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Transforming Pharma to Deliver Sustainable Long-term Growth

Stefan Oelrich, Marianne De Backer, Christian Rommel

Thank you, Ariane for your introduction and welcome everybody to today´s presentation about our Pharmaceuticals business.

I am very excited to provide you today with a strategic update of our business, insights into our ongoing transformation process and our path forward to create value towards 2024 and beyond.

Let me first start with our management team at Pharma which has changed quite a bit since I rejoined Pharma back in 2018. In fact, about 50% of my leadership team have been replaced since then. With me today as new team members are Marianne De Backer who joined us from J&J as Head of Strategy and Business Development and Licensing and Christian Rommel who came from Roche about six weeks ago to head our Research and Development.

This new team is dedicated to drive the transformation of our Pharma business, to manage the upcoming loss of exclusivity for both Xarelto and Eylea and to return the franchise to growth thereafter.

This team will be focused on redefining how we bring new break-through innovation and medicines to patients.

While we successfully delivered on our late-stage pipeline with three potential blockbuster products we will focus now on realizing the full potential of these medicines as well as of our marketed products.

Our aim is to provide the resources needed to successfully commercialize our pipeline and we plan to continue our investment in innovation. This may result in a re-allocation of resources to free up the required funds for the most promising R&D projects.

As we broaden and expand into new modalities, we have entered into the field of cell and gene therapies. It bears the potential for the pharma industry to tap into unprecedented opportunities of the emerging bio-revolution in this area. We will be at the forefront here and have implemented a comprehensive cell and gene therapy strategy last year.

Last but not least, external innovation has always been one of the growth pillars for Pharma and external innovation will play an even greater role in the future for us.

We have defined five strategic focus areas that guide our transformation.

In the area of portfolio and pipeline, we need to maximize the value of our current portfolio and manage the loss of exclusivity for Xarelto and Eylea. With Nubeqa, Finerenone and Elinzanetant we will bring three potential blockbuster products to the market. Verquvo adds another half a billion in peak sales potential. These assets should support the topline during the Loss-of-Exclusivity phase and drive growth thereafter.

Historically, our strength lies in small molecule research & development and we need to protect this strength. On the other hand, we will continue to broaden our access to new modalities to take advantage of breakthrough innovation such as cell & gene therapy.

Digitalization across the entire value chain will also have a major impact on how we do things in the future. In the past two years, we have made significant progress in this area as well. Be it with our collaborations in R&D or by developing digital health solutions with our investment in One Drop.

Oncology represents an important pillar for future growth. We aspire to build into an at-scale Oncology player in our areas of focus. Driving growth and maximizing the value of our inline brands will be just as important as pushing for growth with new product launches.

To sustain future business expansion, we need to evolve our regional strategies, especially in China and in the US. Both countries represent our largest Pharma markets.

Obviously, managing the loss of exclusivity for Xarelto and Eylea will be one of the key tasks for us. Both products are on track to deliver their peak sales potential of more than 5 billion Euros for Xarelto and more than 2.5 billion Euros for Eylea. Already now these products belong to the leading brands in the industry.

Due to its compelling efficacy and safety profile, Eylea remains an important treatment option in the treatment of retinal diseases. We expect further growth of Eylea. This should be mainly driven by continued generation of real-world evidence across key markets and wider acceptance of Eylea's treat & extend dosing regimen.

Eylea will lose exclusivity between 2020 and 2025 in key markets. We would expect more moderate generization dynamics, given that it is a biological product. This is especially true for ex-US markets where we own the marketing rights for Eylea.

Despite the emerging competition, we still maintain a leading market position

Let's now take a closer look at Xarelto.

In 2020, Xarelto recorded sales of about 4.5 billion Euros. It is now the world´s number 4 brand in the pharmaceutical industry. It also remains the most comprehensively licensed NOAC with the strongest real-world experience, as almost 74 million patients are estimated to have been treated with Xarelto since launch.

The loss of exclusivity for Xarelto will not be a singular event but will span over several years across the main markets.

It already started at the end of last year in China. In Europe, the compound patent will expire in September 2023 and in the US in August 2024. Both may come with six months of pediatric extension of exclusivity on top.

In addition to these compound patents, we have been granted a US-patent which covers the once-daily use of Xarelto. Based on a settlement, licensed generics may enter the market in 2027.

The regional sales distribution of Xarelto reveals that more than half of Bayer´s sales are generated in Europe. Just 11% are coming from the US. This component represents the royalty income from J&J.

The regional sales distribution is an important factor to keep in mind when assessing the potential impact of the loss of exclusivity for Xarelto.

Historic genericization patterns of other small molecules reveal that post patent expiration, sales are decreasing moderately over time in Europe and in many emerging markets while in the US, the sales decline can be very pronounced.

We expect a staggered impact of the loss of exclusivity for Xarelto on our top-line. This is reflected in our long-term business projection which can be divided into three main phases.

The first phase comprises the time until the loss of exclusivity for Xarelto. Our overarching goal during this phase is to drive further growth of our franchise. In addition, we already expect to generate significant sales contributions from our launch products Nubeqa, Finerenone and Verquvo.

During the second phase we expect a moderate sales decline with a top-line trough in 2024. Compared to 2023, we would expect a low- to mid-single-digit decline in overall Pharma sales.

More importantly, we plan to return to growth thereafter. This stands in contrast to market estimates. For us, this raises the question what we may have not communicated sufficiently to the market to bringing both projections into closer alignment.

Looking at the mid-term period of 2020 to 2027, we expect sales of our marketed products to decline by about 3 billion euros overall which will be largely driven by the decline in Xarelto sales. The anticipated sales decrease for Eylea is expected to be mainly compensated by growth of our IUD franchise as well as of Stivarga and Xofigo.

During the same period, sales of our potential blockbusters Nubeqa, Vitrakvi and Finerenone as well as of Verquvo should gain momentum. We expect combined sales of these products of around 4 billion euros until 2027.

We also calculate first risk adjusted sales from Elinzanetant and the P2X3 receptor antagonist into our projection. This will be complemented by increasing sales from AskBio, including their license income and the contract development and manufacturing business.

Beyond 2027, we expect the full value of the cell & gene therapy platform to crystalize and our mid-term pipeline like the factor XI inhibitor portfolio to enter the market. During the same period, we expect the sales decline for Xarelto to bottom out.

Thus, during the past two years we established four main building blocks to lay the foundation for future growth.

These include our late-stage pipeline in cardiovascular diseases and women’s health, namely Verquvo, Finerenone and Elinzanetant.

Another building block for creating sustainable value is Oncology. With three product launches during the last years, we have significantly advanced our presence in select areas of the field.

In addition, we expect substantial growth contributions from our cell & gene therapy platform.

On top of this, external innovation, in-licensing and bolt-on acquisitions will remain an important element to replenish our pipeline and to add to long-term top-line growth.

During the remainder of our presentation we will provide you with more insights in how we plan to develop these foundational building blocks for future growth.

First, I would like to hand over to Christian Rommel who will give you his view on key innovation highlights across our pipeline. It's great to have him with us today. Christian, the floor is yours.

Thank you, Stefan. Ladies and gentlemen, it´s a pleasure for me to be here today and to update you on R&D at Pharma. During today´s presentation I will give you my initial high-level view on key R&D projects. More details are to come in tomorrow´s Pharma R&D presentation.

Looking at the late-stage pipeline, I was really excited about the level of progress, differentiation as well as the potential impact that comes along with Nubeqa, Finerenone and KaNDY NT-814. Each of these products has blockbuster potential.

Nubeqa is an androgen receptor antagonist for the treatment of non-metastatic, castration resistant prostate cancer - CRPC. The distinct profile of the molecule translated into a significant overall survival benefit and it showed a favorable and differentiated safety profile. Besides non-metastatic CRPC we expanded the clinical program into the much larger metastatic hormone-sensitive prostate cancer setting. A first trial in this indication is expected to be completed later this year. The launch of Nubeqa in the first indication is in full swing and early launch experience is exceeding our expectations. We continue to expect peak-sales of at least 1 billion Euro for the product. You will hear more about it from my colleague Robert LaCaze who is leading this success.

Finerenone is a novel, selective, non-steroidal mineral-corticoid receptor antagonist. In a first pivotal phase III trial it demonstrated renal and cardiovascular benefits in patients with chronic kidney disease and type 2 diabetes. We applied for approval in this indication in key markets and FDA granted priority review. We now also investigate Finerenone in patient with heart failure with preserved left ventricular ejection fraction. Again, we expect peak sales for the product of at least 1 billion Euro.

Elinzanetant, formerly KaNDy NT-814, is a potential non-hormonal treatment of vasomotor symptoms during menopause. Up to 75%, or in other words three out of four women going through menopausal transition experience such symptoms. Given the limitations of the current standard of care, which is hormone replacement therapy, new treatment options are needed. Based on exciting phase II data, we plan to start Phase III this year. Given the high unmet need, the novel therapy could generate peak sales of more than 1 billion Euro globally.

It's not only these late-stage assets which got me excited. Also, our early- and mid-stage pipeline comprises several attractive, scientifically sound and differentiated opportunities.

We talked about Finerenone and Elinzanetant.

In our mid-stage pipeline, our factor XI inhibitor portfolio represents one of the broadest in the industry. Blood coagulation factor XI could be a promising target for new approaches in anticoagulation with potential for reduced bleeding risk. Our portfolio includes an oral, an antibody and an antisense approach which are currently all in phase II development.

We are pursuing a multi-indication opportunity with our P2X3 receptor antagonist. The P2X3 receptor is a major regulator of afferent nerve fiber signaling and a prominent mediator of pain. We currently investigate our P2X3 in phase II across different indications such as chronic cough, overactive bladder, endometriosis and neuropathic pain which reflects the broad potential this asset may have.

Among our early pipeline assets we have some exciting projects in oncology.

In the field of precision molecular oncology, I would like to highlight the EGFR exon 20 inhibitor and the ATR inhibitor.

Mutations in exon 20 of the epidermal growth factor receptor gene are important oncogenic drivers in non-small cell lung cancer and correlate with a poor patient prognosis. Our EGFR exon 20 inhibitor is currently in IND enabling studies and may have the opportunity to address a significant unmet medical need.

ATR is a central DNA damage response kinase activated by replication stress and DNA lesions. Inhibition of ATR kinase in tumor cells may lead to cell death and thus may offer a new approach for the treatment of cancer. Our asset demonstrated compelling preclinical activity as a single agent and in combination with immunotherapy PD-1 and DNA repair blockade via PARPi.

I am particularly excited about our unique access to targeted Thorium conjugates, which may represent a completely new platform for potentially several cancer therapies. Thorium conjugates combine the alpha-radiator Thorium-227 and antibody, peptide or small molecule to direct high energy alpha-radiation to the targeted tumor cells.

Bayer did a great job in building an industry leading platform in cell and gene therapies which will propel our presence in this area. Marianne will talk about this later on in the presentation.

Already today, collaborations and use of external innovation are integral to our innovation strategy. That is why we work within a network of alliances with start-ups, top-ranked academic institutes, industry, and other partners.

Our partnership on cardiometabolic risk with the Broad institute, the successful strategic collaboration with Evotec in the area of women's health and the already mentioned collaboration with Atara in oncology are just a few examples to name here. In the future, we will further enhance our focus on external input to drive of our innovation model at Pharma.

Like many of you, we are too excited about and committed to digital innovation.

The opportunities resulting from applying data science and artificial intelligence in drug discovery and clinical development are tremendous. They may not only increase the speed in bringing new drugs to the market. They may also enhance efficiency, insights and patient outcomes in clinical trials. R&D will look differently in the future and I am excited that we have already established promising drug discovery collaborations in the field.

Medical conditions never exist in isolation. Individual circumstances influence the ability to implement treatment and advice. Through Integrated Care we want to address such patient specific circumstances. We are approaching digital health beyond the doctor's office into the realm of everyday life. Patients will be equipped with digital solutions, allowing them to move from treating diseases towards managing their own health and staying healthy. With "One Drop", we are building on an existing diabetes management platform and plan to jointly develop integrated care solutions for Cardio-Renal Diseases, Women's Health and Oncology.

The One Drop transaction was only one of many deals executed last year by the Pharmaceuticals Business Development and Licensing Team under the lead of Marianne. With that, I would like to hand over to her so that she can share insights into the work she is doing.

Thank you Christian and a warm welcome from my side. It's a pleasure to be here today to provide you with an update on our business development and licensing activities.

Over the past year, we have significantly increased our focus on external innovation to accelerate the replenishment of our pipeline and broaden access to new modalities.

Despite the pandemic and associated lockdowns, we could show an unprecedented deal flow for Bayer Pharmaceuticals in 2020 with more than 25 transactions signed, covering the entire spectrum from collaboration combined with equity investments through LEAPS, to licensing agreements to acquisitions.

Importantly, these alliances were carefully curated to help drive growth in our five strategic focus areas. We have continued to augment our core therapeutic areas (e.g. with the acquisition of Kandy therapeutics), broadened our oncology pipeline, grew our commercial footprint in China and ventured into the digital health arena.

Strategically though, the most important step we made last year was to build a leading cell and gene therapies business. Through a series of partnerships we laid the foundation for a series of world class therapy platforms with application potential across many diseases for which there is high unmet medical need.

Traditionally used modalities fall short in adequately treating many diseases, particularly when the target is e.g. an undruggable protein, or the disease is multi-factorial, or the disease is caused by one or more gene defects. Cell and gene therapies offer the possibility to address the root cause of disease and may offer even curative approaches. Based on early evidence, we believe this field will dramatically alter the standard of care across multiple conditions to the benefit of patients.

Our cell and gene therapy strategy is based on four distinct, yet interlinked platforms. Let me take you through them:

First, with the acquisition of AskBio last year we brought into Bayer one of the most advanced and industry leading gene augmentation platforms based on Adeno-associated Virus or AAV technology. It has already demonstrated clinical and commercial applicability across different therapeutic areas. AskBio also has a revenue generating contract development and manufacturing organization which we believe will contribute to help fill an important global demand gap for development and manufacturing of gene therapies.

Second, with the acquisition of BlueRock in late 2019 – we acquired a pioneering induced pluripotent stem cell (iPSC) platform to generate differentiated cell therapies in the fields of neurology, cardiology and immunology. BlueRock´s first breakthrough program in Parkinson's disease just initiated first in human studies.

Next to our gene augmentation and stem cell platforms, last year we also entered into an exclusive and strategic collaboration for a CAR-T cell therapy platform with Atara Biotherapeutics. Here we aim to develop next generation, mesothelin-targeted CAR-T cell therapies for treatment of solid tumors. Atara is a pioneer in allogeneic - which means donor independent - T-cell immunotherapy. This collaboration is a fundamental element of our strategy in the area of allogeneic cell therapies.

Finally, gene editing is the cross-functional enabling technology for most gene and cell therapies. Here we have access to the latest CRISPR/Cas technologies again through a series of external partnerships.

Our governance model allows partners such as AskBio and Bluerock to operate with great autonomy and to be fully accountable to develop and progress their portfolio and technology while benefiting from the broad capabilities and global reach at Bayer. In our view, this is bringing together the best of both worlds and positions Bayer as a partner of choice.

As a result of all these partnering activities, we have been able to bring together a vibrant pipeline of cell and gene therapies :

six clinical assets across multiple disease areas such as Pompe disease, a rare and often fatal metabolic disorder, congestive heart failure or hemophilia. For Parkinson´s disease, a progressive, degenerative disease affecting 7.5 million people globally - and for which there is substantial unmet medical need - we have two pioneering approaches: one through AskBio´s delivery of Glial Derived Neurotrophic Factor (GDNF) AAV therapy and one through BlueRock´s dopaminergic neurons derived from iPSCs. More to come on that from my colleagues tomorrow.

We expect this pipeline to continue to grow in the years to come as several pre-clinical assets are currently in IND-generating studies.

Our partnering achievements in 2020 have also been reflected in several rankings. The acquisition of AskBio for example was among the top 10 largest biopharma M&A deals in 2020. The acquisition of KaNDy Therapeutics ranked among the top 20 largest deals. Additionally, we had the most transactions in the area of artificial intelligence in our industry.

External innovation and new business development is an integral part of how we do business. We will continue to look for external opportunities to complement our inhouse activities and expertise. With that, I would like to hand it back to Stefan.

Thank you very much, Marianne.

Let’s switch gears and take a closer look at Oncology, which represents one of the most exciting and promising future growth drivers for Pharma.

In the last five years, we doubled our oncology portfolio and have significantly advanced our presence in select areas of Oncology. Our oncology portfolio now comprises six marketed products and a compelling early- and mid-stage pipeline.

Our commitment is to build an at-scale player in key areas of Oncology.

A centerpiece of our strategy to achieve this goal will be Nubeqa. For the first time, we have a product with true blockbuster potential in our oncology portfolio.

We are very excited by the initial launch uptake and we are optimistic that Nubeqa delivers its peak sales potential of more than 1 billion Euro.

For Vitrakvi the global launch is progressing. Vitrakvi demonstrated pan-tumor potential in TRK fusion cancers with an impressive overall response rates of 71 percent in adults and over 90 percent in children. The challenge for Vitrakvi is the identification of the right patient, given the need for

genetic testing. We are working diligently to increase testing rates and we are convinced that Vitrakvi will deliver substantial contributions to our topline in Oncology.

We will continue to work on our oncology pipeline and proceed the most promising assets. Some of them were already mentioned by Christian.

To achieve our long-term growth aspirations, we also have to continue to invest in next generation technologies like we did with Atara. We will continue to look for potential in-licensing opportunities and external growth opportunities through bolt-on acquisitions or through our impact investment arm “LEAPS by Bayer”.

I mentioned earlier that one of our strategic focus areas is to evolve the regional strategies in the US and China to sustain future growth.

The regional composition of our portfolio differs quite a bit compared to the pharma market.

Because of our lack of marketing rights for our two flagship brands in the US, we have an underrepresented sales contribution coming from the US market. In fact, if we had these rights, we would most likely be one of the top 10 pharma companies.

We are a Europe and China centric Pharma company with a relative low sales contribution coming from the US. At the same time, all our current US launches perform at or above our expectations, as demonstrated in the areas of WHC, oncology and such medicines as Adempas.

We expect that ongoing portfolio evolution will change our geographical imbalance significantly.

With the upcoming launches, for which we hold global commercial rights, our commercial footprint in the US will significantly expand. With the acquisition of KaNDy Therapeutics, we are capitalizing on our strength in Women’s Health where we are clearly a leading company. The same holds true for Radiology. In Oncology, Nubeqa is a key growth opportunity for us and our early launch success in the middle of the pandemic confirms that. We will also expand our position into the cardio-renal market segment with Finerenone and through co-promotion of Verquvo. This should all contribute to building our position in the US, which is still the most valuable Pharma market globally.

At our last Capital Markets Day in 2018, I highlighted the growth opportunities for us in China and I am happy to report that we exceeded our set goals ahead of time. Even though the market environment has significantly changed since then, we still see significant potential for growth.

The Chinese pharmaceutical market holds a lot of potential for future growth. This growth is based on strong market fundamentals. Disease diagnosis and treatment rates are still comparably low. Together with an aging population and increasing prevalence in chronic diseases it will drive future growth.

We aim to sustaining future growth in China through a dual track strategy. On the one hand, we are targeting to keep our strong market position of our established product portfolio by leveraging the significant volume opportunity.

On the other hand, we are pursuing an innovation driven growth strategy by addressing unmet medical need. In total, we are expecting 5-7 new product launches by 2025.

We have now talked a lot about our five strategic focus areas and the opportunities associated with each of them. What all of them have in common is that they contribute to our vision “Health for All - Hunger for None”. The same holds true for sustainability which is fully embedded in our strategy.

In 2019, we have announced measurable sustainability targets which are also linked to our incentive scheme. We are planning to provide 100 million women in low- and middle- income countries with access to modern contraception by 2030. We are implementing patient affordability programs around the world to broaden access to our pharmaceutical products. This is part of our comprehensive sustainability measures and commitments from 2020 onwards and is in-line with the Sustainable Development Goals of the United Nations.

Well, we now talked a lot about the ongoing transformation of our pharmaceuticals business. But how does all of this translate into our financial outlook and our mid-term targets?

Our new mid-term financial targets fully account for the impact of the loss of exclusivity of Xarelto. As announced with our full year results end of February, for 2021 we expect sales to grow by about 4%. Until 2023, we expect sales growth to range between 3% and 5%, reflecting the uptake of our new launches and further growth contributions from Xarelto and Eylea. In 2024, we expect to see the trough of the top-line impact from Xarelto´s loss of exclusivity in main European markets. Compared to 2023, we aim to limit the impact to a low- to mid-single-digit percentage decline in sales. More importantly, we expect to return to growth thereafter as new launches are expected to mitigate the top-line impact of the Loss of Exclusivity.

Profitability wise, we expect the adjusted EBITDA margin to range between 32% and 34% until 2023 through continued stringent cost management. For 2024, we expect an adjusted EBITDA margin of above 30%.

Ladies and gentlemen, let me summarize:

The transformation of our Pharma business is in full swing and we are excited about the future prospects of our business.

We expect limited impact from the loss of exclusivity of Xarelto, as it is reflected in our new mid-term financial targets.

We have laid the foundation for sustainable long-term growth thereafter, which will be driven by four main building blocks.

We have successfully established a Cell & Gene Therapy platform and we will continue to invest in potential breakthrough technologies.

We are also evolving our regional strategies especially in the US and in China to develop and exploit new growth opportunities for us in these geographies.

And overall, all of this is guided by our commitment to sustainability to achieve our vision of Health for all - hunger for none.

Ladies and Gentlemen, this concludes our presentation about the strategic update of our Pharma business with insights into our ongoing transformation process and our path forward to create value towards 2024 and beyond.

We are now looking forward to answering your questions during the Q+A session later today.

With that I hand it over back to Ariane. Thank you.

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