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We welcome the fact that President Macron has a clearly defined, strong and ambitious vision for patients and the future health of the nation

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Josephine Yang Comiskey, president of GSK France, gives insights into GSK's corporate culture, portfolio and priorities in France. She also highlights the need for collaboration and a better dialogue between industry and authorities, to ensure quicker market access for innovative products in the country.

You were appointed as the president of GSK France eight months ago. What have been your first impressions of the French market?

The French people are passionate about healthcare and they certainly have the willingness to drive a cause forward.

We welcome the fact that President Macron has a clearly defined, strong and ambitious vision for patients and the future health of the nation. Already we are seeing signs of progression when it comes to making France an epicentre of innovation in medical science. This goes hand in hand with a newfound willingness to engage in dialogue with industry with a view to enhancing economic competitiveness and investor appeal.

Following the publication of the Social Security Financing Bill (PLFSS), are you still quite as optimistic as you were before?

There has been a high level of expectations towards the Strategic Council of the Healthcare Industry (CSIS) as it mobilized all parts of the healthcare ecosystem and as it came after several years with no real space for dialogue. Prime Minister Edouard Philippe, himself, fronted the discussions, which signifies that healthcare is one of the big priorities for France. His engagement with all stakeholders and speech outlining concrete commitments towards improving the business operating environment in the life sciences sector has given private enterprises like GSK the reassurance needed to press on with ambitious investment plans.

Nevertheless, there is still an obvious disconnect between the political vision at the top and the day-to-day execution of policy and implementation of the reforms. The unveiling of the draft PLFSS in September 2018 was a disappointment and has had the effect of deflating expectations again because it implies a continuation of downward pricing pressures. There is a mismatch between the political will being espoused and the realities on the ground that companies like us are encountering. We still remain hopeful that these inconsistencies can be ironed out, but there remains a lot of work still to be done to create the sort of market access environment that industry and government are aspiring to.

As a company, we require better predictability if we are to be able to stick to operate efficiently and continue investments. From our side, we are trying to improve the dialogue with the regulatory authorities so that the process is less of a black box in order to make sure that French patients have access to our high quality and innovative medications and vaccines as quickly as possible.

Which parts of GSK's extensive portfolio are reflected best locally?

Our Pharmaceutical business has a broad portfolio of innovative and established medicines. For almost 50 years, we have been offering next generation and high-quality medicines for asthma and COPD. Our vaccines business has a broad portfolio, ranging from vaccines for meningitis to pertussis, to help protect people throughout life. We have a leading position with 23 vaccines available in France. Outside of Pharma, ViiV Healthcare has developed the first antiretroviral treatments. Today, 12 treatments are covering the 5 major antiretroviral drug classes. GSK maintains especially strong leadership and know-how in this domain as a result of our longstanding commitment to delivering patient-centric therapeutic pathways that don't leave any patients behind. With 160 years of experience, our Consumer Healthcare division develops and markets consumer preferred and expert-recommended brands in oral health, pain relief and nutrition to ensure that everyone preserves their health capital.

How helpful are French initiatives such as the ATU (Temporary Usage Authorization) for innovators such as GSK?

To be able to thrive, we absolutely require more predictability and need to be able to better understand the pricing policies of the authorities, especially considering our upcoming innovation pipeline. We have, indeed, witnessed the introduction of some very welcome measures, not least the extension of the Early Access Scheme (ATU) to line-extensions, but we still need to understand the plan for fair pricing for innovative products for patients with an unmet medical need.

At the end of the day, our mission is to deliver innovative and high-quality products as quickly as possible to French patients and we need to work together in harmony to achieve this. There is a commitment to reduce the delays and the ATU could be a great instrument and vehicle for reaching this objective.

GSK's relatively new CEO, Emma Walmsley, has spoken openly about the need to "get out of our own way" and to better incentivize output-orientated behaviours. What is the tangible impact of this change of corporate culture in the French affiliate?

The main priority is to keep our organization engaged in launching products with focused execution. The challenge is to seize the opportunities we have in front of us while maintaining true to our duty to give patients access to our high quality, innovative medications and vaccines, wherever possible. This should also help us in how to think about our capabilities of the future and ensure that we can meet evolving needs as and when they arise.

While we have strong leadership and heritage in the respiratory, vaccines and HIV areas, we also have the possibility to move ahead into future fields, such as oncology and immuno-inflammation. Here we rely on the expertise of our R&D team under the leadership of Hal Barron, to continue to inject the ideas of what GSK will look like in the future. Our new R&D approach focuses on science related to the immune system, use of genetics and advanced technologies. For this, expertise in these fields is needed, which is the reason why we have established strong relations with academic and research institutes and experts from across France to drive the value of our innovation.

There is also a visible shift in corporate culture. There is a new focus on performance, maximizing innovation and how to build trust both internally and externally. With a significant number of new senior leaders coming into the company or taking new roles, there has already been a dramatic

shift in energy, drive and fresh thinking.

GSK maintains a strong industrial footprint in France. The new Ellipta production unit at the Evreux site constitutes an investment of EUR 106mn over three years. Why was France selected for such a big-ticket investment?

GSK has been the biggest international pharma company in terms of presence and employment in France for many years. GSK has an integrated presence in France at all stages of the supply chain. Between 2018-2020, we anticipate spending circa EUR 335m in R&D and manufacturing in France. Two out of three of our French production sites (in Saint-Amand-Les-Eaux and Evreux) manufacture innovative products, bringing investments and highly qualified jobs across France.

France has strong assets including continued public investment in health, an attractive R&D tax credit, highly skilled people and a quality infrastructure network. Within our company, there is obviously heavy competition between the country affiliates for this funding. We have recognized how the French government is moving forward, with the will of investing in businesses and innovation. France has been sending positive signals for investment. However, there is a disconnect between the vision and the implementation of the strategy and this could hinder our ability to invest in the future. We need concrete progress that dramatically enhances the predictability of the French drug policy and demonstrates the French government's commitment to support Pharma attractiveness and market access for innovation.

With the ever-increasing likelihood of a hard Brexit, what are the contingency plans in place?

We have evaluated the impact of Brexit on our business operations, including our supply chain and quality oversight. Our priority is to maintain continuity of GSK's supply of medicines, vaccines and health products to our patients and consumers in the UK and the EU. Uncertainty remains about the future relationship between the UK and the EU. As a result, we have agreed on a risk-based approach to mitigate across the organization. Implementation of our contingency plan has been underway since January 2018, with an immediate focus on our supply chains. This includes expanding our ability in the EU and the UK to conduct re-testing and certification of medicines; transferring Marketing Authorizations registered in the UK to an EU entity; updating packaging and packaging leaflets; amending manufacturing and importation licenses and securing additional

warehouses.

We currently anticipate that the cost to implement these and other necessary changes could be up to EUR 80 million over the two to three years, with subsequent ongoing additional costs of approximately EUR 58 million per year.

What are your immediate priorities for the next two to three years?

In France, GSK has the opportunity to launch multiple products not only in the respiratory area but also new innovative vaccines like the one against Meningitis B. Vaccines is a priority as the government has set an ambitious target to invest more in prevention. The extension of the mandatory vaccination program (from three to 11 vaccines) has been launched by the Minister of Health in 2018, to support this priority.

GSK is funding a study called Vaccinoscopie published by Dr Robert Cohen, which has been ongoing since 2008 and highlights promising results of mandatory vaccination. Our goal is to share this publication among medical communities and health authorities for this important issue, as there is a lot of hesitancy among the French public around vaccination. We welcome the government's current stance towards vaccination and believe that this commitment will be key to restore immunization coverage and trust in vaccines.

Besides, as we are entering the Oncology and Immuno-inflammation fields, our priority is to build our scientific, medical et commercial capabilities in this fields in order to give access to new therapies that will help patients living with cancers.

A few words to conclude?

I am excited to continue driving enhanced access to innovative medicine in the fields of respiratory and vaccines as well as very soon in oncology and immuno-inflammation as I truly believe this will make a huge difference in patient's life. GSK has a strong innovation and high quality established portfolio and we are looking forward to open and constructive dialogue with our external stakeholders, especially the government and the administrative authorities. We can be considerably stronger when we are working on solutions together.

New innovations answering patients' needs, investments in a country with highly skilled people and a good network in R&D and manufacturing, contributions to social and economic development. For

all these reasons, France is very important for GSK and so is GSK for France. We further need to reinforce trust and dialogue and cooperation between private and public actors to build sustainable solutions for the future of health.

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