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GSK plc

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Julie Brown, Tony Wood

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Sachin Jain Analyst

Sachin Jain here from the European team, Bank of America. It's my pleasure to be hosting Glaxo. We have Julie Brown, CFO, Tony Wood, Head of R&D; and then IR folks, Constantin and Mick in the front. We have about 40 minutes, and I'll aim to split it roughly half-half between Julie and Tony, but perhaps if you wanted to make some introductory comments and we'll get into questions.

Julie Brown Executive

Yes, sure. Good morning, everybody. Good to see everybody. So obviously, in GSK, we're very focused on four major therapeutic areas. We've had a good year so far.

We've upgraded to the top end of the guidance range for the year. And very importantly, the Specialty business is driving a considerable amount of the growth. Oncology is performing extremely well, as I'm sure we'll talk about, together with Respiratory, Immunology and Inflammation. And the HIV business is equally with the new 2-month long-acting is really performing well. We have got also long-term guidance out in the market, which is more than GBP 40 billion by 2031 in terms of sales.

And we've had a really good track record. We had 13 Phase III positive readouts last year. We're on track for five major approvals this year and four launches this year with the major ones being Blenrep and also depemokimab coming at the end of the year for respiratory, asthma. So I think in terms of overall shape, we're a growth-orientated company with a lot of ambition and obviously, the longer-term guidance of more than GBP 40 billion by 2031 has been upgraded

from GBP 33 billion just a few years ago. So the company is generating real growth and real momentum.

Sachin Jain Analyst

Anything you want to say?

Tony Wood Executive

Yes. And let me just build on that sort of an exciting and busy time in R&D ahead of us. Obviously, with 13 successful Phase IIIs last year, which was a record for us, this year has been incredibly busy seeking to secure the five license applications that Julie mentioned. Ahead of us, you can sort of think of the portfolio in the key areas as follows. Very pleased with the progress we're making in respiratory, particularly in COPD and the long-acting formulations, the oral medicines that we have there.

Great start with Nucala in the COPD label in an area that is difficult for biologics as I'm sure you'll appreciate, as you've watched the landscape there in general terms. We have -- I think we're very well placed for long-acting options there across not only IL-5 as we move into Phase III for depe in COPD, but also IL-33 and TSLP. I'm excited about what's coming alongside that in the fibro-inflammation portfolio with the recent deal we did on efi and FGF21. And also I think something you probably haven't looked at that closely in the liver portfolio is depe and the results we're going to get out of as well. And then in oncology, let's call it, the world of ADCs.

Obviously, we have Blenrep to finish off this year, but the opportunities that sit particularly in B7-H3 and H4, I think, lay out for an interesting next period ahead of us. I'm sure we'll get into more detail on those, so I won't go any further.

Sachin Jain Analyst

Yes. Perfect. Thank you so much. So I'll kick off, Julie in MFN and policy, industry response due by next week. What should we expect?

What do you think the path forward looks like?

Julie Brown Executive

Yes. It's has been, I guess, a year that has not been expected, to put it that way, at the beginning of the year. First of all, with tariffs and then followed by MFN. It's difficult to know exactly because the proposals have been more sort of conceptual around the fact that there's a real desire for other countries across the world to pay for innovation. And we do believe in this because innovation is the lifeblood of the pharmaceutical industry, and it makes a difference to human health.

So we're a big advocate of paying for innovation. Obviously, President Trump wants to see U.S. prices come down, but very importantly, particularly European prices and other country prices go up. We've done a lot of work in the area comparing prices. It's clear that the healthcare systems are so different that a like-for-like comparison is impossible.

The U.S. is the only country with PBMs, for example. So I think in terms of -- we've got a dialogue with the government going on, the U.S. administration, we will find a solution to this. And I think as you've seen with the work we've been doing on tariffs, as time's gone on, we've understood the challenge better.

We've managed to mitigate, to a large extent, the risk that was coming from tariffs at the beginning of the year. And so with MFN, I think we'll have to just see how it develops, we will get more detailed proposals, and we'll take it through accordingly.

Sachin Jain Analyst

When you say more detailed proposals, is that what you expect the next step to be? Because the letter was basically MFN Medicaid, our perspective has been sort of manageable. New product launch is parity price, you can decide not to launch in Europe and then DTC, which basically bypasses the PBM. So if that was what was enacted, is that enough of a win for them? And is that -- do you think where we get to it, do you think there's another round of letters and proposals coming?

Julie Brown Executive

I think it's really hard to prejudge these different stages. As you say, it's multifaceted. The DCP could go ahead. Some companies have already started it. I think it's only going to apply to certain parts of the range.

It's unlikely to apply to oncology, for example, more likely to apply to, we talked about the GLPs. It could apply to that. In terms of the -- the other question really is around the mechanism that's used to implement MFN. So you've got the launches. And clearly, you're looking -- in fact, we were looking already because reference pricing was in place.

You're always looking at the launch prices. You're always looking at the phasing of the launches. It's probably put heightened scrutiny on that right now. And then you've got the products that are already on the range is the third category. And that's where there is already an existing mechanism through the IRA.

We've got two products going into the IRA this year that affect 2027. So I think we'll have to just see how this pans out. As we found with tariffs, after those initial announcements, it took a while to get to the actual tariff rates and the enactment of the tariffs. And I think probably MFN may take the same, but we have to see. Can't really prejudge it.

Sachin Jain Analyst

Sure. And the last question on this, how the IRA negotiations going for you in this round versus the last round?

Julie Brown Executive

They're going well. I mean we've got two products going in Trelegy and Breo this time. Obviously, Trelegy has been performing extremely strongly. We've been getting very strong double-digit growth rates, including last year when we had the MCAP industry issue. So net-net, we're really pleased with Trelegy.

It's one of our strongest performers. In terms of the negotiation, it's going well. It will be decided during the course of October with the announcement latest being the first of November, and then it affects our results from 2027 onwards. But net-net, I think it's nothing unexpected at this stage.

Sachin Jain Analyst

So can I just -- I'm going to push in and feel free not to answer, but the last average price cut to net was 23%. So there's been a few that this administration would push harder this time around, are you experiencing that or doesn't sound like it?

Julie Brown Executive

I wouldn't say it's been markedly different from our expectations. And I think what we need to remember with the more mature parts of the range like Trelegy and Breo then you've already got a rebate and a return adjustment that's going through before you reach the net sales position. So that, I think, gives some degree of protection already just because of the nature of the product.

Sachin Jain Analyst

Okay. I'm going to shift to where you kick off actually the midterm guide. So your GBP 40 billion consensus a long way below that. I think on the 2Q call, you've talked about the next 18 months, two years being an unlock. Perhaps you could just touch on which products or franchises you see the greatest variation and then hopefully linking into -- again to Tony, what data is coming that you think allows to unlock?

Julie Brown Executive

Sure. There are two -- so at the moment, we're at more than GBP 40 billion by 2031, consensus is at GBP 34 billion. So there's a GBP 6 billion gap. The major reason is Oncology. And some of it is understandable because traditionally, the market will wait for the readout.

So there's usually a lag between a company's long-term guidance at 2030 and where the market is. But -- and then usually, the gap is around 20%.

But in terms of the big gap, Oncology isn't the #1. And within Oncology, it won't surprise you that the biggest gap is Blenrep. So if you look over the period of the five years from '26 to '31, half of that gap is actually centered on Blenrep and Tony will talk about the Blenrep inflection shortly. Very importantly with Blenrep, we have got a number of rest of world markets already approved. So Europe, Switzerland, U.K., Japan, Canada, UAE are already approved.

So that's underway. The other difference in Oncology really rests with Jemperli life cycle, where we've got head and neck and rectal coming through, but also B7-H3, B7-H4, which are recent licensing deals that we did last year, in fact, performing so far really well. Tony will talk about that. And then the other difference is in respiratory, immunology and inflammation. And the main difference there really is there's a little bit with depe, depemokimab, which is due for approval in December.

And then the other difference is camlipixant, which is due for its Phase III readout next year. So those are the big -- the big movers and shakers to keep an eye on to see.

Sachin Jain Analyst

So just to summarize, half oncology, of oncology, bulk Blenrep and then [indiscernible] immunology.

Julie Brown Executive

It's a bit more than half oncology now because the Blenrep news affected it, the oncology gap went up.

Sachin Jain Analyst

Okay. Very clear. And I'll come to all of those assets in a second too, if that's all right. If I could just move forward, [indiscernible] in '26 pushes and pulls as you think about the strong business momentum you referenced upgrading guidance, how much that can continue into next year?

Julie Brown Executive

Yes. We've really pleased with how this year is performing, not only, I think, on the top line, but also we're getting good leverage in the P&L. As you've seen, our profit growth rate and EPS is growing considerably higher sales, largely driven by gross margin accretion because we've got a more push towards Specialty. But also very importantly, SG&A productivity is delivering really good returns. So looking into 2026, we've got a number of important launches.

Nucala COPD with a great label is underway. Depemokimab, we're expecting at the end of this year and then, of course, Blenrep is already launched in a number of countries, and we've got the PDUFA date on the 23rd of October. So -- and then we've got the readouts for camlipixant and a number of other bepi, bepirovirsen reading out shortly, too. So I think overall, it's an encouraging picture for GSK.

Sachin Jain Analyst

Could you just comment to R&D spend trends into next year? I think you touched on it briefly, but as you sort of called it out in 2Q, how is that going to grow next year relative to sales?

Julie Brown Executive

Yes. Well, because we've got so much faith in the pipeline and the fact that we're delivering strongly, we're actually allocating more of our capital towards R&D. So last year and this year, we've said R&D will grow at a higher rate than sales because we want to get these assets through to the market as soon as possible. And in the case of B7-H3 and 4, a wide number of tumor types available. So we want to -- we've actually accelerated considerably the development of those two assets.

So I think net-net, I would expect us to continue to have R&D growing into a higher rate than sales. I'm not guiding any further than this year at this stage. But we would expect because the emphasis don't -- bless you -- the emphasis on growing it as much as we can.

Sachin Jain Analyst

Okay. How do you think about depe and Blenrep consensus for next year? Obviously, Blenrep pending approval, but I think forecast for both, to me, look conservative, but any perspective you can give?

Julie Brown Executive

I definitely think they're conservative. I agree with you. I agree with you. The difference in depemokimab is relatively small on the scale of things, but there is a difference. And I think most likely consensus or the market will be waiting for the approval.

We're anticipating it in December. And then usually, they will see how the launch pans out. But depemokimab has got superb data, a 72% reduction in exacerbations that caused hospitalization, which is a major -- and pulmonologists, over 80% are indicating intention to prescribe. And this is a class that has a really low level of biologic usage, around the low 20% range, whereas rheumatoid arthritis is up in the 60s. So there's an opportunity to really

penetrate this market with biologics and particularly depe because it's once every six months, which is a major change for the market.

So I would expect consensus to move as we get the approval in the early readouts. And then Blenrep, I think, will hinge largely on the rollouts in the rest of the world, but very importantly, the U.S. approval of PDUFA date in October.

Sachin Jain Analyst

If you -- I don't think you have a -- have you given any color on the Blenrep U.S. versus ex U.S. split of your GBP 3 billion?

Julie Brown Executive

Yes. So we've guided Blenrep to be more than GBP 3 billion, and we stand by that. Obviously, that doesn't include -- we've got first-line trials running DREAMM 10, and that doesn't include the first line. It's only second and beyond. In terms of we haven't -- the second part of your question was?

Sachin Jain Analyst

Ex U.S. split.

Julie Brown Executive

Yes. So the ex-U.S. split, I mean our normal course of business, our normal business is around 50% U.S. We wouldn't expect Blenrep to be significantly different from that. It is -- we've guided more than 3, depending on the label and the guidelines.

It could be potentially significantly more because the overall survival data with Blenrep is 3 years, which is phenomenal results.

Sachin Jain Analyst

So here's just -- this -- as you said, but do you think you can beat consensus next year, just ex U.S. because I think consensus is like h?

Julie Brown Executive

Let's see. Let's talk again, obviously, following the PDUFA.

Sachin Jain Analyst

Even ex U.S., that was the question.

Julie Brown Executive

Ex-U.S., what we've said, and I think it's really important is that we want to go slow with Blenrep to basically ensure that the oncologists treat the product in the way that we believe is the right way to treat it. And we want to ensure oncologists have the right support network and they are linked appropriately to ophthalmologists or optometrists. We want that to be absolutely embedded in the launch phase. So Luke always talks about going slow to go bigger, and that would be the emphasis we will put on it.

Sachin Jain Analyst

Okay. I'll spend the last couple of minutes [we have] on HIV [indiscernible]. So one of the events that you have talked about and mentioned in intro was the potential HIV event next year for Q6M. So I ask the question, sorry, I often get asked, if Glaxo is actually going to cut the midterm guide Blenrep/Arexvy and you can provide your perspective on that. Perhaps you could touch on the opposite potential to upgrade the guide should Q6M pan out?

There's two aspects to that question.

Julie Brown Executive

Yes. So Q6 -- well, first of all, with HIV, HIV is performing really strongly this year, as you probably saw, and we just upgraded from mid-single to high single-digit growth. The growth is really very strongly being driven by Cabenuva and Apretude despite the launch with lenacapavir from Gilead. I think what's happening is prevention market is growing. So it's good news.

We've got some very important readouts for Q4M coming up next year. And therefore, we're anticipating launching Q4M for treatment and for prevention during the course of 2027. The prevention market is about 10% of the total, just to put it into perspective. So the guidance of more than GBP 40 billion includes Q4M. And then we've got Q6M as [Sachin] mentioned.

In terms of Q6M we've got a whole series of options. In terms of -- the gold standard is an integrase inhibitor and we've got a number of options relating to the combination that we use, whether it's Cabenuva long-acting, VH184, and we'll combine that with N6LS or a capsid. And so we've got a portfolio of options that Deborah will articulate the regimen selection around the middle of next year. And therefore, we decided to have a Meet The Management in Q2 2026 to be able to show the progress of these molecules and the regimen choice for Q6M. In terms of dolutegravir patent expiry, it occurs between '28 and '30.

And then between '29 and '30 is expected to be the more material loss of the dolutegravir franchise.

Sachin Jain Analyst

Two follow-ons. Q6M, is that in your GBP 40 billion and at the event could you therefore add it?

Julie Brown Executive

I think we undoubtedly will, but we obviously -- we only add assets, and this is really important to actually what you're saying. We only add assets once they've got to a certain stage of development. So this GBP 40 billion when we did the charts at the end of the year, you see the risk adjusted, which is the GBP 40 billion and the non-risk adjusted, which is considerably higher. So as assets are inflecting, you move more towards the second number. And Q6M, because we're still going through the regimen selection, we wouldn't put it in.

None of the early phase, none of the BD is in.

Sachin Jain Analyst

But sorry to belabor the point, but that might change in the middle of the year.

Julie Brown Executive

It should do. We have to see. I mean, we have to see how we get the data panning out and the choice of the molecule and the combination. So we don't want to prejudge it. But yes, we would expect it to.

Sachin Jain Analyst

Last question, the shape of HIV, in your mind, relative to consensus. Do you think that's a delta, so consensus has HIV sort of falling from GBP 7-ish billion to GBP 4 billion by the end of the forecast period? Do you think that's correct? And the shape of that decline given the various launches you've got?

Julie Brown Executive

So obviously, we wouldn't comment on an individual number within consensus. Clearly, we will go through the loss of the dolutegravir patent expiry. And we would expect there for there to be impact on the sales. We have got the strength of long-acting solutions and the HIV market increasingly is moving to long-acting, patients, 90% preferred long-acting solutions, injectables. So we do believe it's going to -- we know the long-acting has grown very strongly.

In fact, it's one of the major growth drivers of HIV at the moment. So net-net, we would expect some erosion. There will be erosion a little bit in '28, some more in '29 and then you lose the final set of patents, Dovato in the U.S. and Juluca at the end of December and July 2030. So we'd expect it to be a gradual picture.

I mean we wouldn't comment on the shape of consensus, as you know.

Sachin Jain Analyst

We're going to try next, Tony.

Tony Wood Executive

Exactly.

Sachin Jain Analyst

So if we can -- I mean, obviously, Julie's reference Blenrep is important, a lot of interest as to how you feel conversations with FDA are going, AdComm was fairly clear, but you sort of noted discussions ongoing, so whatever color you can give.

Tony Wood Executive

Yes. And look, I appreciate people are very eager to hear more about this. You'll also appreciate that we're right in the middle of confidential conversations with the FDA. And I'm going to respect that position. I'd say a few things.

As we said at the time, those conversations are constructive. The major amendment was on the basis of new information that we submitted. We don't have too much longer to wait now. The PDUFA date is the 23rd of October. But try and create the sort of setting and understanding for what we see as being the basis of our confidence in Blenrep, I think, is critically important.

And that is the fact that Blenrep still remains as the only off-the-shelf option in the second-line setting, particularly in the community. Even in a hospital setting, people like Paul Richardson will tell you that probably 70% of the second-line patients are ineligible for anything other than Blenrep. And we have a medicine that extends life by 3 years projected on OS, which is very unusual for a myeloma medicine with no life-threatening side effects. Now as Julie mentioned, one of the key things that we have to do for Blenrep, not only in the U.S. but also ex-U.S., and it's not untypical for new oncology medicines is to begin to understand and help treating physicians to manage the profile of the medicine.

And what I would say against the safety, ocular side effects, just to underscore something there is that this is an examination which is performed using standard equipment that you will find in an optometrist's office, it's a slit lamp examination. And in terms of, let's call it, the significance of the side effects, the bilateral, we look at it from -- GSK looks at it from a standpoint of bilateral effect and approximately 30% of the Blenrep patients experience a bilateral Grade 3 event for about 10% of their treatment. So I think our confidence is based on that unique benefit risk profile. We're obviously working closely with the FDA, and I'll be able to say more post October 23.

Sachin Jain Analyst

I'll try a couple. So you kicked off with the community feedback. And we've also very clearly received that. It was clearly vocalized at the AdComm. And yet you had the participants not ignore it, but sort of give great [indiscernible] party of the debate.

What's the mechanism for that community feedback to feed into an FDA process?

Tony Wood Executive

I mean, typically, of course, there are a number of stages. It's not unusual for oncology medicines to have AdComms. And it's not unusual for poor AdComms to still result in labels. So the three stages that I look at the AdComm, obviously, we were surprised by that. We're working closely with the FDA, as I've said.

What then follows is the label and the associated REMS for that and then ultimately, the NCCN guidelines, all of which figure into the practice of prescription. And then beyond that, there is, as we said, educating the treating physician, both in hospital settings and community settings, to ensure that they can take care of their patients in an appropriate way. And Luke and the MedAffairs team are doing a lot of work to set that up.

Sachin Jain Analyst

Just on the last point, can the guidelines look different to the label?

Tony Wood Executive

They often do.

Sachin Jain Analyst

And then my last question on Blenrep. The AdComm, I felt was very focused on the dosing work that may or may not have been done from their perspective. And almost as if they boxed you in by saying you didn't do it and not going to do [best] approval. Is that -- how is that not a rate-limiting step to the extent you can comment?

Tony Wood Executive

All I would say is that again, it's not unusual for oncology medicines to be initially launched without a full understanding of the dosing and scheduling. It's typical that you might expect some post approval commitments associated with that. We want to continue to do that in the context of the overall Blenrep clinical plan anyway. So we'll be working closely with the regulator and understanding that in the context of dose optimization in the second-line setting. And of course, that becomes important for the first-line setting, as well as the appropriate choice of comparator and combinations.

You'll appreciate this is a very quickly moving area. And just to finish the last component of that, so people are aware, a significant focus on the U.S. patient representation in those studies.

Sachin Jain Analyst

Okay. Anymore on this. There's a question in the back. Just wait for the microphone, please, we can't hear you, sorry.

Unknown Attendee Attendee

What about vaccine and Shingrix, so shingles, the last quarter was weak. Is it a trend that we should expect or there's a strong potential behind it?

Julie Brown Executive

Yes, yes. So with Shingrix, we've got, I suppose, we split two major regions, the U.S. We've got now we're up to 42% penetration in the U.S. market with Shingrix. And now we're anticipating gaining about another 3 to 5 percentage points of penetration per year.

Clearly, having reached this higher level of penetration, you're then dealing with harder-to-reach cohorts. So year-on-year, we wouldn't expect growth to be driven by the U.S. Where the growth has been driven from in Shingrix is all down now to outside the U.S. And about now 2/3 of the business is outside the U.S. And the penetration level in those countries is an average of less than 10%.

So there is a real opportunity. We just recently have a launch in France with the national immunization program, for example. So Europe, Shingrix in Europe is on fire at the moment, literally because we're rolling it out with NIPs in different countries. So I think the key thing is it's still a growing asset, but is largely driven outside the U.S. And the big sort of swing factor then is really relating to China.

So we launched with the partner, Zhifei, a couple of years ago. Clearly, the Chinese market has been under some pressure just for the macroeconomic situation. And I think that's the one to watch really because as the China market improves, that could have a big difference to Shingrix. Very importantly, there are like 500 million people who could benefit from Shingrix in China, of which 150 can privately pay. So there's a golden market opportunity when the environment becomes more favorable.

Sachin Jain Analyst

Can we do a couple of minutes each on the Phase III reads next year, Tony, so kick off with then camli. So two buckets: one, trial design, molecule differences versus a failed Merck, and then we'll get on to some of the endpoints in commercial.

Tony Wood Executive

Yes, sure. Let me just start to get everybody on the same page with trial timings within that as well. So we're running two Phase III studies, CALM-1 and CALM-2. CALM-1 will be [indiscernible] on first visit at the end of this year. CALM-2 we're projecting the middle of next year.

As with all of our parallel Phase III studies, we won't read out the final results until we've seen the data from both. Everything is very much going according to plan. What we've been doing as we've been designing these studies is adjusting them to ensure that we take account of the variability that Merck experienced that was, if you like, operational characteristics behind the

CRL. I don't want to get into too much of the detail on that because you'll appreciate that some of those operational characteristics speak to how we deal with placebo effect and what have you and I don't want to risk on blinding studies in answering the question. But I think it's important to say that with regards to the placebo effect, the detailed technicalities of the cough counting and the analytical treatment, we -- and indeed the representation of the spectrum of coughing frequency, which goes from relatively low-cough frequencies per day all the way through to 500 or more coughs per day.

And that takes you from the spectrum of, let's call it, stigmatization associated with coughing all the way through to the realities of incontinence or even organ damage caused by the consequences of high-frequency coughing. So that has all been accounted for in the context of the CALM-1 and the CALM-2 designs. This is, as you'll appreciate from gefapixant a Phase III study, which -- whose operational characteristics need to be considered very carefully. Importantly, the molecule itself is far superior to gefapixant and the key issue here, as I -- for people who haven't followed it, is that this is a target for which the closely related side effect comes from a subclass of the receptor. It's a P2X3 versus X2.

The -- if you hit X2, you get a very significant foul taste. That unblind study, it causes a significant degree of discontinuation. Merck had something like 60% of significant taste effects in their studies. For camlipixant, the number is 6%. So we have a molecule whose characteristics are entirely consistent with the benefit we expect to see both in terms of the patient experience, but also importantly, the blinding or unblinding of the study itself.

We have a study which has been designed to take account of the placebo effect and difficulty associated with that. So -- and what I'm doing is making sure that we execute this effectively. You'll appreciate that rushing to get to the wrong answer is not what we're about with this. So very comfortable about where we are with camlipixant and the underlying characteristics of the molecule.

Sachin Jain Analyst

And the second study and timing relative to first study, what drove that slide 6 months...

Tony Wood Executive

It was the opportunity to begin to adjust the relative proportions of coughing frequency in the two studies. The pharmacology, which is associated with the upregulation of the receptor that I've talked about, it becomes more clearly distinct at the higher end of the coughing frequency.

Sachin Jain Analyst

So that's trial design, trial -- and what I've struggled a little bit more we talked about this earlier, is the actual addressable market as to how real that market is. I know it's more of a lead question, perhaps if you could just touch on a number of patients, unmet need, where you think you're positioning it.

Tony Wood Executive

Yes. And if I answer for Luke, the sort of position he would take is the funnel we see here is about 30 million patients in total, 9 million of which we feel ultimately addressable through the differential diagnosis, 1.8 million who are currently diagnosed and sitting with pulmonologists.

Sachin Jain Analyst

And the cough frequency in that 1.8 million just to give us some context.

Tony Wood Executive

It will be at the higher end. I don't think we've disclosed that, but it will be at the higher end of the coughing frequency.

Sachin Jain Analyst

Okay. Any more on camli. On to efi, if I may. It doesn't come up as much, but obviously, data coming next year. So I'll just kick off high level.

What do you think the promise of this asset is relative to what's out there?

Tony Wood Executive

Yes. And look, if you were to ask me what's the asset in our portfolio that is underappreciated, I would go to bepi. A few things about chronic hepatitis B, first of all, very poorly diagnosed and typically 10% or less. Despite that, the prevalence is still something like 300 million individuals. Now the majority of those, obviously, ex-U.S., but when Luke looks at the forecasting for this, so the revenue, about the same in both U.S.

and ex-U.S. So what we have is a disease with significant long-term sequelae. Chronic hepatitis B infection often results in hepatocellular carcinoma or cirrhosis. We have recent real-world evidence data showing that if you have functional cure and functional cure is the ability to suppress both the HBV DNA and surface antigen marker below levels of quantification. That has a significant impact in the 80% region for reduction in risk associated with those late life sequelae.

So there is a huge premium here for a molecule that can produce a functional cure for hepatitis B. I would expect diagnosis rates will then go from the 10% further north against the massive epidemiology that we talked about. Bepi is the only molecule that has shown effective functional cure in any clinical study. The interferon has in the past shown around about 5% to 8%, but the side effects associated with constant interferon use essentially make that a not viable treatment. Our Phase II study showed around about a 10% effect in the broader population.

What we did alongside that study, though, was very carefully analyzed. The systems pharmacology for effect and the phenotype for effect. This is a nice example of us using AI/ML. And from that, we have a selection criteria that went into the B-Well study. We believe, based on projections means we will be in the 15% plus range for the total population in B-Well.

15% is what's deemed clinically relevant here. Obviously, the lower your surface antigen goes, the greater the effect you would expect to see. And then following behind that, I think about bepi very much as a 2-step process. So there is an initial valuable proposition, both U.S. and ex-U.S.

with the B-Well. I'm calling it monotherapy, but it's on top of existing nucleotide therapies. And then excitingly, the Daptom license that we secured, I think, 18 months ago or thereabouts now, allows us to take that selected bepi population from the Phase II study that I described and expand them still further because what Daptom does is suppresses surface antigen. So you can think about ultimately the sequential combination will take whatever we get for bepi, extend it to a broader ITT population but also importantly, deepen the effect for everyone. So you should see an increase in functional cure.

So two steps, but the initial ability to shift from essentially no functional cure in a disease that carries significant sequelae into even 15% or 20% is a significant start.

Sachin Jain Analyst

So I'll just take one follow-up, so we wrote [indiscernible] the feedback I've had, so acknowledging the 2% goes to 15%. Can you just frame why KOLs saying 15% is clinically relevant and what I get back is the hep C functional cure rates are much higher and people are comparing contrasting, why in your mind, is that not appropriate?

Tony Wood Executive

I think we're back to the sequelae of not treating. And this is a substantial cost in terms of liver transplant on healthcare systems, for example.

Sachin Jain Analyst

Okay. And then in the last couple of minutes, I'm going to jumble two bits together. So what data we get on Jemperli next year? I think Julie referenced that as one of the key deltas. And then what early data do we got in the ADCs that builds out into some of the later stage later?

Tony Wood Executive

Yes. Yes, let me try and do this in two minutes real quick. So for Jemperli, the key studies are the AZUR and JADE studies. What you'll see next year is the first data appearing in the dMMR rectal setting. After that, locally advanced colorectal in the dMMR setting as well.

JADE for head and neck comes in '28, if I recall correctly. Again, very much on track with that. We're confident in Jemperli's efficacy in the dMMR setting. Just to bridge then into the other ADCs, the middle of next year with our partner, Hansoh, you should see a lot more data emerging there. And the way to think about this for B7-H3, first of all, and this is the broader of the two ADCs.

Very much for us, the initial focus there is going to be on GI cancers. We'll also be looking at lung, we're in squamous cell. That's an important early indication, and you'll see sarcomas as well. This is all about building the reputation of the molecule in the KOL setting. I expect that we'll also be extending our interests there into colorectal on the back of the position that we have for Jemperli.

Again, I look forward to telling you more about how we're viewing the landscape there for the future. But GI/GU for both B7-H3 and B7-H4, sorry, for the GU setting as well. What's key there, again, is building on Jemperli's leading position in endometrial with both OS and PFS and recognizing that in endometrial and ovary, and I'm going to go and just answer this quickly. There's opportunity in the maintenance platinum sensitive setting, an opportunity in the platinum resistant setting and ultimately, to be able to take either of those ADCs and swap out one component of chemo doublet in an earlier line. So more on this as data develops.

I think the headline for B7-H3 and H4 at the moment is that we're very much in signal identification territory. At the moment, the partnership with Hansoh is going fantastically well. And of course, in signal -- in the context of signal identification, they're able to reach large numbers of patients and generate data really quite rapidly.

Sachin Jain Analyst

Say one last one, even though I can just go on. So you called out Jemperli is one of the deltas in oncology. If you could just frame the relative sizes, I don't know if you can do it exactly, but the relative size of rectal, colorectal, head and neck like which of those three are the most important or any rank, order or color as to which of the studies is most important to that ungating?

Tony Wood Executive

Yes. Rectal dMMR relatively small, dMMR colorectal, relatively small, sort of low teens percentages. The key, of course, is can we expand the dMMR setting into the MSS setting as it's called in colorectal. That's a little bit of understanding, what are the characteristics there and how to position the molecule in combination, which is a piece that I don't want to get pulled on too much. Head and neck is a large opportunity, but again, a very heterogeneous tumor.