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Ameet Mallik, Executive VP and Head of Oncology for the US at Novartis Oncology highlights the company's culture of 'curious, inspired, and unbossed,' how Novartis differentiates itself in a highly competitive oncology landscape, learnings from recent product launches, and how Novartis is working to make its CAR-T therapy more accessible to all patients.

Ameet, since you assumed your position as EVP and Head of U.S. for Novartis Oncology in November 2017, it has been three action-packed years for Novartis, including new CEOs for the overall Novartis organization, Vas Narasimhan, MD, as well as Novartis Oncology, Susanne Schaffert, PhD, the integration of Advanced Accelerator Applications (AAA) and the USD 2.1 billion acquisition of Endocyte in December 2018. What has been the impact of these developments on the US affiliate?

It has been an exciting three years. The business has seen steady growth during that period, with really strong performance in a number of new launches and growth products that were able to more than offset the impact of patent expiries on a couple of products.

In terms of leadership changes, Vas became CEO in February 2018 and Susanne became President of Novartis Oncology in January 2019. Both of them have had long careers at Novartis and are strong and passionate leaders, which have helped accelerate the overall growth of Novartis.

In terms of both acquisitions you mentioned, I actually worked on them in my previous capacity as SVP and Head of Global Marketing, Value and Access. We see radioligand therapy (RLT) as a really important platform for us. With these acquisitions, we have solidified ourselves as the only company in the industry today able to lead cancer innovations across all four of the major treatment platforms: targeted therapy, differentiated immune therapies, cell and gene therapies, and RLT. This puts us in the unique position to not only tackle cancer within each of these therapeutic modalities but also through combinations across the platforms. Our therapeutic and overall pipeline strategy has really come together over the past few years and now we are in a very exciting, highly differentiated position.

Finally, another development in the past few years is the culture of innovation that has developed within Novartis, along with the accompanying talent that has been critical to all these achievements. We have been on a great culture journey to be more ‘curious, inspired, and unbossed’. I have been with Novartis for over 15 years now, working with different CEOs, and what is striking is that we have a lot more autonomy now than we did before. Our US leadership team spends time aligning with Vas, Susanne and the rest of the global executive team on where we want to take the business over the next few years and to define what we want to achieve, but subsequently, we receive autonomy to deliver on that mission.

As you have alluded to, under CEO Vas Narasimhan, Novartis has instituted a transformative change in its organizational culture. How does this manifest within the Novartis Oncology US affiliate?

A very tangible comparison in a role like mine is that in the past, we would have had multiple performance reviews to assess our progress. Now, the sense is that we are all in this together and what our headquarters really wants to do is to enable our success and to support us. I feel like I have a lot of empowerment and accountability to run the US oncology business. Of course, there are areas where I am dependent on global drug development and Novartis Business Services, and there are inevitably issues with competing agendas that crop up when you work in a huge global company with a matrixed organization. But this ‘unbossed’ culture reminds us to keep the bigger picture in mind and resolve these issues.

From an ‘inspire’ standpoint, as an organization, we really talk a lot about patients and the impact we can have on them. We set our goals in these terms. Our focus is on leveraging our platforms to extend patients’ lives and improve their quality of life in a sustainable manner – and ultimately

cure cancer. When you center everything around the work of reimagining life for patients with cancer, that inspires people because it is such a bold and audacious ambition.

Being curious means getting to the bottom of things and really working to understand the situation instead of jumping to conclusions. Instead of leading with hierarchy, let us listen to different points of view. This also means fostering a culture of diversity and inclusion so that we have different points of view. The world is too complex for any one person to have all the answers. It is only through our collective thinking that we can arrive at a better answer.

As you have highlighted, Novartis has taken four technology approaches to oncology. How does this serve to differentiate Novartis within the increasingly competitive oncology landscape in the US?

At Novartis, we do not shy away from competition. It is a good thing and it demonstrates the attractiveness of the market. There is a reason the oncology space is so competitive. There are huge unmet needs in oncology; in the US as it is in the majority of countries globally, cancer is one of the leading causes of death. The number of new cases is expected to grow to almost 24 million by 2030 worldwide. The global oncology market is expected to reach USD 200 billion by 2022 and about half of that would be in the US. Both globally and in the US, market growth is in double digits. This is why the industry is pushing scientific boundaries to a new level and drawing in more funding, competition and innovation.

The reason we think our four-platform strategy is so important is that we want to have as many tools as we can in the toolbox to deal with cancer. The word ‘cancer’ is really a misnomer because when you look at the genomic composition, cancer is really thousands of different diseases. In addition, cancer is very smart. When it is attacked by one therapy, it is very good at developing resistance and finding other ways to proliferate. Cancer treatment is moving into combination therapies so having four platforms gives us an edge here.

Looking at CAR-T, for instance, it has been such a transformative technology. For the patients with cancers like relapsed or refractory acute lymphoblastic leukemia (ALL) and diffuse large B-cell lymphoma (DLBCL), prior to CAR-T, there were really no other viable treatments. With CAR-T, we see significant improvements in long-term survival rates – but we are still not at 100 percent. If we combine CAR-T therapies with other modalities like immuno-oncology, could it make the treatments even more effective? The future of cancer treatment is in leveraging multiple modalities of care and combination therapies to attack cancer on all fronts simultaneously.

At the same time, there is a lot of consolidation happening in the US market, both in terms of hospital systems, driven partially by the benefits of the Federal 340B Drug Pricing Program [created in 1992, this program requires drug manufacturers to provide outpatient drugs to eligible healthcare entities at significantly reduced prices], and in the community oncology centers, driven by economic factors. Companies with portfolio and capability scale are well positioned to partner with these growing provider groups.

The companies that are going to succeed in this marketplace are not only companies with a differentiated portfolio but also differentiated capabilities. For instance, in the last three years, we have strengthened our capabilities in areas like consumer marketing, precision medicine, data and digital, patient services and so on. That has to continue. When we think about the patient journey, we want to make it as meaningful and as easy as possible for all stakeholders. That requires increasingly strengthened capabilities and we have to customize the approach to each product.

For our first-in-class breast cancer drug Piqray®, for the treatment of a certain type of metastatic breast cancer with a PIK3CA mutation, which we launched in June 2019, the companion diagnostic was a critical aspect. However, breast cancer diagnostics were not well-established outside of a few areas in the US, so we needed to educate and change the behavior of not just prescribing oncologists but also pathologists, electronic medical record (EMR) technicians and so on. That is where the scale of a company – in terms of both portfolio and capabilities – is an advantage. In a more crowded environment where your customer base is consolidating, you need more specialized capabilities and more investment; you cannot launch your product ‘normally’ with a field force and a small marketing team. Consequently, big companies with large portfolios and specialized capabilities that can nevertheless remain agile are in the best position to succeed in the US market.

Last year, Novartis Oncology saw two extremely successful launches: breast cancer treatment Piqray® and sickle-cell disease therapy Adakveo®. Could you share the learnings from these two cases?

Let me start with Adakveo®, which was launched in November 2019. It is the only approved product for the reduction in the frequency of vaso-occlusive crisis in sickle cell disease. There were a few things we knew we had to get right. One was access. The majority of the patient population are either on Medicaid or Medicare, and reimbursement for an infusion product typically takes a longer time. We started our planning early and did not rely on a pre-determined model. We knew,

for instance, that just over 20 states accounted for the majority of patients so we based our strategy on that. We built a team of specialized people dedicated to this disease area and they had a year to prepare and to really understand the landscape in the US. We wanted to know each provider and their potential hurdles, and we also invested in educating state policymakers so that they understood the innovation we were bringing. All these efforts helped to create a very successful launch. Today, just six months into the launch, we already have positive coverage determination in the majority of states and we also worked with the Centers for Medicare & Medicaid Services (CMS) to receive a J-code to facilitate billing under Medicare.

We also knew that from a patient's standpoint, there is some distrust of the system. We had to engage with, listen to and educate patients to build their trust. In addition, every state is different in terms of how they work with Medicaid which causes complexity in navigating available services. We provided assistance through our Adakveo® Support center to help patients access not only the services we could offer but also the public services available to them.

We also worked closely with physicians. For an infusion product, physicians often have to bear a lot of risk in terms of the reimbursement dynamics. We provided accommodations like expanded payment terms to buffer them from these risks as much as possible.

Ultimately, when it comes to product launches, we have to understand every single barrier that could get in the way of patients accessing the product they need – and do our best to address it, either with our own resources or with other available resources.

Our breast cancer product, Piqray®, was a bit different. We already had two products in the area with Afinitor® and Kisqali® but Piqray® was a little different because we had a few priorities. The first was to drive awareness around the need for testing, which is still not very established when compared to lung cancer or melanoma. Outside of human epidermal growth factor receptor (HER2) and estrogen receptor (ER) testing, there is not much testing done. We needed to change that paradigm. We worked with Qiagen and Foundation Medicine to create companion tests and with NeoGenomics Laboratories, one of the largest breast cancer testing labs in the US, to expand testing support upfront. Prior to our efforts, testing was in the low-single digits but we raised it to about 35 percent today.

The second was side effect management. We knew the therapeutic benefit was significant but we also wanted to ensure that the side effects were well-understood and well-managed. This was important because some of the side effects like hyperglycemia were newer to breast cancer doctors. We wanted to educate and equip physicians with the tools to manage them appropriately

so patients could have good quality of life.

At the same time, Novartis' breakthrough CAR-T therapy Kymriah® is still not covered by Medicaid in every state despite its approval two years ago. How can this medicine finally deliver on its full promise?

When it comes to reimbursement, Kymriah® is in a rather unique position. First of all, it is a therapeutic that can be given inpatient – thereby falling under Medicare Part A with the Diagnosis-related group (DRG) system – or outpatient – thereby falling under Medicare Part B. While Kymriah® is moving towards outpatient use, today most of the usage is inpatient – unlike most cancer drugs. In general, inpatient reimbursement takes a long time because it takes time for CMS to update the DRGs. The existing DRGs were not adequately set up to reflect the breakthrough innovation in this product. Currently, CAR-T therapies still fall under DRG 016 in the same category as bone marrow transplants with complications. While there was rapid commercial access to Kymriah®, the reimbursement under Medicare and Medicaid was insufficient even with a new technology add-on payment (NTAP) measure, which did affect access. In May this year, CMS proposed the creation of a new hospital payment category for CAR-T therapies, which would price these treatments more sustainably for providers. This should improve the situation significantly.

I sit on the board of the Biotechnology Innovation Organization (BIO) and this is a concern across the entire industry in the US: ensuring that CMS' reimbursement cycles adequately value the innovation in new therapies. Nevertheless, looking across Novartis' portfolio and launches, I would say oncology is still a space where you can receive pretty favorable access and reimbursement in a relatively short amount of time, in comparison to other therapeutic areas. I do not see this as a major barrier. Our RLT therapy, Lutathera®, quickly received reimbursement across all sites, commercial and government, with 96 percent of lives covered within the first year.

How has the COVID-19 pandemic changed the rules of the game for the industry at large?

With every change, it is how you look at it: as a challenge or as an opportunity. During times of disruption, the first thing we try to do is make sure that every patient who can benefit from our therapies continues to receive them. The next priority is to keep our people safe and engaged. The third priority is to support the community. We established various funds to help patient

communities provide vital services to patients and we also donated a million dollars to the American Society of Clinical Oncology's (ASCO) Conquer Cancer foundation. In addition, we also started exploring the potential of our therapies in the treatment of COVID-19, with ruxolitinib and canakinumab being two examples.

Beyond that immediate response, we also thought a lot about the changing world. I think some of these changes will be permanent. Even before COVID-19, the pharmaceuticals business model was already starting to shift. Looking at the last three years, we have increased the number of products in our portfolio without having to expand our sales force. We have increased digital spend in the US more than three-fold in the last two years. We were already on a digital journey and as I look towards the future, that pace of change is only accelerating. Moving forward, digital will become a much bigger part of our operations.

We are shifting to an omni-channel engagement model. It is about how we engage, personally and digitally, with healthcare practitioners in a much more personalized, coordinated and meaningful manner. We have also stepped up consumer engagement and consumer advertising. Where a lot of companies have focused on TV advertising, we have invested more dollars into digital engagement with patients. We think that is where the future is.

Take our lung cancer medicine, Tabrecta®, which was approved by the FDA in May. It had to be a completely virtual launch, even internally. A lot of our engagement with physicians is happening virtually. We needed enhanced websites that are much more educational. We recently launched a Twitter livestream, which is a really novel way to provide peer-to-peer education. We are trying many different things and tactics, and we are learning a lot from these experiences.

With change, you either lean into it and see it as an opportunity – disruption can be a time where you create that competitive advantage for the future – or you hunker down and hope it goes away. We choose the former option and to be honest, we are very excited about the future. We want to create a more transformative and positive impact for patients and physicians on their journeys.

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