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Bayer´s Growth Strategy in Key Areas of Oncology

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Hello, my Name is Robert LaCaze and I am head of Oncology at Bayer. I am pleased to share with you an update of our overall oncology strategy as well as our recent oncology product launches.

In the past five years, significant progress has been made at Bayer in oncology. We have been able to double the number of marketed products from three to six with multiple global approvals across a number of tumors. We also broadened our innovative approach with precision oncology including the launch of Vitrakvi, the first drug to ever receive an initial tumor agnostic approval in EU including both adult and pediatric patients. Additionally, we have expanded our footprint in the prostate cancer market place with the introduction of Nubeqa for men battling with non-metastatic castrate resistant prostate cancer. And finally, we are making investments in the next wave of immuno-oncology treatments, targeting cell therapy approaches. It is our goal to make Oncology a future growth driver for Bayer Pharma.

As we view the global oncology market, it is no surprise that the modalities that are the key growth drivers will remain to be the targeted therapies and immuno-oncology. However, we do see other modalities, such as radiopharmaceuticals and they will begin to contribute to the growth of the overall market as well.

Our growth strategy in oncology is based on three important components.

1) Ensuring good launches of our most recent launch brands, Nubeqa and Vitrakvi

2) Continue to drive growth of our inline brands, specifically brands like Stivarga that have potentially an upside potential with life cycle management opportunities. And lastly,

3) Focus on three research platforms, which are:

   a. Precision Molecular Oncology,

   b. Radiopharmaceutical with a focus on targeted alpha radiation therapies, and

   c. Developing the next wave of innovation in immuno-oncology therapies.

While our R&D activities in oncology are covered in Christian Rommel´s presentation, let me just give you more specific examples of our focus. We are targeting to significantly expand our presence in select areas of oncology where one blockbuster can build a franchise. For example, prostate cancer, Nubeqa has an unsurpassed clinical profile that we feel is best in class. We are conducting multiple phase III trials along the treatment continuum to help position Nubeqa as the foundational drug for the treatment of prostate cancer.

Additionally, Xofigo is the first radiopharmaceutical to show an overall survival advantage in prostate cancer patients whose disease has metastasized to the bone. We are also conducting multiple phase III trials with Xofigo in different areas of metastatic prostate cancer. Xofigo also serves as an area of “Know how” across the value chain as we develop some of our early pipeline assets like the targeted alpha therapies. These medications will be an important new modality in the treatment of cancer offering both single agent benefits as well as a new approach to combine with current therapies like the checkpoint inhibitors. I will speak more to Vitrakvi and Stivarga later in this

presentation. However, I did want to highlight the importance our business development and licensing activities that seek opportunities consistent with our internal platform strategies as well as our Leaps organization whose investments in disruptive technologies will help to ensure that we will continue to drive the next wave of innovation. Partnerships will be extremely important as we progress in the next wave of immuno-oncology drugs.

The addition of immune check point inhibitors e.g. PD1 and PDL-1 inhibitors have led to major clinical advancements in the treatment of cancers. I have often been asked: “Can Bayer become a major Oncology player without a PD1 or PDL-1 inhibitor?” My answer to that is yes, but we must understand the market and market dynamics and be able to identify the unmet need. We use strategic approaches that are scientifically and clinically driven to combine our current assets with checkpoint inhibitors where they are approved such as our approach in liver and gastric cancers. However, we are also developing approaches in lung cancer where about 50% of the patients are treated with targeted therapies due to the underlying molecular diagnosis. Lastly in the tumors where check point inhibitors have not shown broad clinical benefit like prostate cancer, one of the largest tumors, we are making major investments to become leaders in that disease area.

As we look at the unmet need in prostate cancer, we see that the newer second generation AR-inhibitors are moving earlier and earlier in the treatment paradigm including non-metastatic disease and even potentially adjuvant therapy at the time of diagnosis. Patients who have this diagnosis need treatment options that not only extend overall survival, but they need an option where the survival benefit should not be compromised with burdensome side-effects. Most of these non-metastatic castrate resistant prostate cancer patients are asymptomatic men, who are fit and are leading very active lives. Prolonged side effects can be very burdensome for these patients and they may actually be on the therapy for three or more years. Additionally, a lot of these men may be on multiple medications for non-cancer reasons, so having a treatment option with limited drug-drug interactions can provide additional flexibility for physicians treating these patients.

Nubeqa is a structurally unique second-generation AR-inhibitor that delivers what we call a ‘quality of survival’. What we mean by that is that Nubeqa prolongs lives without negatively impacting the everyday lives of men with non-metastatic castrate resistant prostate cancer. In the ARAMIS trial, which was published in the New England Journal of Medicine, Nubeqa delivered an overall survival benefit with a 31% reduction in the risk of death. Furthermore, there was a 40-month metastasis free survival benefit as well. Regarding the AE profile, the frequency was comparable to ADT alone. It was observed that Nubeqa’s tolerability profile remained this way, even with longer follow up. This is particularly important for key adverse events that really matter to patients such as mental impairment, fractures, falls, and hypertension. In fact, fatigue was the only adverse event that was greater than 10% with a rate of 13% vs 8% for the placebo group. What this means is that patients are able to stay on full doses of therapy for longer, as shown by the discontinuation rates due to adverse events of Nubeqa being no different to placebo. Lastly, Nubeqa had a favorable drug-drug-interaction profile which again is particularly important for this patient population. All of these key attributes and benefits combine to make Nubeqa a very attractive treatment option for these patients.

To date, we have seen strong Nubeqa launch performance, with rapid approvals by regulatory bodies and rapid acceptance by payers. As a reminder, when we look at Nubeqa’s launch

performance we only look at the non-metastatic castrate resistant prostate cancer market indication where it is actually approved. This is a much smaller market than the metastatic disease market. And while it is not easy to launch a new brand in the middle of a global pandemic, and despite having limited face to face calls with physicians by our field teams, we are seeing market share gains in the non-metastatic castrate resistant prostate cancer are with continued month over month growth of new prescribers and good recognition of the differentiated profile with positive repeat prescribers. We are still in the early phases of the global launch with 2020 seeing approval in about 44 countries and 26 of those countries have submitted for pricing and reimbursement. External validation of the differentiated profile can be seen by the recently granted accelerated review and approval of Nubeqa in China despite not having local patients being enrolled in the ARAMIS trial. Additional validation comes in Germany where Nubeqa was the only second-generation AR-inhibitor to be awarded an HTA assessment of a “considerable benefit” rating by IQWIG and GB-A. This rating is very difficult to achieve and highlights the importance of not only the clinical benefit but also the favorable adverse event profile of Nubeqa.

As mentioned earlier, we are focused at Bayer to becoming a global leader in prostate cancer. We believe that the highly differentiated product profile of Nubeqa will make it a great foundational product to build our leadership vision. Hence, we are conducting multiple phase III trials across the treatment continuum of prostate cancer from the adjuvant setting to the metastatic setting with or without chemotherapy. In addition, we are conducting additional phase III trials with Xofigo in men with castrate resistant prostate cancer that has metastasized to the bone, again with or without chemotherapy. We continue to partner with the prostate cancer community to ensure that we understand the needs and deliver important therapeutic options that can be the cornerstone of care.

One of our key platforms at Bayer is identifying and developing molecular targeted cancer drugs as part of our precision oncology strategy. Vitrakvi is our first drug to be approved with a companion diagnostic. However, Vitravki is also the first drug in the industry to be approved in the US and EU with a tumor agnostic indication for both adults and pediatric patients as the initial indication. Vitrakvi treats a rare form of cancer called TRK fusion cancers. TRK fusion cancers are present in less than 1% of the overall cancer population. So, the challenge is to find and identify these patients. However, when the appropriate patient is treated with Vitrakvi, the results are usually very impressive.

This slide demonstrates the response of TRK fusion cancers to VITRAKVI. The response rate occurs across all tumor types with impressive overall response rates of 71% in adults and over 90% in children as well as in primary central nervous system tumors and tumors with central nervous system metastases. However, what is even more impressive is that 2/3 of the responders are still in response after two years of treatment with an impressive 36.8 months of median progression free survival. And lastly, Vitrakvi is well tolerated with less than a 2% discontinuation rate due to drug adverse events.

To date over 1,000 patients have been treated with Vitrakvi and we maintain our peak year sales potential of greater than 750 million euros. Currently Vitrakvi has gained regulatory approvals in 42 countries with additional launches expected in 2021. The largest single hurdle to use is testing and finding the patients. Estimated testing rates have increased since we first launched the brand in 2018 from about ~24% to ~35% in 2020 in the US and from about ~28% to ~36% in Germany. As

more and more patients benefit from comprehensive genomic testing, we anticipate that testing rates will continue to increase. We are also working with different diagnostic companies to develop and deliver quality tests and to accelerate testing. Vitrakvi is an exquisite example of innovation and is at the leading edge of precision medicine. As the market continues to move towards precision medicine, Vitrakvi is well positioned to offer unprecedented clinical benefit to TRK fusion patients.

Another important element our overall strategy is to drive the growth of our inline brands. Stivarga has seen two consecutive years of greater than 15% year-over-year growth and achieved 2020 global sales of 475 million euros. Stivarga showed growth in 2020 across all markets. One of our overall Pharma strategies is growth in China. Stivarga was launched in 2018 in China and by 2020 had achieved approximately 100 million euros of annualized sales. Globally, Stivarga will continue to grow in the near future and has the potential to become a blockbuster brand. Stivarga currently has three indications in second line HCC, third line CRC, and third line GIST. Stivarga has shown potential benefit in IO combinations as noted in this data with the PD1-inhibitor in gastric cancer. This data will be confirmed in a phase III trial. In areas of very high unmet medical needs such as glioblastoma promising phase II data has also been reported for Stivarga, again, which we are confirming in a phase III trial. In addition, there are phase II studies underway across multiple tumors with PD1-inhibitors. The plan is to continue to invest in Stivarga as growth brand to ensure we realize its full potential for both patients and for Bayer.

In summary significant progress has been made in Bayer Oncology in the past five years. Oncology is now poised to play a major role in the transformation of Pharma’s overall business. We have a near term strategy of maximizing our inline and launch brands, with a specific focus in the prostate market and Nubeqa while at the same time investing strategically in focused R&D platforms, including molecular targeted approaches, radiopharmaceuticals specifically alpha radio-therapies and partnerships to develop next generation of I-O approaches including cell therapies. External innovation with BD&L and R&D partnerships will play a vital role in our pipeline growth, which should lead Bayer to becoming a future leader in key segments of the oncology market.

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