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Three pillars—healthcare resilience, health equity, and climate action—are the foundation of how we work with stakeholders

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AstraZeneca has made remarkable progress over the past three years in Saudi Arabia, gaining significant leadership in therapeutic areas like oncology and respiratory care, and expansion into rare diseases. Sameh ElFangary, Country President of AstraZeneca GCC & Pakistan shares insights into the company's strategy and strong alignment with Saudi Arabia's Vision 2030, discussing localization efforts, partnerships, and investments in manufacturing, research, and human capital.

Could you provide an update on the key developments and milestones AstraZeneca has achieved across your region?

Since 2021, much of the discussion revolved around AstraZeneca's strong foundation in the region and our growing footprint, which we were very proud of. At that time, we were outlining our ambition to become a more integrated part of the healthcare ecosystem and ultimately position ourselves as a leading industry partner of choice. We also had plans to launch multiple new products across all business units, and we were restructuring the business to ensure it was ready for the future—which is now the present. A key focus was also expanding our operations in strategic countries, particularly in Saudi Arabia, to align with Vision 2030.

Looking back now, I am incredibly proud of what we have accomplished.

In terms of therapeutic leadership, we have made great strides. We are now establishing ourselves as leaders in respiratory care and have launched several products that position us strongly in the cardiovascular and metabolic spaces. In oncology, we have significantly improved, moving from being ranked seventh to third in the region, and we are well on our way to becoming an oncology leader by 2026.

An exciting addition to our portfolio over the past three years has been rare diseases. This was not within our scope during our last conversation, but the global acquisition of Alexion has allowed us to broaden our offering. This means we can now serve patients across a spectrum: the many represented in millions in cardiovascular, renal, metabolic, asthma, and COPD care; the few thousands in cancer care; and the rare hundreds battling debilitating rare diseases. Rare diseases often receive less attention within healthcare systems because the focus is typically on large-scale non-communicable diseases. We are proud to play a role in ensuring these underserved patients are not forgotten.

Are there any updates or new launches that you would like to highlight across your region, and for the Saudi market specifically?

Oncology is an area where we have a truly unique pipeline and portfolio—both for the present and the future. Unlike many oncology companies that focus on a single tumor type or one or two blockbuster drugs, we have a more comprehensive approach. We are already leaders in Breast, lung and ovarian cancer, and with the recent launch of our antibody-drug conjugate (ADC), we have brought an entirely new definition for HER-2 treatments to the market. This has revolutionized the management of not only breast cancer but also for several pantumors in the region. . It has been a game-changer for our patients as well as for us, at AstraZeneca. .

Building on our leadership in Breast, lung, and ovarian cancer, we are now making significant strides in breast cancer and expanding into other areas such as colorectal cancer, hepatocellular carcinoma, and prostate cancer. Our broad portfolio across multiple tumor types not only differentiates our offerings but also ensures sustainable growth. We are not reliant on a single blockbuster drug; instead, our wide range of products drives consistent progress across various types of cancer.

In respiratory care, the landscape for asthma and COPD was relatively static a few years ago. However, within AstraZeneca, we have been fortunate to introduce innovative treatments, including new products for asthma, severe asthma, and biologics. Additionally, we have expanded

into immunology with a product for systemic lupus. These launches have reinvigorated the respiratory segment, where we were already the market leader. These advancements have solidified our our leadership in this area = through 2030 and beyond.

For the cardiovascular, renal, and metabolic (CVRM) space, which is our largest therapy area in terms of size, we continue to make a significant impact. Our diabetes treatments now include indications for chronic kidney disease and heart failure. This underscores our commitment to addressing not just diabetes as an isolated condition but the broader spectrum of its effects, including complications involving the heart and kidneys. This holistic approach will remain a key growth driver for us in the future.

Across all business units, our pipeline is supported by not only the introduction of innovative products but also the projects and initiatives that accompany them. These initiatives enable us to offer comprehensive, end-to-end solutions for patients. Having this broad and integrated approach strengthens our ability to deliver meaningful outcomes for patients across the region.

How is AstraZeneca’s rare disease portfolio represented in the region, and what factors are influencing the dynamics of this specialized therapeutic area?

Rare diseases present a unique challenge because, while the incidence of individual conditions is very small—sometimes only tens or hundreds of patients across the GCC—collectively, they represent a significant burden on healthcare systems. In some cases, the total number of patients for a specific rare disease across the region may be as low as 20. Compounding the issue is the fact that 90 percent of rare diseases have no available treatment. For the patients affected, it can take an average of seven years to receive an accurate diagnosis, often after being misdiagnosed and treated symptomatically for more common non-communicable diseases.

Many patients, particularly those in rural areas or underserved parts of the healthcare system, may never receive a diagnosis and, tragically, might die without knowing the nature of their condition. This reality underscores the need for focused attention on this therapeutic area.

Our entry into the rare disease space is driven by multiple factors, building on the strong legacy of Alexion—acquired in 2021—and its exceptional portfolio. Historically, Alexion operated in the region through distribution models, hospitals, and select key opinion leaders who understood how to manage these conditions. However, their presence was limited. This is where AstraZeneca’s scale and expertise allow us to make a significant impact on the healthcare ecosystem.

In addition to bringing innovative new treatments to the market, we are deeply involved in shaping the broader system of care for rare diseases. For example, in Saudi Arabia, we are collaborating with the Ministry of Health to establish a Center of Excellence. This initiative focuses on early diagnosis and improving the patient journey to ensure better outcomes. Our goal is not only to provide medicines but also to create a comprehensive support system for these patients.

This approach reflects our long-term ambition in the rare disease space. By addressing gaps in diagnosis, treatment, and care, we aim to transform how rare diseases are managed in the region, driving meaningful progress for patients and healthcare systems alike.

In your last interview you mentioned that AstraZeneca has been deeply aligned with the "Saudization" aspect of Vision 2030. What progress has been made in the company's local investments?

All of our strategy in Saudi Arabia is driven by the importance of the Kingdom to AstraZeneca's overall ambition. The recently launched biotechnology strategy provides further clarity on how we can align with Vision 2030 and ensure our efforts are relevant to the Kingdom's priorities. In alignment with Vision 2030, AstraZeneca is advancing its commitment to local manufacturing, exemplified by our strategic partnership with SPIMACO. This collaboration focuses on the full manufacturing of four medical products (nine SKUs) through technology transfer and substantial financial investment.

Localization is a key focus area for Saudi Arabia, particularly with the ambition to become an export hub for the region. Saudi Arabia is ideally positioned for this, both geographically and strategically. We began with secondary packaging of our products but quickly advanced, ahead of schedule, to full manufacturing for about 50% of our portfolio—covering nine stock-keeping units. This was made possible through a joint venture with SPIMACO, where we are building a high-tech facility within their premises. While this facility is not fully owned by AstraZeneca, it represents a significant partnership. By leveraging this collaboration, we are manufacturing 50% of our small molecule portfolio entirely within Saudi Arabia, from start to finish.

This is a bold step for us, and we are already discussing the next phases of localization. Saudi Arabia is interested in advancing into biologics, vaccines, and oncology products. These areas present challenges due to scale and efficiency—particularly because the domestic volume alone may not justify the investment. However, if Saudi Arabia can position itself as an export hub for the broader region, these plans could become viable.

For now, we are making excellent progress on our localization strategy and remain committed to working with stakeholders to explore and realize the next steps. The journey is ongoing, but our achievements so far reflect the deep alignment between AstraZeneca and Vision 2030.

Other than manufacturing, have there been any additional investments made by AstraZeneca in Saudi Arabia?

We have expanded and redefined the concept of localization in Saudi Arabia, working closely with stakeholders to go beyond traditional manufacturing. While manufacturing remains critical to meeting self-sufficiency goals, we believe our true value lies in areas like technology transfer for R&D, clinical trials, and future-focused innovations such as drug discovery. This aligns with the National Biotech Strategy, where stakeholders increasingly recognize the importance of these contributions.

For example, we are collaborating with institutions like King Abdullah International Medical Research Center (KAIMRC) and King Faisal University to facilitate technology transfer and position Saudi Arabia on the global drug discovery map. One notable initiative is our ongoing discussions with KAIMRC to transfer CRISPR gene-editing technology. This would enable the discovery of treatments tailored to local diseases, creating a win-win situation for Saudi healthcare and the global pharmaceutical landscape. This broader view of localization is gaining traction among stakeholders.

Localization also includes building Saudi Arabia’s human capital. For instance, we spearhead clinical trials in the region, conducting nearly 25% of all trials in Saudi Arabia, primarily in Phase 3. However, our efforts extend further into enabling local R&D capabilities. We are facilitating exchanges where Saudi scientists visit AstraZeneca’s R&D sites in Cambridge and China to gain hands-on experience, while our global experts conduct workshops and training sessions locally, as seen during the recent RGMBS event. This initiative not only fosters knowledge sharing but also inspires young scientists to explore the potential of innovative science.

We are also investing in regulatory capabilities and investigator expertise. Through partnerships with the Saudi FDA, we help refine clinical trial regulations and organize summits to train investigators in writing protocols and conducting trials. These efforts aim to create a robust framework for clinical research in the country.

Another major focus is human capital development. Vision 2030 emphasizes creating value-adding roles for Saudis, and we have aligned with this vision by surpassing basic Saudization requirements. Currently, 100% of our field force comprises Saudi nationals, and over 70% of our organization’s workforce, including managerial roles, is Saudi. This commitment reflects our long-term investment in local talent and leadership development.

Public-private partnerships are another key area, particularly in integrating digital and AI solutions into healthcare. For example, we are introducing validated AI tools and digital applications for early disease screening and diagnosis. These include AI models for detecting lung cancer at an early stage or identifying patients at high risk of progressing to chronic kidney disease from diabetes or hypertension. These tools not only improve patient outcomes but also support physicians in monitoring chronic conditions like severe asthma and diabetes through digital follow-up applications.

Globally, we leverage digital and AI technologies across R&D and operations, and we are now embedding these innovations locally to streamline processes, simplify workflows, and enhance decision-making.

All in all, by focusing on various areas of strategic investment, we aim to support the biotech ambitions of Vision 2030 and position ourselves as a lasting partner to the Kingdom of Saudi Arabia.

Having brought many assets from AstraZeneca’s portfolio across a wide coverage of therapeutic areas to Saudi Arabia, how would you characterize the access to innovation in the Kingdom today?

Access to innovation in Saudi Arabia has significantly transformed over the past few years. From a regulatory perspective, the Saudi FDA has evolved into a benchmark for the Middle East and Africa region. Initially focused on building foundational capabilities and processes, the agency has matured rapidly post-Vision 2030. It is now progressing toward becoming a wave-one market for pharmaceutical launches. Parallel submissions with leading regulatory bodies like the FDA and EMA are increasingly common, transitioning Saudi Arabia from a secondary registration market to one where innovative therapies are available at the same time as in the U.S. and Europe.

This evolution has greatly benefited patients, who now have early access to cutting-edge treatments. Initiatives like breakthrough therapy designations, accelerated reviews for life-

changing products, and orphan drug designations for rare diseases have further streamlined access. The Saudi FDA has also made strides in revising pricing and reference structures to better align with the value of innovation.

While these initiatives represent significant progress, one area for continued focus is ensuring that innovation is appropriately rewarded. For multinational companies to prioritize Saudi Arabia as a wave-one market, predictable frameworks for pricing, IP protection, and regulatory data protection are essential. This approach mirrors the models in the U.S. and key European markets, where innovation is incentivized through robust pricing structures and strong IP safeguards. If these efforts continue to progress, the Kingdom is well-positioned to attract more innovative therapies and play a leading role in shaping the future of healthcare access in the region.

How would you assess the willingness and openness of regulators to collaborate with the industry to foster discussions and find mutually beneficial solutions around access?

I feel that the willingness and openness of regulators in Saudi Arabia to collaborate with the pharmaceutical industry have certainly improved in recent years. This shift reflects a proactive effort by the Ministry of Health and other key institutions to accelerate patient access to innovative therapies.It also reflects the Saudi Food and Drug Authority (SFDA)’s commitment to driving regulatory advancements. These advancements align with Saudi Arabia’s Vision 2030 to establish itself as a regional leader in healthcare innovation, including through initiatives such as the National Biotechnology Strategy. This strategy focuses on critical areas such as vaccines, biomanufacturing, genomics, and local production capabilities, reinforcing SFDA’s standards for clinical trials and biomanufacturing to support timely access to advanced therapies. Previously, the time from a product’s approval by the Saudi FDA to actual patient access within institutions could take up to 18 months. This delay was due to the necessary, but lengthy, processes for evaluating benefits, securing funding, assessing cost-effectiveness, and conducting budget impact analyses. However, significant progress has been made, with timelines now reduced to 9 to 12 months. While this acceleration is welcome, there is still room for improvement to minimize delays without compromising the thoroughness of the evaluation process.

One of the key challenges lies in the absence of a unified national reimbursement system. Certain disease areas, such as oncology and rare diseases, benefit from government funding, but broader accessibility remains a challenge, particularly in the private sector. Many diagnoses occur in secondary and tertiary hospitals. If treatments are not readily available within these institutions,

patients can face critical delays in receiving care. As the industry, we are eager to collaborate with stakeholders to streamline the process and anticipate these evaluation steps to reduce wait times.

Additionally, the Health Sector Transformation Program (HSTP) is reshaping Saudi Arabia's health sector into an integrated, value-based system that prioritizes patient-centered care and improves service delivery. With US$12.8 billion allocated to projects such as establishing 224 primary healthcare centers and adding over 20,000 hospital beds by 2030, the Kingdom is building a comprehensive healthcare infrastructure to support sustainable advancements.

Another positive development is the growing openness to public-private partnerships. Historically, multinational organizations sought to engage with Saudi stakeholders, but the acceleration of the biotech strategy under Vision 2030 has ushered in a more open-door policy. This framework fosters rapid innovation adoption while maintaining rigorous safety and efficacy standards, creating an ecosystem where public, private, and non-profit entities can thrive. This includes greater receptivity to collaboration with consultancy firms, multinational organizations, and other countries that have advanced healthcare systems.

Looking ahead, what are AstraZeneca's top priorities for the Saudi market?

We aim to be among the top three companies overall while maintaining our leadership position in all the therapeutic areas where we operate.

Our priority is also to be recognized by stakeholders as their partner of choice. This goes beyond delivering medicines and innovations early to patients. It includes shaping the entire patient journey and offering end-to-end solutions. We want to support the Kingdom's biotech strategy in various areas, including localization, research and development, digitalization, AI, and contributing to the economy and human capital development. Across all these aspects, we aim to reinforce our role as a trusted partner.

Lastly, we remain focused on our people and employees. They are passionate about science and proud of what we are achieving, so it is crucial to continue fostering an environment where they feel energized and valued. We are committed to being a great place to work—a goal we are already achieving, as evidenced by certifications. However, being the best place to work is an ongoing aspiration. Each year, we strive to redefine what more we can do to keep our people engaged and motivated.

AstraZeneca has outlined its ambition to go beyond its mission of providing disease treatments to also driving sustainability outcomes. Could you walk us through these ambitions and the specific areas of focus for AstraZeneca in this regard?

At AstraZeneca, we have a unique approach to our strategy, which is built on three main pillars that guide everything we do. These pillars are consistent across all therapy areas and levels of the organization—from our field force to senior leadership. It is a unified framework that makes AstraZeneca stand out.

The first pillar is healthcare resilience. COVID-19 taught us how vulnerable healthcare systems can be. During the pandemic, we saw systems collapse under pressure, with many cancer patients or those needing regular follow-ups being deprioritized as resources were focused on COVID-19. This led to delays in treatment and, sadly, loss of life. Building a resilient healthcare system that can withstand future pandemics is critical.

To address this, we partnered with the London School of Economics and the World Economic Forum to assess healthcare system resilience globally. Saudi Arabia and the UAE were included in this effort. We published the Saudi Arabia report during the Global Health Exhibition in 2023 and the UAE report at Abu Dhabi Global Health Week in early 2024. These reports provide a blueprint and recommendations for building stronger, more resilient healthcare systems.

The second pillar is health equity. A good example is rare diseases, which often lack prioritization due to limited advocacy or visibility. Patients with rare diseases may remain undiagnosed or untreated, leading to tragic outcomes. But health equity is not just about rare diseases or affordability. In regions like Saudi Arabia, which have strong GDP per capita and advanced healthcare infrastructure, the challenge lies in areas like early diagnosis. Many patients are diagnosed late because there are no systematic screening programs for some diseases, such as chronic kidney disease or certain cancers like breast cancer. Our focus is on addressing these gaps to ensure every patient gets the care they need at the right time.

The third pillar is climate action, which is a unique focus for AstraZeneca. Globally, we have committed to achieving net zero emissions by 2045. Our CEO leads a group of seven healthcare CEOs as part of the Sustainable Markets Initiative, established during COP26. The healthcare industry contributes around 5% of global greenhouse gas emissions, making it one of the largest emitters. At the same time, healthcare is deeply affected by environmental issues, such as the rise in respiratory diseases, cancers like lung cancer, and communicable diseases caused by climate change.

Our efforts include several initiatives to address this, such as forestation programs in Saudi Arabia, transitioning to sustainable offices, reducing travel, and waste management. Beyond these efforts, we are focusing on decarbonizing healthcare pathways. This means assessing the carbon footprint of a patient's journey—from diagnosis to treatment—and finding ways to reduce it. For example, diagnosing early reduces the need for multiple hospital visits, and better follow-up care keeps patients healthier and away from hospitals.

These three pillars—healthcare resilience, health equity, and climate action—are the foundation of how we work with stakeholders. Whether it is patients, society, or the planet, our goal is to make a meaningful impact in all areas. We are committed to improving health outcomes for people, building stronger healthcare systems for society, and protecting the planet for future generations.

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