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Two years into his role, Ipsen's EVP and Chief Medical Officer Prof. Dr. med. Steven Hildemann MD discusses his vision of patient-centricity and how he is leading a medical transformation that puts data-driven insights at the core and aims to make a real difference to both clinical practice and patients' lives. The French mid-cap has recently announced that it delivered a strong financial performance in 2021 and that it was entering into exclusive negotiations with Mayoly Spindler to divest its Consumer Healthcare business.

Ipsen has been undergoing an organisational and cultural transformation in recent years, with medical affairs now established as a strategic pillar between R&D and commercial. Could you begin by introducing your role?

I serve as EVP and chief medical officer at Ipsen, leading on medical affairs, patient safety, and patient affairs globally. My absolute priority in the past couple of years has been to deliver a deep medical transformation at Ipsen. Since 2020, we have been working hard on expanding our medical and scientific capabilities and establishing the function as a key organisational driver along with R&D, Commercial and Business Development. Our goal is to ensure that both patient and HCP

needs shape our decision-making and translate into measurable improvements to patients' lives and outcomes in our areas of focus – oncology, rare disease and neuroscience.

Even prior to my arrival, Ipsen had decided to elevate the CMO role to the executive leadership team (ELT) to make sure it receives proper attention, resourcing, and strategic exposure. That was one of the things that first attracted me to the company, along with its strong tradition and deep commitment to patient-centricity. Over the years, I had been exposed to this tradition and commitment when I saw Ipsen colleagues in action at various congresses and meetings; a culture of patient-centricity permeates the company, which is a pleasure to contribute to and live by.

Can you outline the rationale behind centralising the medical affairs, patient affairs, and patient safety functions in one role and what the synergies between them are?

Consolidating medical affairs, patient affairs, and patient safety operations under the Chief Medical Office (CMO) is a reasonably new industry trend that a few other companies have also followed. In the specialty care arena, we are seeing a deep shift to putting data and insight generation at the absolute core of the CMO function, but also in R&D and Commercial. Fundamentally, the CMO function sits at the meeting point between patients, physicians and data-driven insights. In practice, it generates novel data and insights on our molecules, assets and science; and provides medical education and product information. At the heart of this needs to be deep scientific expertise.

This expertise needs to cut across the entire firm; knowledge transfer within and outside the company is critical to the operation of a modern biopharmaceutical player, which is where the synergies with safety come in. Over the years, safety has moved from a regulatory mandated function to today covering data generation that far exceeds the traditional case gathering operations. Key trends include the systematic monitoring of social media and piloting uses for our global safety database that go far beyond just producing reports for health authorities and regulators. For any given oncology product, there may be decades of experience hidden in the safety database and it will be critical to mine those insights to generate knowledge that may benefit patients in the future.

Sometimes the value is very close at hand but just happens to sit in different drawers and needs to be looked at holistically, which we have begun to do. We are by no means there, but this is a journey towards a common data architecture that will allow us a holistic view across our assets before we go to the outside, and then go to more advanced applications and more advanced analytics. We have to be extremely open to collective intelligence, to learning from each other, and to applying that knowledge.

Having worked in medical affairs for several years, how have you seen the CMO role change?

In essence, the CMO today is more externally focused, insight-driven, late phase, and closer to the patient. Having said that, different companies see the role with slightly different nuances. There is the all-encompassing traditional CMO who is head of R&D along with added medical, safety, regulatory, and other functions. However, such a role has faced a significant challenge in modern times given the rapid explosion of knowledge in our industry. Against such a backdrop, we feel that greater focus on making sense of the science is warranted.

Immuno-oncology is a prime example. The paradigm has completely shifted in just the last five years, with targeted therapies, traditional chemotherapy, both ex-vivo and in-vivo gene therapies, and myriad combinations coming online. Even the best educated, top key opinion leaders (KOLs) in the leading centres worldwide would struggle to manage this explosion of knowledge. Therefore, our industry must make sense of the data, focus and prioritise the key themes, and then clearly and ethically communicate what this data may mean for patients and physicians. That requires deep knowledge and strong ethics; patients and stakeholders need to perceive the company as an ethical expert that has physician and patient value at the core of its mission. This will bring

credibility and, in the long run, success.

A lot of the data you are dealing with today is perhaps less quantifiable and more challenging to draw insights from. How are you navigating this new data universe?

The way we navigate the data sphere continues to evolve in tandem with the sphere itself. As an example, in solid tumour oncology, especially for diseases like kidney cancer, we have seen combination therapies lead to dramatic improvements in well-established core metrics like progression free survival (PFS), response rates, and overall survival (OS). These classic, benchmark endpoints are still at the centre of our communications because they matter to oncologists and, in the end, to patients.

However, from that base we are now beginning to expand to other dimensions, such as quality of life. In kidney cancer, combination therapy between classic chemotherapy, immunotherapy, and novel targeted therapies such as tyrosine kinase inhibitors (TKIs) has led to a quantum leap in both PFS and OS, meaning that patients will potentially have many years to live. In collaboration with patient societies such as the International Kidney Cancer Coalition we are therefore now working to determine what matters to patients with the time they have left; especially if nine or ten months has become several years. Questions that emerge include how patients can continue to work and how they can balance work and family life in the face of a serious but potentially survivable disease. This is where side effects such as diarrhoea, fatigue, and organ-specific quality of life come into play.

Encouragingly, in just the past year – from the European Society for Medical Oncology (ESMO)'s 2020 to 2021 congresses – we have seen a noticeable and measurable shift in the perception of top kidney cancer KOLs on quality of life, with a much deeper understanding of what it means to patients.

This shift in perception regarding the true value of a therapy will require alignment not just between KOLs and industry sponsors, but also regulators and payers; the entire ecosystem. How far along the road are we towards this alignment?

We have moved from humble beginnings where patient-centricity was perceived as listening, empathising, and connecting, and where engagements were rather transactional. While this was an important first step, we are now moving towards a much more advanced data-driven approach

where we systematically work with patient organisations, some of which are very sophisticated. In partnership with these groups, we define patient reported outcomes (PROs), develop surveys, validate them, and integrate them into our R&D and late-phase study environment. This is really a dire need; after conducting a literature review, we found that of the two dozen or so major kidney cancer trials between 2010 and 2020, fewer than half included systematic quality of life measurements. In that sense, we are probably nearer the beginning of this journey than the end.

This data collection piece is making the work of HCPs increasingly complex. What do you see as the role of sponsor companies in alleviating this burden and making sure they can stay focused on their core mission of treating patients?

We need to listen to both patients and HCPs more than we have ever done it before. At the University of Freiburg where I am a Professor of Medicine, we have recently resumed bedside teaching, and I was so happy to be with my patients, teach my students, and be at the bedside again. This has not been possible for over a year and a half, which has had a huge impact on the education of young physicians, creating a major gap in terms of being able to talk to, see, and touch their patients at a critical time in their training.

Intensive care systems have been overburdened throughout the world, even in advanced countries like Germany, so we need to better empathise with our colleagues in the clinic and ask them what they need. As an example, when the pandemic started, cancer patients were unable to access their medicines – whether IV medicines, subcutaneous injections, or even tablets – because they were typically dispersed in the oncology outpatient clinics or in physicians' offices that were overloaded by the pandemic. Therefore, within 72 hours we created a patient support program that made sure that medicines were made available at patients' homes and that injection support was made available to patients or caregivers, either by training caregivers and patients to self-inject, or by providing nurse-supported injections. While this may not seem like the most radical innovation, it did ensure that patients could continue with their treatment regimens during the pandemic.

An equally important concern is the significant drop-in diagnostic rates in many forms of cancer that the pandemic has led to. This is particularly pronounced in solid tumours, where early stages of cancer are notoriously difficult to detect. With ultrasound, X-rays, and other imaging diagnostics not happening to the extent they should be and far fewer patients accessing hospitals, the data shows that up to a third of tumour diagnosis could be being missed. This means that we will very likely see cancer patients with more advanced stages of the disease, and a greater complexity;

creating something of a pandemic within a pandemic. Along with my colleagues at Ipsen, my efforts will be directed towards ensuring that these patients' voices are heard and that cancer diagnostics, cancer prevention, and early intervention are given priority and focus.

Several patient advocacy groups have told us that there is a lot of room for improvement in how pharma companies communicate with patients, often focusing too much on science at the expense of lived experience. What is your take?

This disconnect is, in fact, very serious. I am proud to say that over the years Ipsen has been a leader in innovating and breaking down barriers in this field. For example, we were the first company to make all of our published research freely available to everyone. While opening the access to our science is of course positive, a 20-page oncology review paper is fairly useless to the average kidney cancer patient. Therefore, over the past year and a half we have worked on laying the foundations for plain language summaries. From July 2022, we will publish, as a minimum, a 250-word plain language summary alongside all company-sponsored journal publications from human studies. Plain language summaries put complex information into everyday language. This means that patients, patient advocates, caregivers, healthcare professionals, policy makers and those whose first language is different to that in which the article is written will be able to better understand our research and what it means for them. While this may seem like a modest step, from a patient perspective it is a major milestone.

Ipsen's innovation efforts in oncology and rare diseases are primarily focused on external acquisitions, with several new companies coming on board in the past couple of years. What role can medical affairs play in ensuring that such a growth model remains patient-centric?

While Ipsen does have a viable, strong, and broad research effort in neuroscience all the way from discovery to very late phase, our focus in oncology and rare diseases is on external innovation, a business model that we share with most of our peers. Our strong growth of 12.3%, amounting to total sales of over €2.86 million, and the seven external innovation partnerships scored by the business development and R&D teams in 2021 are testament to the power of our strategy. We now have a cumulative remaining firepower of €3.5bn to invest in external innovation by 2024, including the divestment of the Consumer Healthcare arm.

I am fully confident in our CEO David Loew's vision and deeply appreciate working with him and colleagues like Philippe Lopes-Fernandes (CBO) and Howard Mayer (head of R&D), especially in terms of the speed and agility with which they operate. Our way of working is strictly data- and value-driven and connects well to our strategy of focusing on bringing value to patients and society. This requires a very targeted approach, looking at potential targets that will truly bring value – with all the risks of due diligence – to the patients we serve in specialty care. This means that our minds must be open to genuine innovation along the three disease areas we serve, but that we must also leave some leeway for genuine innovation in fields that have not traditionally been part of Ipsen's core focus. For example, we now have a very focused effort on including haematology assets in addition to solid tumour oncology assets, where we have been strong for many years. In the neurosciences, we are venturing into neurodegenerative diseases such as added-value Parkinson therapy. In rare diseases, we are working with GENFIT to advance research for people living with primary biliary cholangitis.

We are making excellent progress at a very good speed. At the same time, this is a hyper competitive, ultra-challenging, and extremely dynamic environment for which my areas – medical affairs, safety and patient affairs – must continue to be well integrated. Ipsen has established due diligence capabilities in each of its therapeutic areas with strong medical directors going deep into the data and science and rapidly coming up with conclusions. Moreover, we have fostered a network of trusted external experts able to give us the best possible feedback on our datasets.

As medical affairs becomes evermore prominent, what talent profiles are you looking for today to ensure that your teams function as well as possible?

Interestingly, I am looking less at certain profiles than ever before. Every day we learn more and become much more eclectic. Of course, scientists and physicians with a strong academic record, with deep therapeutic area and industry knowledge and a desire to join the industry will remain a key target group. We are increasingly capable of hiring top experts from top companies around the world, having brought some fantastic external expertise on board over the past couple of years.

However, in addition to this we are now looking more at roles in the data sphere, covering bioinformaticians and biostatisticians as well as epidemiologists, real world data specialists, and people with pure data expertise from tech. The word 'geek' is a cliché, but I have learned that the hardcore coding and data driven tech approach can have a very energising and focusing influence on organisations.

After a couple of years in the role, what are your ambitions at Ipsen for 2022 and beyond?

From a big picture perspective, late 2020 and 2021 have been a pivotal period for our industry. Biopharma has been able to bring a decade's worth of innovation to market in record time in terms of COVID-19 vaccine solutions, which ultimately represent the exit strategy from this pandemic. My deepest respect goes to my colleagues working in this field for having revolutionised the speed, depth, and energy with which clinical development can be conducted.

I hope that this epic accomplishment and the ultra-rapid implementation that the pandemic has forced us to adopt will continue to add value in the future. In terms of what that means for my work at Ipsen, we need to focus even more on what matters to patients and be even more rigorous in our prioritisation. In some cases, this means concentrating our efforts on delivering research, data and insights in areas where our strengths are and where we can make a meaningful difference to patients. This process is already well underway. In the past couple of years, we have trimmed the portfolio of our medical affairs late-phase studies by almost half and have moved to larger, more impactful, advanced, and complex research questions. These questions come with a greater risk but have a much greater chance of delivering benefit for patients.

My ambition is that we will carry that spirit, in an even more focused and agile way, into the future, which of course includes integrating many new assets into our late-stage development and our pre-launch medical platform; making sure that we do our absolute best to make those treatment options available to patients as soon as we can, and as broadly as possible.

Looking at the healthcare and life sciences ecosystem more widely, my plea to health policy decision-makers is to learn from how the pandemic was managed and to integrate these lessons in a transparent and rigorous way. With this, we will be able to implement innovation more broadly, more quickly, and more effectively, thereby avoiding unnecessary suffering and death.

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