Bill Sibold – Executive Vice President, Sanofi Genzyme

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Speaking exclusively to PharmaBoardroom, Sanofi Genzyme Executive VP Bill Sibold outlines Sanofi's strategy for its specialty care unit, the wealth of potential breakthrough assets in its pipeline, product launch strategies, and the post-COVID industry of tomorrow.

Bill, you have been with Sanofi Genzyme for nearly a decade, having joined in 2011. With Sanofi's new CEO Paul Hudson joining in September 2019, what can you tell us about the new direction of the company?

It has been a real pleasure working with Paul over the past ten months. He has brought a great energy and focus to the Sanofi organization. In December 2019, we launched our *Play to Win* strategy, which comprises four pillars: grow, lead with innovation, accelerate efficiency, and reinvent how we work. Let me take you through each of them.

With a renewed focus on growth, we implemented a portfolio prioritization journey, eliminating some programs, and ultimately identifying six priority assets for Sanofi. This is fundamentally important because you cannot feign success in this industry. Any pharma company is going to be judged by how they grow their top line, which means that they need great assets.

This means leading with innovation. Sanofi brought in John Reed, M.D. Ph.D. as EVP, Global Head of R&D a couple of years ago and he has really refocused our R&D engine on first-in-class and best-in-class assets. That has delivered – and will continue to deliver – the kind of innovation that will drive

the growth we seek.

At the same time, we also want to accelerate efficiency. Jean-Baptiste Chasseloup de Chatillon joined nearly two years ago as EVP, CFO and has made great strides in helping the organization become more efficient. The only way to ensure that we maximize our returns on investment is to place them where they could make the biggest difference: our innovative, growth-driving portfolio.

Finally, the success we seek also means reinventing how we work. This started with the restructuring of the organization into three core global business units: Specialty Care, Vaccines, and General Medicines, with Consumer Healthcare becoming a standalone organization. Paul is a fervent believer in empowerment and accountability and wants people throughout the entire Sanofi organization to behave in ways that will drive the company's transformation. He has put in place an executive committee that embraces this *Play to Win* strategy and we are all committed to seeing this strategy through.

Whereas many of your peers have structured their business units based on therapeutic areas, Sanofi has gathered all Specialty Care portfolios under the Sanofi Genzyme business unit. How does this organization support the pursuit of innovation?

Placing our specialty therapeutic areas under the Sanofi Genzyme umbrella has helped us become an industry leader. Of course, under that umbrella, we still have dedicated teams for each therapeutic area focusing on oncology, neurology, immunology, rare diseases, and rare blood disorders, and we even have an entire team dedicated to our current flagship product, Dupixent®. In each of the therapeutic areas, we also have subgroups dedicated to individual product franchises. I fully believe in having such dedicated resources. You need expertise in these specialties to truly bring value to the communities you serve but at the same time, by bringing these therapeutic areas together under Sanofi Genzyme, we are able to draw from successes and learnings in one therapeutic area and apply them to the others.

Our long-standing expertise in rare diseases taught us how to work closely with the patient and physician communities. We applied this knowledge when we launched our MS and Immunology franchises. This is central to our approach as a company; patients and science are at the center of everything we do. Working closely with patients is key to understanding how to develop products that truly bring value and help solve the problems they are facing. We also need to understand the science behind the disease to offer the best solution possible.

There is an urgent need to deliver transformative therapies to these patients, many of whom are suffering without adequate treatment options. It is our obligation to continue to fuel our pipeline, move products through development faster, and remove the barriers to starting or staying on therapy and provide relief for these patients.

Dupixent® has been touted as a 'blockbuster' for Sanofi. What is the potential of Dupixent®?

Dupixent® has been a once-in-a-career type of product. Its unique mechanism of action targeting the type 2 inflammation pathway is fundamental to the underlying biology of many inflammatory diseases. We started with two indications: atopic dermatitis (AD) and asthma, which are areas with high unmet medical needs; Dupixent® was the first biologic approved for the treatment of AD. Asthma and AD are the leading indications but we're also looking at adjacent indications in dermatology and respiratory diseases. For instance, Dupixent is also approved in the US to treat severe chronic rhinosinusitis with nasal polyps (CRSwNP) which is a very complementary indication to asthma. Nasal polyps affect the upper part of the airway while asthma affects the lower part as well as the lungs. Dupixent® therefore is able to treat inflammation of the entire airway.

In addition, Dupixent® has an extremely strong safety profile, again due to the fundamentals of the biology behind the drug. In the US, we recently received approval for Dupixent® for the treatment of children between the ages of 6 and 11 years old with AD.

Looking at the global market, another exciting milestone is Dupixent®'s approval in China, which could potentially be a huge market for us. This approval came nearly two years earlier than our original assessment, a testament to the novelty and value of Dupixent®, which was recognized by the Chinese regulators. As I highlighted earlier, our ability to rapidly develop, launch, and commercialize products successfully is predicated on innovation.

Could you also share a little on the six priority assets Sanofi has identified?

The first is a BTK inhibitor, which we licensed from Principia Biopharma, that has the potential to treat broad spectrum multiple sclerosis (MS). I have personally been in this space for over 15 years and it is so exciting to see new innovation in this therapeutic area. Our investigational BTK inhibitor has the ability to reach the central nervous system at pharmacologically relevant levels and has the potential to address drivers of neuroinflammation that play a critical role in disease

progression, addressing an important unmet need for people living with MS.

We have just enrolled our first patient in our Phase III trial and we are very excited. Sanofi is a leader in MS with an existing EUR 2 billion franchise and close connections to the MS community. We are hopeful that the BTK inhibitor could be a new treatment option for patients who are still struggling with their disease.

The next two products are both for hemophilia. The first, BIVV001, acquired from Bioverativ, is a very long-acting factor VIII therapy for hemophilia A, which allows patients to be protected at near-clotting levels with a once-a-week dose. This effectively means that patients could forget that they have hemophilia A for the week in between doses. The second, fitusiran, acquired from Alnylam Pharmaceuticals, is an RNAi therapeutic for the treatment of hemophilia A and B. It is a once-a-month subcutaneous product with great coverage. From market research, we realized that patients are not only concerned about the efficacy of their treatments but also the convenience. With both products, we can offer patients a choice.

The fourth is venglustat, an oral therapy being developed in a number of indications for ultra-rare diseases like Gaucher disease type 3 and Fabry disease, but also more common diseases like autosomal dominant polycystic kidney disease (ADPKD) as well as some sub-types of Parkinson’s disease.

The fifth is our oral selective estrogen receptor degrader (SERD) that has the potential to be a transformational product in hormone-receptor-positive breast cancer.

The last is nirsevimab, a potentially cost-effective vaccine against respiratory syncytial virus, with initial focus on protecting infants.

For a while, Sanofi used to rely heavily on its legacy portfolios but in the past few years, a number of significant products have been launched, particularly from Sanofi Genzyme. Can you share some insights on product launches globally as well as in key markets like the US?

Since I joined in 2011, it feels as if my time with Sanofi Genzyme has been one constant, giant launch! It has been a great experience and as I alluded to previously, the fundamental challenge but also opportunity in specialty care is the need to understand the challenges and priorities of the individual patient and physician communities. The biggest mistake companies can make is to take a standardized approach to product launches globally or even with a single market. This is one of

the reasons some companies have struggled with specialty care for years and perhaps also explains why many companies have established standalone Oncology business units –the ways of operating are so different from the rest of the organization that they do not quite know how to manage in an integrated manner. Each disease and patient are different so companies have to organize around that heterogeneity, which is not an easy feat.

Today, we are considered global leaders in other therapeutic areas like MS and dermatology as well. We have worked hard to establish ourselves and build the capabilities needed to excel in our areas of focus. A large part of that success stems from hiring and training a core group of talent in each of these areas.

Sanofi prides ourselves on dedicating time, effort and resources to understand and manage the heterogeneity of the markets so that we can deliver long-term value to the different communities we serve. At the end of the day, if you listen to patients, physicians and other stakeholders, you will be able to provide a solution.

As you have highlighted, the US is a fundamentally important market for Sanofi Genzyme as well as Sanofi overall. With such a fragmented healthcare system in place here as well as the ongoing events within the country, what are your expectations for Sanofi Genzyme in this market?

We are a global company and are committed to bringing our innovations to global markets. At the same time, the US will always be one of the most important markets for us, even as we grow in developed and emerging countries. For Sanofi Genzyme particularly, looking at our Q1 2020 figures, the US market represented 60 percent of our revenues – compared to the US market representing just a third of Sanofi's overall revenues. There are a number of different reasons for this: first, specialty medicine tends to have larger proportions of their sales from the US, and additionally, Dupixent® has already been approved and launched for all available indications in the US but not globally.

The US will remain a critical and also an incredibly attractive market for us. It is a market that rewards innovation. Sanofi Genzyme is the only Sanofi business unit that is headquartered in the US and we have deeply rooted expertise and experience within this market.

As you mentioned, the US is a highly fragmented, complicated and ultimately rather opaque market. There is a lot of misinformation out there, as well as a lot of confusion in general over how

the system functions. What Sanofi has decided to focus on is the core issue: affordability and access for patients.

In 2017, Sanofi announced a number of pricing principles as a way of advancing responsible leadership. We were the first pharma company to take such a definitive step towards supporting the long-term sustainability of the US healthcare system. We set out three principles: first, we would provide a clear rationale for pricing at the time of launch of a new medicine (i.e. taking into account unmet medical needs, clinical trial outcomes, market activity, etc.). Second, we committed to not increasing prices for existing drugs above the projected growth rate of US National Health Expenditures. Third, we committed to disclosing annually the average list and net price changes across our portfolio of products.

Sanofi does a lot to improve patient access to our products, with copay assistance and generous free drug programs – the value of medicine we provided via patient assistance programs in 2019 was USD 727 million – but in order for the overall system to genuinely become sustainable and accessible, all stakeholders have to come together and work on delivering solutions that place patients at their center. To illustrate, in 2019, the average aggregate list price for all our products in the US increased by 2.9 percent. But the average net price – what we receive after discounts, rebates and fees paid to other actors within the system – actually fell by 11.1 percent. Those savings are going somewhere but if they do not reach patients, they are not serving their purpose.

Finally, on a more topical note, I would also like to express my admiration and respect for how the US Food and Drug Administration (FDA) has moved so quickly in their approach to handling COVID-19, approving clinical trial applications and reviewing data. This type of speed is very difficult to maintain and the US FDA – along with regulators globally – should be acknowledged for their hard work and efforts.

What considerations should leaders have in mind when they envision the industry of tomorrow?

I have worked in this industry my entire career. I love this industry and I genuinely believe it is the greatest in the world. No other industry saves and transforms lives every day – literally. This COVID-19 pandemic has given us an opportunity to demonstrate the best of our work – in less than a year, we now have over 500 therapeutics and vaccines in development – and we should take advantage of it.

Secondly, we have advanced to a point where science can work on targeted solutions for exceptionally complicated and serious diseases. I believe there are so many exciting opportunities to work on breakthrough therapies and cutting-edge science.

The final piece – which industry and stakeholders really have to consider – is the notion of being a responsible corporate citizen. Our industry's goal is to provide transformative medicines to people. That is great, but as a society, we need to have sustainable mechanisms for patients to access these innovative medications, otherwise these therapies do not benefit anyone. Sanofi is doing our part by participating in a number of different initiatives. For instance, with our partner Sobi, we committed to donating up to a billion IUs of factor therapy to the World Federation of Hemophilia. In Massachusetts, where our headquarters is located, we work with over 90 community partners on different initiatives.

Healthcare is personal and as a healthcare company, we have made a personal commitment to not only resolve the immediate medical needs of the individual patient or address broader public health challenges like pandemics, but also societal issues like the long-term sustainability of the healthcare system. As an industry, we need to feel and act like a partner rather than just transacting.

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