that the maturation inhibitor has more of a potential in the treatment-naïve population; I was just trying to understand why that was? Is it because it is easier to combine with dolutegravir or what is driving that?

Then thirdly, we just wanted to clarify around accounting for the royalties of the late-stage development products, I just wanted to clarify – will they be treated as a contingent liability on the balance sheet or will they be amortised or will they be expensed? Thanks.

David Redfern: Thanks, Richard. I will have one more go on the accounting first. For the late-stage deals, for the clinical assets, this is an asset deal so the royalties won't go on the balance sheet, they will go through core P&L as they are paid. The discovery part of the deal is business acquisition accounting so the deferred consideration that is contingent on future sales performance will go on the balance sheet, but obviously it is probability adjusted; these assets are very early, so the charge, the liability you are going to see is pretty small, very small. Hopefully that sorts out the accounting.

You are right on the maturation inhibitor, it is the programme that we are probably most excited for at the earlier stages of treatment. Fostemsavir, as Dominique said, is really for heavily treated, experienced patients, but John, do you want to comment on exactly what the potential of the maturation inhibitor and vis-à-vis potential first-line over time?

John Pottage: Yes, partially it is a work in progress. As I said, the Phase IIb study in treatment naïve patients with the maturation inhibitor with a three drug regimen is now fully enrolled and we will get data towards the end of next year on that. That will help to really help focus on the efficacy as well as the tolerability. So far the tolerability is looking reasonably good going forward and I think that the fact that the drug is once-a-day, links up better with dolutegravir, so when we think about a treatment naïve patient you want

something that is highly effective and very well tolerated. The bar is high, but it does have to be once-a-day in terms of that.

The attachment inhibitor with it being a twice-a-day dosing makes it less optimal for a treatment naïve patient, but again, as we see the data emerge on it, where they settle in to where they are in the treatment cascade remains to be determined, but the line that we have lined up there is that the maturation is really more focused towards the treatment naïve patients.

Richard Parkes: That is perfect, thank you.

Alexandra Hauber (UBS): Thank you. A couple follow-up questions here firstly. Again, on the maturation inhibitor when you talk about the treatment naïve study I can't seem to find that on clinical trials. The one I see is a combination study where Bristol tried to come up with a completely NRTI free combination of the maturation inhibitor, the protease inhibitor and dolutegravir, which I assume is probably targeted more towards the treatment experienced population so that treatment naïve – is that just going to be the attachment inhibitor plus NRTI backbone or is dolutegravir also part of the treatment naïve initial combination?

David Redfern: John, do you want to have a go at that?

John Pottage: Yes, again we have to keep straight what we are talking about in terms of the attachment inhibitor and the maturation inhibitor.

Alexandra Hauber: I was talking about the maturation inhibitor, I'm sorry.

John Pottage: The maturation inhibitor the naïve trial, the Bristol-Myers number is AI438-038. It is on ClinTrials and so as I said, it is a fully enrolled trial, it is a dose-ranging trial and it's in combination, as I said, with nucleosides and so it is a trial up running with it. Again, that will form the core of our data for it in terms of its activity and give us a lot of information on the safety.

You did talk about the experienced trial, that's a second trial, that's AI438-048 is the BMS trial number and it is also a Phase IIb trial and as you said it is a number of different combinations which is looking at nucleoside sparing and so it's in combinations with dolutegravir as well as added atazanavir which is boosted and so that's actively recruiting at this time. I think BMS has been pleased with the enrolment thus far and so that data will be coming after the naïve trial with that.

Does that answer your question?

Alexandra Hauber: Yes it does, thank you very much.

Dominique Limet: I could possibly add that regarding the first-line setting and the potential use of the maturation inhibitor, we see a really attractive potential if and when we will be able to demonstrate that dolutegravir and the maturation inhibitor can work well together. That would be a way to strengthen the vision that we have about the dual treatment therapies because that is a very attractive vision we have of a booster-free, NRTI-free regimen with some new classes which could completely transform the way we treat HIV in the years to come.

David Redfern: Alexandra, are you done? [Yes] Okay, very good. Next question.

Steve Scala (Cowen): Thank you. I have three questions. First, as far as I can tell the attachment inhibitor was in Phase II for three years which seems a long time to generate 24-week data, so I am just wondering why it was in Phase II for so long.

Secondly, can you tell us the patent expirations of the two late-stage assets and then lastly I am just curious; the attachment inhibitor is a pro-drug converted to 529. Why is it delivered as a pro-drug and not delivered as 529 directly? Thank you.

David Redfern: Okay, thanks Steve. I think John we will come to you in a minute to comment on the attachment inhibitor, both the trial time and the pro-drug. Dominique do you want a word or two on the patent life?

Dominique Limet: Yes, the patent life is (expected to be) 2032 in the US and 2034 in the EU for the maturation inhibitor and that is more or less the same –

David Redfern: Yes, it's (expected to be) around 2030 for the attachment inhibitor. John, do you want to comment on the length of time?

John Pottage: Yes, part of it related to just the issues with the formulation and as you mentioned, it is now a pro-drug. Initial studies were done with the active agent and I think the reason they went to a pro-drug approach are the issues with solubility and really getting high enough levels to treat the virus. What the pro-drug does is that it is acted upon by alkaline phosphatase from the gastrointestinal drug and releases the active agent and improves the absorption, enhances the levels with that.

But the issues of that led to some of the delays and now we are kind of on track and things are moving in a much more predictable way.

David Redfern: Thanks, Steve. Next question.

Trung Huynh (Credit Suisse): Hi, just a quick follow-up question and I may have missed this, but how many Bristol employees are being offered the chance to transfer to ViiV?

David Redfern: We've said I think around 20, predominantly Discovery employees. Okay, anything else?

Trung Huynh: Okay, thank you.

David Redfern: Any other questions? [*Pause*] Okay, I think that may be it. I know everyone is very busy at this time of year, so if there are no further questions, we really appreciate your time and hope everyone has a very happy Christmas and we'll see what 2016 brings.

Thank you very much.

[*Ends*]