# Q1 2023 results presentation for investors and analysts

## Wednesday, 26 April 2023

### Introduction | Nick Stone

Thank you, operator. Hello everyone. Welcome to our Q1 2023 conference call and webcast for investors and analysts. The presentation was sent to our distribution list by email, and you can also find it on gsk.com. Please turn to slide 2.

### Cautionary statement regarding forward-looking statements

This is the usual safe-harbour statement - we will comment on our performance using constant exchange rates or CER unless stated otherwise.

As a reminder, following the Consumer Healthcare demerger in 2022 to form Haleon, we are presenting performance and growth of the continuing operations for GSK. Please turn to slide 3.

### Agenda

Today's management presentation will last approximately 30 minutes, with the remaining 30 minutes for your questions. For those who wish to ask questions, please join the queue by raising your hand. Press *9 to raise and lower your hand if you are on the phone. And we request that you ask 1-2 questions so that everyone has a chance to participate.

Our speakers are Emma Walmsley, Tony Wood, Luke Miels, Deborah Waterhouse and Iain Mackay, with David Redfern joining the rest of the team for the Q&A portion of the call. Julie Brown, who will officially start as CFO next week, is also with us today on the call in a listening capacity as part of the CFO succession handover.

Turning to slide 4, I will now hand the call to Emma.

## Strategic summary | Emma Walmsley

Thanks, Nick, and welcome to everyone. Please turn to the next slide.

### Q1 2023 – Strong start

Our purpose is clear: to get ahead of disease together by uniting science, technology and talent. We are preventing and treating disease at enormous scale and delivering a new chapter of growth. As a world leader in infectious diseases, we are also focused on building our business in HIV, Immunology/Respiratory and Oncology.

And we are off to a strong start in 2023, showing our strategy continues to deliver for all stakeholders.

Excluding pandemic solutions, we have delivered double-digit sales growth, including a fifth consecutive quarter of growth across the full portfolio with excellent commercial performances in Vaccines, Specialty, and General Medicines.

- Our adjusted operating profit excluding COVID-19 solutions also grew by 5% –below the rate of sales growth this quarter due to some one-off factors, as well as planned investment in new launches. Iain will cover this in a moment.
- Our adjusted EPS grew by 14%, and we are firmly on track for our guidance this year.
- Our clear capital allocation priorities mean we continue to invest for growth and to deliver shareholder returns. The Board approved a dividend of 14 pence for the quarter.

### Strong contributions from growth vaccines and medicines driving mix shift

Our continued commercial success comes with a focus on driving the performance of our key growth products, contributing a new record high 44% of our Q1 sales, adding 500 million pounds of additional revenue vs Q1 of last year. Notable contributions came from both *Shingrix* and our HIV two-drug regimens.

Our growth drivers and new launches will support our growth over the decade and beyond. Our business mix continues to shift to Vaccines and Specialty Medicines, which are now delivering more than 60% of sales, and we are confident this shift will progress further to around three-quarters of our revenue by 2026.

A large portion of the growth is due to our pipeline launches in recent years. New products launched since 2017 delivered 2.2 billion pounds during Q1 alone, underpinning our confidence in continuous future investment in pipeline development.

### 2023 pipeline delivering momentum

#### World leader in infectious disease with a broader pipeline based on science of the immune system

Our R&D progress is delivering on our priority to strengthen our long-term growth prospects.

In Infectious Diseases, we are advancing our RSV older adult vaccine through the regulatory process and are on track to get the first US FDA approval in May. And we reported positive data last month on our pentavalent MenABCWY vaccine for adolescents. We continue to invest in our priority vaccines platforms including

protein-based antigens, mRNA following some encouraging early data in flu this year and bacterial platforms like MAPS.

In HIV, we presented positive data on long-acting *Cabenuva* compared to a daily oral medicine.

And we continue to enhance our portfolio with business development. In March, we signed an exclusive licence agreement with SCYNEXIS [SI-NEX-US] to access a first-in-class, novel antifungal, adding to our growing anti-infectives portfolio.

And we were also delighted to announce the proposed acquisition of BELLUS Health last week, further strengthening our specialty medicines and building on our respiratory expertise with a potential best-in-class treatment for refractory chronic cough.

We expect to do more targeted business development in the year ahead.

Tony and team look forward to sharing updates on our continued pipeline development and progress throughout the year with a series of therapeutic area focused meet the management events.

I will now hand it over to Tony for some more pipeline details.

## Innovation | Tony Wood

Thank you, Emma. Please turn to slide 9.

### Innovation: four focused therapeutic areas

Two thirds of our development portfolio comes from infectious diseases and HIV

Our R&D strategy is focused across 4 therapeutic areas, shaped by our world-leading capabilities in Infectious Diseases, our understanding of the immune system and our technology capabilities. Our pipeline today comprises 68 assets in clinical development, around two-thirds of which target infectious disease and HIV, and we are making good progress in continuing to strengthen our growth prospects for 2026 and beyond.

This quarter, we saw two US FDA approvals, two advisory committees and several assets progressing through clinical development, including a phase II start for our oligonucleotide NASH asset GSK'990.

We also started recruiting into our phase III programme for bepirovirsen for the treatment of chronic hepatitis B. Our ambition for bepi is to improve functional cure rates for chronic hepatitis B patients and establish a new standard of care. We look forward to presenting data from the phase II B-TOGETHER trial in the second half of this year.

### Innovation: significant developments in the prevention and treatment of infectious diseases

Elsewhere in our infectious diseases portfolio, we reported three important developments in the quarter.

Firstly, we received a positive recommendation from the FDA's advisory committee for our RSV vaccine, *Arexvy*. We remain on track for an FDA decision anticipated by May 3rd.

Our phase III RSV study re-randomised subjects for a second season to receive either vaccine or placebo. These second-season data will be important to better understand the duration of protection provided by *Arexvy*. Data collection is ongoing, and we expect a study report around mid-year.

Secondly, we announced positive data from our MenABCWY phase III trial, which demonstrated that our pentavalent vaccine has comparable protection to *Bexsero* and *Menveo*, and was well-tolerated with a safety profile consistent with *Bexsero* and *Menveo*.

Invasive meningococcal disease is an uncommon but serious infection which can cause life-threatening complications and death. Five serogroups are responsible for most meningococcal infections, and there is currently no single approved vaccine which can protect against all five of these groups. Our pentavalent vaccine combines the antigenic components of Bexsero and Menveo. If approved, it could provide the broadest meningococcal serogroup coverage of the class and we expect a simplified immunisation schedule will lead to increased vaccine uptake.

We will present preliminary data from this phase III trial at ESPID in May. We look forward to sharing these data with regulators, to make this important vaccine innovation available as soon as possible.

Finally, at ECCMID, we presented positive phase III data for gepotidacin in the treatment of uncomplicated urinary tract infections. In the US alone, there are around 15 million UTI episodes each year, around a quarter of which are resistant to existing treatments. Gepotidacin has the potential to become the first new class of antibiotics for uncomplicated urinary tract infections for over 20 years.

To complement gepotidacin, we have also been active in business development. At the end of last year, we added tebipenem, a novel antibiotic in phase III for complicated UTIs, to our infectious diseases portfolio. Also in March, we agreed to in-license *Brexafemme*, a novel, oral glucan synthase inhibitor approved for treating vulvovaginal candidiasis. Together, these three novel agents will broaden our anti-infective portfolio, covering an area of significant societal need.

### Long-acting injectable *Cabenuva* is as effective as daily oral therapy[1]

In HIV we reported data from SOLAR, the first head-to-head study of our long-acting HIV treatment *Cabenuva*, versus a daily oral therapy. SOLAR demonstrated non-inferior efficacy, a very low rate of virologic failure and a strong patient preference for *Cabenuva*, with 90% of participants in the trial expressing a preference for the long acting regimen.

At CROI, we also presented proof of concept data from N6LS, our broadly neutralising HIV antibody. These data demonstrate high potency from a single antibody, even at the lowest dose tested.

Our neutralising antibody is just one asset currently in development as a potential combination partner for cabotegravir.

### Camlipixant, a potential best-in-class P2X3 antagonist in phase III development for treatment of refractory chronic cough (RCC)

To augment our respiratory and specialty franchises, we are delighted with our recent agreement to acquire BELLUS Health, a late-stage biopharma company working to better the lives of patients suffering from refractory chronic cough, or RCC. When completed, the acquisition will provide GSK access to camlipixant, a potential best-in-class and highly selective P2X3 antagonist currently in phase III development for the first-line treatment of adult patients with RCC.

RCC affects around 28 million people globally and is defined as a persistent cough lasting for more than eight weeks that does not respond to treatment for an underlying condition. There are no approved medicines for RCC, which has a significant impact on quality of life, with some patients experiencing over 900 coughs each day.

Camlipixant has the highest P2X3 selectivity in the class. Phase II reported a very low incidence of dysgeusia, a taste disturbance attributed to P2X2 selectivity that frequently leads to patients discontinuing treatment. Phase III trials are underway and are expected to read out by 2025. We are confident that the phase III programme will confirm a best in class profile and provide an excellent addition to our specialty medicines portfolio, building upon our expertise in respiratory therapies.

## Innovation: *Jemperli* demonstrated potential to redefine treatment in 1L EC

72% reduction in the risk of disease progression or death in dMMR/MSI-H population

In oncology, we were pleased to report two significant developments adding to the evidence supporting dostarlimab.

The RUBY trial, presented at the SGO and ESMO meetings in March, demonstrated a 72% reduction in the risk of disease progression or death in the dMMR population of patients with first line advanced endometrial cancer. In the overall population, preliminary overall survival data showed a clinically meaningful trend and a 36% reduction in risk of death or progression in favour of dostarlimab treatment.

Endometrial cancer remains a significant unmet medical need. Over 400,000 new cases are reported annually, with around 15-20% of patients presenting with advanced disease at the time of first diagnosis.

In February, a US FDA advisory committee voted to support our proposed trial design to evaluate *Jemperli* in treating locally advanced rectal cancer. This trial is now recruiting patients.

## Select R&D events in 2023

As pipeline momentum continues to build in vaccines, HIV and infectious diseases, this slide highlights important regulatory events and clinical data readouts anticipated in the next 12 months. A more comprehensive view of the portfolio is provided in the appendix.

We anticipate an FDA decision for *Arexvy*, our RSV older adult vaccine candidate, in early May, with additional data to support the vaccine launch, including those from a high risk 50-59-year-old cohort, additional flu combinations, and second season outcomes.

In oncology, we anticipate an FDA decision for momelotinib in the treatment of myelofibrosis in June.

We also anticipate presenting data from the B-TOGETHER phase II trial, which will provide evidence on the durability of response for Hepatitis B patients receiving bepi and interferon, part of our programme to develop a functional cure for some of the 300mn people living with chronic hepatitis B infection today.

The continuous progress we are making underpins my confidence that our pipeline will drive growth in the latter half of the decade. Recent data, pipeline progression, and business development have further strengthened our R&D portfolio, and I look forward to sharing more data with you over the coming quarters and in future meetings.

I will now hand over to Luke on slide 15.

Thanks, Tony. Please turn to the next slide.

## Performance: broad-based commercial execution driving growth

### Balanced product group and regional growth

Strong commercial execution in the quarter continues to drive growth across our business.

As you can see on this slide, not only are our product areas contributing to growth, but we've also increased sales in each region, providing a balanced and solid portfolio with room to grow.

Our improved commercial execution capabilities will play an essential role as we launch new products of value coming through the pipeline, including our RSV vaccine for older adults.

## Performance: Q1 2023 sales £6.8bn[1], +10%[1]

### Continued strong performance across all product groups

This quarter, we delivered strong performance with sales up 10%, excluding pandemic solutions.

In Vaccines, strong growth of 9% excluding COVID-19 solutions in the quarter was supported by *Shingrix* up 11% and meningitis up 25%.

*Shingrix* delivered another record quarter of sales and a fifth consecutive quarter of growth, including increasing contributions across all geographies. *Shingrix* is now available in 31 countries, with 39% of sales coming from outside the US.

In Specialty Medicines, including HIV – which Deborah will speak about shortly – we increased sales by 13%, excluding Xevudy, to £2.2 billion.

In Immunology and Respiratory, we continued to see growth from our market-leading medicines, *Benlysta* for SLE and lupus nephritis and *Nucala* for severe asthma and other EOS-driven diseases.

*Benlysta* continues to be the leader across all major markets. However, there's still plenty of room to grow, with about 25% bio-penetration in the US and even less in other key markets.

*Nucala* remains the first and only biologic approved in four eosinophilic diseases, with new indications driving growth and differentiation. In China, the NRDL listing for EGPA has accelerated momentum, setting the foundation for our upcoming launch in severe asthma. And we look forward to our phase three COPD data in 2024.

In Oncology, sales grew 2% to £136m, despite recent US label changes for *Blenrep* and *Zejula*. We remain focused on execution across the portfolio and look forward to the anticipated launch of momelotinib in myelofibrosis following the US PDUFA date in June.

Our General Medicines portfolio grew 9% to £2.7billion. The performance predominantly reflected the strong growth of *Trelegy* across all regions, which grew 28% this quarter. We also saw a benefit from the strong allergy season in Japan and continued post-pandemic recovery of our antibiotic, *Augmentin,* which contributed £177m, further emphasising our expertise in this space as we move forward with novel antibiotics emerging from our pipeline and business development efforts.

Considering this Q1 performance, we now expect General Medicines sales to be broadly flat to slightly down in the full-year. We remain on track to deliver our existing 2023 sales outlooks for Vaccines and Specialty Medicines. You can find these on slide 35 of the presentation.

**Performance: RSV vaccine anticipated regulatory approval is imminent**

Ready for launch of new vaccine with multi-billion *Shingrix*-like sales potential

As Tony mentioned, we expect an FDA decision for our candidate RSV vaccine very soon.

RSV disease remains a significant unmet medical need. Our vaccine data showed exceptional overall efficacy, particularly in the most vulnerable populations. We expect to be the first approved RSV vaccine in major markets, including the US, Europe, and Japan.

Our teams have begun disease awareness activities where needed, and our launch preparations are well underway.

Overall, we have a competitive vaccine profile with compelling clinical evidence and multi-billion *Shingrix*-like annual sales potential - we look forward to keeping you updated as we launch this important vaccine.

With that, let me now hand over to Deborah on slide 19.

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**Performance | Deborah Waterhouse**

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**HIV: 15% growth in Q1 2023 driven by oral 2DR[1] and long-acting regimens**

Our HIV business delivered sales of one point five billion pounds in the first quarter of 2023, growing 15%. Our performance benefited from strong patient demand for our oral two-drug regimens and long-acting injectable medicines, contributing around ten percentage points of growth. US pricing favourability contributed around five percentage points of growth, and the inventory build we saw in the US in Q4 of last year has been slower to burn through than initially anticipated. We continue to believe this will burn through during the first half of this year.

*Dovato* delivered 396 million pounds in the quarter. Market performance reflects HCP's belief in *Dovato,* which has become our number-one-selling HIV medicine. We were also pleased to receive EU approval of *Triumeq* PD in the quarter – the world's first single tablet dispersible regimen for children living with HIV.

Turning to *Cabenuva*. Sales for the quarter were 127 million pounds, reflecting strong patient demand with high market access and reimbursement levels across the US and Europe. Our sales and medical teams are reporting positive customer feedback after releasing the SOLAR data at CROI, and our new direct-to-consumer advertising campaign is currently rolling out across the US.

Moving on to prevention. Sales of *Apretude*, the world's first long-acting injectable for the prevention of HIV, delivered 24 million pounds in the quarter, and we are pleased by the growing momentum across the US.

We are encouraged by the progress of our pipeline, which is focused on innovative long-acting regimens. We have three clear target medicine profiles: to provide the world's first self-administered long-acting regimen for treatment. And to provide ultra-long-acting regimens for treatment and prevention with dosing intervals of three months or longer. We are excited about the potential of these medicine profiles and will be ready to regimen select in H1 2024.

In summary, our Q1 performance positions us well to deliver the mid-single-digit growth we expect this year, and we remain very confident in our ambition to achieve a five-year mid-single-digit sales CAGR to 2026. The changing mix of our portfolio towards long-acting and the success of our pipeline offers the potential to significantly replace the revenue from dolutegravir post-loss of exclusivity.

And with that, I will hand it to Iain on slide 20.

## Performance | Iain Mackay

Thank you, Deborah. As I cover the financials, references to growth are at constant exchange rates unless stated otherwise.

As Luke and Deborah have covered the primary revenue drivers, I will focus my comments on:

the income statement, including the main cost drivers,
margins, cashflow, and guidance for 2023, including our latest phasing expectations.

Please turn to slide 21.

### Performance: Q1 2023 results and total to adjusted reconciliation

Before I go into the details of the quarter, I want to provide some context around the key factors influencing the performance of both total and adjusted results:

- As noted by the team, excluding COVID-19 solutions, we have shown strong operational delivery across the business, growing sales by 10% in the first quarter.

- Including pandemic solutions, sales were down 8%, mainly reflecting lower sales of *Xevudy* relative to Q1 2022.

- The 10% sales growth drove 5% adjusted operating profit growth, excluding COVID-19 solutions. This included a 4-point adverse impact from legal charges primarily related to the *Zejula* royalty dispute.

- Including the impact of COVID-19 solutions and those legal charges, adjusted operating profit was stable at 2.1 billion pounds. On a total basis, the lower sales, along with the Gilead settlement income of 0.9 billion pounds in the comparator, resulted in operating profit being down 15%.

- On earnings per share, excluding COVID-19 solutions, there was 14% growth on an adjusted basis. The contribution from COVID solutions reduced this growth rate by 7 percentage points, with adjusted earnings per share up 7%, at 37 pence. Total earnings per share were 36.8 pence, down 8% on a continuing basis.

Turning now to the main adjusting items of note between Total and Adjusted results for continuing operations in the quarter. These were in:

Transaction-related, with the net credit primarily reflecting ViiV contingent consideration liability movements, the majority of which related to foreign exchange.

The currency impact was a favourable 5% on sales and 8% on Adjusted earnings per share.

**Performance: Q1 2023 adj. operating margin**

Improvement to 30.1%

The adjusted operating margin was 30.1%. This was a 250 basis points improvement versus Q1 2022 at constant exchange rates.

The improvement was primarily a function of the factors I have already described, with lower sales of low-margin *Xevudy* benefitting cost of goods sold, partly offset by higher SG&A, which included the legal charges primarily related to the *Zejula* royalty dispute.

In addition to these factors, there was continued commercial and pipeline investment behind key products.

Turning to the key cost line dynamics of the quarter:

Within cost of goods sold, the 9.1 percentage point margin benefit was primarily from lower sales of low-margin *Xevudy,* but was partly offset by an unfavourable comparator to a one-time benefit from inventory adjustments in Q1 2022, as well as higher freight costs.

SG&A growth was ahead of sales and had an adverse 4.9 percentage point margin impact. This primarily reflected launch investment, particularly focused on HIV and *Shingrix*, to drive demand and support market expansion. There was also increased investment in preparation for the anticipated launches of our candidate

RSV vaccine and momelotinib later in the year. The aforementioned increased legal charges added 4 percentage points to SG&A growth.

R&D spend grew 6%, with continued investment across a combination of both early and later-stage programmes, particularly in Vaccines and Specialty Medicines.

Within Vaccines, this was driven by our pneumococcal, mRNA and phase II MMR programmes.
Within Specialty, the early-stage key assets included CCL-17 for osteoarthritic pain and IL-18 for immune-based diseases. In later clinical phases, there was higher investment behind *Jemperli*, momelotinib, depemokimab and bepirovirsen as those programmes progressed.

These dynamics were partially offset by decreases related to the completion of late-stage clinical development programs for otilimab, Cell & Gene therapy discontinuation, and reduced R&D investment in *Blenrep* versus Q1 2022.

Royalties benefitted from Biktarvy's contribution, which included an additional month in 2023 versus last year. Note that our Gardasil royalty stream will cease at the end of 2023.

**Performance: Q1 2023 adj. OP to adj. profit attributable to shareholders**
Moving to the bottom half of the P&L, I'd highlight that:

Net finance expense mainly benefitted from the net savings from maturing bonds, including the Sterling Notes repurchase in Q4 2022, and higher interest income on cash, and that

Non-controlling interests were lower due to the Q1 2022 'Other' NCIs not repeating, which was as expected.

On the next slide, I'll cover cash flow.

**Performance: Q1 2023 free cash outflow of £0.7bn**
Q1 2023 cash generated from operations of £0.3bn (-88%)
In the first quarter, there was a free cash outflow of 0.7 billion pounds.

Within free cash flow, cash generated from operations decreased to 287 million pounds, down 88%.

This primarily reflected an unfavourable comparison due to the upfront income from the settlement with Gilead received in the first quarter of 2022 and the unfavourable timing of profit share payments to Vir Biotechnology related to sales of *Xevudy*. There was also an increase in seasonal inventory and lower payable balances, reflecting increased investment in 2022.

Below cash generated from operations, there were higher tax payments.

Q1 performance on cash generation was in-line with expectations and we are on track to deliver outlooks in this area.

Turning now to slide 25 and considerations for our guidance for 2023.

## Performance: 2023 guidance reconfirmed

### Q1 delivery affirms full year expectations

We have delivered a good start to the year and are very much on track to deliver full-year guidance.

Given Q1 performance, we now expect full-year phasing to be slightly different to that shared in February.

Our Q1 performance benefitted from slower than expected HIV inventory burn and particularly strong General Medicines delivery due to the anti-infectives market recovery and Japan allergy season dynamics, which we don't expect to persist through the year.

For the second quarter, we expect to see de-stocking in HIV and for General Medicines growth to moderate due to the seasonal effects. We therefore expect sales growth in Q2 to be lower than in Q1.

With these considerations in mind, we now expect first and second half sales growth to be broadly similar. Within this, we now expect General Medicines to be broadly flat to slightly down this year.

In the second half, we continue to expect the sales growth to be influenced by the comparator periods. In HIV, these included US channel inventory build and favourable US pricing, particularly in Q4. In Gen Meds, there was a post-pandemic recovery in the antibiotic market and the launch of *Flovent* authorised generic in the US in Q2 2022. For this year, we would also expect ongoing pricing pressure in Gen Meds, especially in the US, and European pricing pressure in the HIV market.

With respect to operating profit growth, we expect this to be lower in the first half of the year compared to the second half, relative to full-year expectations. This is informed by continued investment behind ongoing and anticipated launches, including our RSV vaccine and momelotinib. As such, we expect SG&A to grow ahead of sales in Q2. We still expect SG&A to increase at a rate broadly aligned to turnover in the full-year.

On COVID-19 solutions, we still do not anticipate significant future sales. However, based on Q1, we are revising the estimate for full-year adverse adjusted operating profit impact to be 5 to 6 percentage points.

We're off to a good start in 2023, with good momentum.

With that, I will hand it back to Emma.

## Purpose: to get ahead of disease together

### For health impact, shareholder returns and thriving people

We have made building Trust by operating responsibly an integral part of our strategy and our culture. Ultimately, we are focused on delivering sustainable growth with returns to shareholders, reducing risk, helping our people to thrive, and delivering health impact at scale.

Our responsible business framework prioritises six material areas. Last month, we published our ESG Performance Report on our progress in each, including a new overall ESG rating that showed we are on track based on 83% of all performance metrics being met or exceeded.

On Access, one of the most material areas of social responsibility in our sector and one where we are committed to lead, we made further progress by expanding availability of our HIV prevention medicine cabotegravir to 90 countries by signing an agreement with generic manufacturers via the Medicines Patent Pool.

And we have enhanced recruitment of diverse patient populations with 100% of our phase III clinical trials, including a demographic plan and have also made great progress in creating a diverse, equitable and inclusive workplace.

## A focused global biopharma company with bold ambitions

So, we are off to a strong start in 2023 with all our growth drivers performing. We are very focused on our upcoming launches, including our potential RSV older adult vaccine, and continuing to strengthen our pipeline organically and through targeted business development in Vaccines and Specialty Medicines.

Our continued momentum supports our confidence in delivering on our outlook and ambitions to sustain our growth through this decade and beyond, and we look forward to sharing more details at upcoming events.

Before closing, I would like to recognise the outstanding contributions made by Iain Mackay as our CFO; this will be his last quarter before retiring from GSK. Iain has been a fantastic leader and has made an enormous impact in his time here, and I would like to sincerely and personally thank him.

Julie has been transitioning into the role with Iain and is officially starting in just a few days, and I know she is very much looking forward to spending time with you all as we continue to deliver progress.

With that Nick, can we please move to the Q&A?

## Question & Answer Session

**Kerry Holford (Berenberg):** A couple of questions please, on camlipixant. Tony, you highlighted that around 28 million people suffer from RCC globally, but I'm wondering are there specific patient sub-groups and/or markets that might be most amenable to drug therapy in this disease, perhaps more severe patients? I'm wondering whether you're willing to discuss potential peak sales that you might target for this asset? I might just throw in a last one - competitor Merck has clearly faced issues with efficacy measurements in this space, how confident are you that your asset here won't suffer the same fate? Thank you.

**Emma Walmsley:** Thanks very much Kerry. This is camlipixant, we're obviously delighted to have announced the deal with BELLUS and I'm going to ask Luke to pick up on the dimensions of opportunities in sub-groups – it's 28 million, but there are more than 10 million who have been living with this for more than a year. We are very excited about the best in class potential and the meaningful contribution that will come after a '26 launch. Luke, I know you've been very close with all of this from the beginning, so perhaps you could comment on the relative competitiveness and opportunity.

**Luke Miels:** Thanks, Emma, and thanks Kerry. I think the important thing here is there's a temptation to focus on the 28 million. So that's all people that technically had cough for more than eight weeks. In our modelling of the peak sales and the uptake we concentrated, exactly to your point, on sub-groups – people who have had Refractory Chronic Cough (RCC) for longer than one year, so they're more likely to present at a pulmonologist, and then we've taken various other cuts around access, compliance, etc.

Then you get, as we put in our slides announcing the deal, about 3.3 million potential patients in the US, and around 3 million in Europe, and about half of that in Japan – so it's quite a sizeable group. What is interesting, when you look at numbers being managed right now by pulmonologists, about 1.8 million patients being managed right now by pulmonologists in the US with ICC. The true number is actually higher, because many of them unfortunately are sent back to the primary care physician because there are limited options in terms of resolving that.

That's why we think this is a multi-billion product, and what I would encourage you to do is, if you have discussions with physicians treating these patients, there are two things they'll tell you: one is frustration in terms of the options available, and secondly, unprompted they will remark on the large volumes of patients they see. You assemble all these things, it's a very compelling asset.

I think versus Merck, I'll let Tony comment on the filing, but the pharmacological profile and the selectivity around P2X3 versus P2X2, this is an incredibly durable, robust differentiation, even if we have equivalent efficacy, and of course the upside is that we have an edge on efficacy versus Merck. The tox profile is just so much more compelling for the Merck product and that again, that is the third thing that physicians make a point around, in terms of the class.

**Tony Wood:** Just to underscore that point, two things about the Merck comparison: to put some numbers around selectivity, the unpleasant taste, dysgeusia, which is a significant impact on patients discontinuing therapy, is driven by selectivity over the P2X2 receptor class, for which camlipixant has a 1500-fold margin –

that's an enormous margin relative to the class, and of the order of 150x greater than the Merck molecule, so we're very confident in our ability to improve on side effects with regard to that particular selectivity. Indeed, you see that in the Phase II studies where there's only a 6% incidence of dysgeusia for camlipixant.

The other issues is with regards to a data treatment or analysis issue associated with the cough countering device and we have exactly the same device and approach as Merck. As far as we can tell that their CRL was based on the methodology used for data analysis, we are in ongoing conversations with the regulator and we are confident that we will be able to work through that data treatment issue, particularly given the medical need for this area that we have emphasised.

**Steve Scala (Cowen):** Firstly, I would like to clarify, when does GSK plan to initiate Phase III trials in adults and infants for the 24-valent pneumococcal vaccine? It is still listed a 2024 readout, but it's not identified as a catalyst any longer in 2024.

**Tony Wood:** We will start the Phase III studies for adults with the pneumococcal 24-valent vaccine at the beginning of next year, that represents an acceleration, relative to the acquisition objectives. You will have noted that we have a pause in our 24-valent infant programme - this is associated with an audit finding with regards to the fill and finish presentation of the vaccine. We are still very confident in the overall profile of the vaccine. In fact, our confidence in the technology continues to grow as we see emerging data from competitors in the field. I am very confident with progression here. We are working to get the 24-valent infant vaccine study back on track as soon as possible.

**Graham Parry (Bank of America):** Firstly just on RSV vaccine, any kind of level of confidence you can give over the likelihood of approval into the Ad-Comm next week? In particular, Guillain-Barre syndrome was obviously raised in both the Ad-Comm and the ACIP meeting, so whether there has been any further requests for data, or information relating to that?

Then secondly, the timing of the two-season data. I think you said data collection on-going and update mid-year, but has the FDA requested to see any of that data? And do you think you will have that data in time for the June ACIP meeting?

How does that play into pricing decisions ahead of launch? If you have that data, but it's not part of a June ACIP recommendation, can you price this for a two-year vaccine at the outset, or are you going to have to start thinking about adjusting pricing post-launch, for example?

**Emma Walmsley:** Thanks Graham, I will come to Tony first and then Luke on the specific pricing, recognising that when you are a week away from going through the regulatory process, pronouncing what is going to happen, we will have varying degrees of specificity on that and likewise, in a competitive situation on pricing, but both of those we should respond to.

**Tony Wood:** Where I might start is just emphasising the profile of our vaccine. I am sure you will recall, particularly with regards to the at-risk populations with regards to hospitalisation, where we see 94% vaccine efficacy, that profile for efficacy and the overall safety profile of course, was recognised in the VRBPAC votes our vaccine, which we were delighted to see. We continue to randomise patients on the Phase III study. We

randomised for the second season to receive second vaccination and placebo, which gives us the opportunity to make an appropriate comparison with regards to second season data.

I will remind you in the first season that our data acquisition was determined by event rate and for the second season it's determined by the close of the season. We remain on track to acquire that data, along with other data we are building the picture for the quality of our vaccine, in particular data for flu co-ad, where we will be moving into the high dose and adjuvanted setting. Again, I would remind you that on the basis of data we have so far, we are the only vaccine for which co-ad shows no impact on the performance of either vaccine. We are also adding data from the at-risk 50-59 population. We expect to have all of those data ahead of ACIP, as Emma indicated and Luke, perhaps I can handover to you with regards to the question for the pricing.

**Luke Miels:** Thanks Tony, thank you Graham. To reinforce, Tony and his team are incredibly focused on the timeline, so our working assumption is that we have that. In an unusual scenario that we just missed a deadline - which, as I said, we do not expect – I think it would depend on the robustness of the signal, but my working assumption is if we had that second season, then we would price it at the upper end of the range. We've signalled in the past that the range is somewhere between high dose flu, which is in the sixties, and *Shingrix*, which is 185 - of course it's now moving more towards the right hand side of that midpoint. If we had that second season, then we would be very much on the right hand side of that midpoint.

**Richard Parkes (BNP Paribas):** I just have two questions, firstly on *Shingrix*, I just wondered if you could disclose what underlying US volume, demand, growth was when you ex out the stocking differences - maybe you could just update us on ex-US launches where you're seeing most traction, and how that will evolve through the year?

The second question was for Tony, on business development and R&D: many of the recent transactions have added late-stage programmes, such as momelotinib, camlipixant, that will help cushion patent expiries that you'll experience later in the decade, but they don't necessarily bring platforms or technology that can help to improve GSK's longer-term R&D productivity. My question for Tony is, now that he's been in the seat a little bit longer, if he feels confident GSK has invested enough through business development to re-tool the company, in terms of technology platforms and capability, for it to be competitive and improve internal R&D productivity longer term? Thank you.

**Emma Walmsley:** Thanks very much, Richard, and obviously I'll ask Luke to comment on *Shingrix*, where we still see a lot of growth ahead, then we'll come to Tony – have we done all we need to? This is always an ongoing piece of work, and it's always at the core of our strategy in R&D. You're absolutely right, we are focused both on assets and on platforms, but Tony can make some more specific commentary on where we're at. Luke, to you first.

**Luke Miels:** Thanks, Richard. In terms of the market research, if we look at pharmacists, *Shingrix* is now our No. 1 priority and some of the challenge that they had around staffing and illness like that have been resolved. If we look at primary care physicians and intention to recommend vaccine, again, it remains unchanged, so all those things are pointing in the right direction. If we look at TRXs, then over 60% of them are first dose, which again, is very consistent, so these are all encouraging elements.

In terms of Q1, it was influenced by two distinct events, which I think will start to be washed through in Q2. The first one was we had an inventory unwind versus Q1 '22, so in Q1 '22 it was 0.9, this quarter it was 0.6, and as we've discussed on lots of calls before, the steady state is around 1-1.2 million doses a month, so we expect - and there are signs - that that's normalising now.

The other thing, linked to that, the strength of retail is very much driven by the 65 and above, which you would expect, with the removal of the co-pay, as you know commercial patients don't have a co-pay. Then the second element influencing this is that we had a lower non-retail Q1 performance, due to a very specific element, which I won't go into, but it is thoroughly addressable, and we expect to recover those patients in Q2.

You put those two things together, that's what explains the numbers, but as I said, very strong. If we look ex-US, 39% of the growth, we continue to pick up reimbursement decisions, we have expansion in Japan, we have just picked up Australia and in a number of markets in Europe, we are now really starting to get traction on. Early days in China in terms of the recovery, then of course in the long term we are very focused on the booster in that IC population, but also potentially people with an additional co-morbidity, to come back and re-challenge the original cohort.

**Tony Wood:** Then in terms of technology platforms, I'm delighted with the platform access we have and the progress we're making. I might start in the vaccines area and refer again to Affinivax, which I feel is the leading protein complexation technology that's available. We are obviously making great progress in our partnership with CureVac, with regards to RNA, and you saw some of the data that is exciting us in Phase I at least, in the context of flu and COVID, earlier in the year.

Add that to our already existing capacity in vaccines protein sub-units, structure-based vaccine design adjuvants, illustrated nicely through the RSV vaccine we've just been talking about, and I think we're in an extremely solid position with regards to vaccines technologies. You will remember that in the medicines part of our business, we added access to what we believe is the strongest oligonucleotide platform at the moment, in the context of a multi-target deal with Wave Therapeutics. As far as what I would refer to as platform technologies, I think we are in an excellent position. We obviously, as Emma indicated, remain vigilant to further areas of development.

In data technology, I would add collaborations like the one we signed with Tempus recently, which will be about helping us to identify patients in Oncology and to support the right combinations. Obviously they go on top of existing collaborations in data and human genetics and functional genomics like 23andMe and LGR for example, giving us access to cutting edge technology. I think we are extremely well placed, across the board, with regards to both platform and data technology, although you will continue to see that as a theme of business development, as I look to augment capabilities when appropriate and target identification as needs emerge in the portfolio.

**Andrew Baum (Citi):** A couple of questions, first for Deborah on ViiV. Could you talk to the anticipated impact of the rollback and continuous enrolment under Medicaid on ViiV? My assumption is the economic impact for the group is going to be limited because of the lower profitability and programmes like Ryan White will plug the gap as anyone loses coverage, but if you could tell me if those assumptions are incorrect? Then secondly, for Luke, you have spoken about the potential for line agnostic indication for momelotinib in MFS, we are waiting

obviously the label, I am sure the NCCN has already reviewed the data. Assuming that do get line-agnostic approval, do you have any sense of which category recommendation NCCN will rate, if you are to challenge Jakafi in that setting?

**Deborah Waterhouse:** Thanks Andrew, I think you are talking about the Braidwood ruling, when you are talking about some of the challenges externally in the environment, if not, stop me. The Affordable Care Act mandates coverage by commercial payors, so that they cover preventative services without cost sharing, which is very, very important. A number of employers with strong religious beliefs don't want commercial insurers to cover PrEP in HIV. A judge in Texas found in favour of the plaintiffs and therefore the Biden administration has actually appealed against this judgement, because actually it doesn't just tackle HIV for PrEP, but actually it's really undermining one of the core planks of the Affordable Care Act, that preventative services would be covered by commercial insurers. It has a number of different layers and that court case, which I think will go all the way up to the Supreme Court, is probably going to take a couple of years.

From our perspective, there are two things, we don't think there is going to be short-term impact, we are going to watch and wait to see what happens in the court case. But also, we work very closely with the community and with the various bodies in the US administration and their view is they are going to put in place policy and other reforms, to ensure that the Affordable Care Act mandate around prevention remains in place, because of their commitment to it. The other thing that is slightly ironic is, obviously the Government and in fact it's bi-partisan, the commitment to ending the HIV epidemic, has set a goal of ensuring that 50% of people who are eligible for PrEP, so that's about 600,000 of the people of the 1.2 million who are at risk, should be prescribed PrEP by 2025. So it's not just butting-up against the Affordable Care Act mandate, it's also undermining ending the HIV epidemic initiative, which is why we know from all of our government partners, they are going to fight to maintain this very strongly. They have some very clear things that they are going to do from a policy perspective and the reform options, to make sure this isn't impacting their mandate. For me, it's a watch and wait, but I am not expecting any short to medium term impact, let's see how it plays out.

**Emma Walmsley:** Thanks Deborah, so Luke, momelotinib?

**Luke Miels:** Thanks Andrew, as you know, the base-case for the deal was second line anaemia patients, JAK-exposed with anaemia, if we did get a first-line label there is clearly an upside there. I have to bite my tongue, I don't want to speculate, because as you can imagine, we're in discussions with a number of people right now.

What I can tell you is that we are very clearly saying that momelotinib of course is the only agent with profound clinical and a durable benefit, in terms of spleen results and symptom relief with patients with anaemia. I think that is landing incredibly well. If we look at unaided awareness coming out of ASH, it's quite striking, it's around 32%, which is double the typical benchmark in haematology. And when you look at aided awareness, it's around 75% of physicians.

What is also interesting is we're not actively out there making this point, but already you have 60% of treating physicians indicate that one of the top three reasons that they switch patients is because of issues with anaemia and transfusions. It's a very fertile environment for us to arrive in and we're hoping that the NCCN recognise that in terms of their labelling and language in the guidelines.

**Emma Walmsley:** Yes, we are very much looking forward to that launch.

**James Gordon (JP Morgan):** Hello. Thanks for putting up with my earlier IT meltdown! Two questions, one on Zantac and one on M&A, sort of linked together though. Zantac - the Sargon hearing wasn't quite as positive as the MDL, but latest thoughts on what that could mean in terms of liability and when this all could be wrapped up by? Given the need to maybe have some funds to address any potential Zantac damages, are you a bit spent up on BD for a while? Is there still room to do much more BD? Or do you have to set aside some funds there? Could you put the Haleon site to work, could you sell that, so then you have the ability to do some more BD?

The second question, also on BD and M&A -

**Emma Walmsley:** I think that was three, but yes!

**James Gordon:** The therapeutic strategy, I think it was more Oncology, and then I thought the focus was more infectious disease, but BELLUS looks to me looks a bit more like general meds/respiratory, is that more of a focus now?

**Emma Walmsley:** There's absolutely no change in our focus here, James, but let me try and succinctly respond to that. First of all, no new news on Zantac, very confident in our position. Obviously, we respectfully disagree with the conclusion in California, we're going to work through that case that's coming up in the summer. Delighted with the federal dismissal at the end of last year and continue to defend our position vigorously.

Completely independent of that, BD remains absolutely core, in terms of our R&D strategy, it is part of the way – like the rest of the industry – that we do R&D, it's been one of the biggest changes we've driven in the company over the last few years, delighted with the deals that we've announced recently. As you alluded to, it was absolutely core to the structural transformation that we've made of this company, with the demerger of Haleon, the re-setting of the balance sheet, a new step-change in operating performance to generate more cash and, obviously, competitive but appropriate distributions, director shareholders as well, which has created all of this capacity which we are deploying, we think, smartly, in ways with a lot of financial discipline, which contribute meaningfully to our growth. We are confident of great momentum this year, the five-year outlook and we're looking forward to that adding to that growth ahead.

There is total consistency in terms of what we've said we are prioritising, in terms of our BD. That is Vaccines and Specialty Meds as the core priorities. That doesn't mean we haven't taken advantage particularly in building out our anti-infectives priority, because we do have expertise in infectious disease and it's such a core global unmet need, the silent pandemic that will kill 10 million people a year, if the industry doesn't address antibiotics. We have a nice set of tuck-ins that Luke has led for us there. But the core priority is Vaccines and Specialty, assets and platforms, and within RTAs, the four that we work on – infectious diseases, HIV, immunology and respiratory, and oncology, which is a small but emerging area for us, where we've been pragmatic and we've just talked about momelotinib, which we're excited about coming up. Hopefully that covers all of your questions, and the next one, please.

**Seamus Fernandes (Guggenheim):** Just one question, I really want to get a sense of the company strategy in flu with mRNA and how you are thinking about the competitive landscape? We just got some mixed data from

competitor Moderna at their recent vaccine's day, but we will get some additional data in the back-half of this year. So I would just love to see how you are thinking about the mRNA flu opportunity for GSK and what you are seeing, as it relates to the competitive landscape?

**Emma Walmsley:** Let's start by saying we are excited about mRNA technology. The early data we are seeing and we expect to continue to invest more in mRNA as a portfolio. I think in terms of the competitive landscape, maybe Luke you could comment a little bit on how we see that.

**Luke Miels:** As you know, we have no presence in high-dose, so anything we can extract and penetrate there is upside. Our working assumption is that there will be a tolerable mRNA vaccine developed and of course we have the partnership with CureVac. I think the advantage of mRNA of course is just the speed at which you can go from bench to the clinic and that is not relevant for areas like shingles, but it is profoundly relevant when you are seeking to select strains and predict a future season. So any compression, enabling greater certainty in terms of the leading hemisphere to select those strains, is going to produce a more effective vaccine and hopefully shift it above 50% that we see in a typical year.

Our working assumption is it's going to be very disruptive. And I think the combination of COVID and the partnership with CureVac, is also very attractive and our expectation is that the urgency around COVID is going to be reduced but flu is going to be durable and therefore a 2+1 vaccine is attractive. Tony, do you want to mention anything in terms of the programme we have?

**Tony Wood:** Just to underscore the point Emma made at the beginning, if we look at the developments in mRNA in the field in general, I think they are all adding up to the need and importance to secure therapeutic index with regards to the gap between immunogenicity and reactogenicity. As I mentioned earlier, the data that we disclosed, or our partner in CureVac disclosed earlier this year, I think it gives us a good start with regards to expectations that both sequence modification and use of modifying bases, are going to give us a strong position.

**Simon Baker (Redburn):** I just quickly wanted to get a quick note of thanks in for Iain for all the help and assistance he has given us over the years. Two quick questions, firstly on camlipixant, although RCC is obviously a very big indication, I just wondered if you could us any thoughts on potential beyond RCC, given P2X3's implications in areas like overactive bladder and endometriosis? Secondly, on gepotidacin, a fabulous job on the development side, arguably the big challenge to come is on commercialisation. So Luke, I wondered if you could give me some thoughts on how you think about selling a new differentiated antibiotic, which historically has been somewhat of a commercial challenge.

**Emma Walmsley:** It's a great point, because I know there has been an enormous amount of thinking from Luke and his team on the dynamics across our anti-infectives portfolio where we are confident we are going to deliver financial returns. So we will come to you in a moment on this. Perhaps first Tony, you can comment on lifecycle innovation, possibilities on camlipixant, which is primarily a female patient profile, as well in RCC.

**Tony Wood:** First of all, our focus on camlipixant is increasing the degree of penetration into the enormous unmet need for the 28 million patients who suffer from Refractory Chronic Cough (RCC). I am sure you have followed this if you looked at the co-localisation of the P2X3 ligated iron channel, with regards to sensory

afference, you can imagine utility and pain, migraine, urge-urinary incontinence, but our focus is really to establish the profile of the molecule in Phase III in RCC, where we see the biggest need and immediate opportunity.

**Luke Miels:** Yes, I think we are very excited about that profile that has been achieved in Phase III with Tony's team.

If you look at typical broad-spectrum antibiotics, they are reserved because as you would expect, people want to retain potency and avoid resistance. There is also incentives around in-hospital use in terms of DRG disincentives, that don't come into play here. I think the main argument, if someone was to challenge on the risk of resistance, is gepotidacin has been developed specifically for pathogens that are resistant, limited to use in uncomplicated UTI and gonorrhoeae, so it's not a re-agent that's going to be used for post-operative infection, Staph, etc.

The other problem we have is, if you look in the US, there are around 15 million episodes a year, about a quarter of those are recurrent, and they're resistant, or the patient is allergic or intolerant for three or more antibiotics, so this is a growing group. The typical strategy, of course, is to try nitrofurantoin and others, but about a quarter of these patients' physicians employ fluoroquinolones, which as you know, are broad-spectrum antibiotics, so they're actually contributing to the problem.

Our argument is, displace fluoroquinolones, use gepotidacin, which has a much lower risk of resistance, and of course you're not destroying activity in other pathogens which could be used for more aggressive infections. Then you have the commercial scale that we can bring and the logic, as Emma has outlined, of assembling tebipenem, gepotidacin and brexafemme is that we get enormous synergy across the Specialty groups and the primary care doctors that are treating these patients.

**Emma Walmsley:** Thanks, Luke. I think that wraps up our call today. A great start to 2023, with all growth drivers performing and good momentum. Very focused on the upcoming launches, and continuing to strengthen our pipeline organically and inorganically, all of which underpins our confidence for the outlooks ahead. Thank you everyone, speak to you soon.

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