Interview: Gary Hendler – Chairman & CEO, Eisai EMEA

"[Brexit] presents an opportunity for the UK to improve its environment for life sciences"

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Confirming Eisai's commitment to keeping its EMEA headquarters in the UK, Gary Hendler, chairman and CEO EMEA, and Nick Burgin, COO and president of global value and access stress how the company is looking at Brexit as a glass half full. Eisai views Brexit as an opportunity to bring with it change that will positively impact processes in the UK and push forward a discussion on collaboration between public bodies and industry.

Gary, what a major change since we last spoke in 2011: Brexit has been voted for. How do you see Brexit impacting Eisai and how are you preparing your organization for the possible scenarios?

Gary Hendler (GH): First of all, I think it is important to stress that both Nick and I voted to remain. We also put Eisai's name in the Telegraph as part of the CEOs that thought it was better if the UK remained part of the EU. Now, we have to shift and adapt to reality—like everybody else. At Eisai, we actually view Brexit as quite positive and I do not think it is doom and gloom at all. On the contrary, it presents an opportunity for the UK to improve its environment for life sciences. As we get closer to Brexit, we see this as an opportunity to be seized upon.
For the pharmaceutical sector, the regulatory environment is the most crucial compared to other industries. Regulatory decisions are indeed protracted. Establishing a manufacturing facility for instance is a decision that is taken five years in advance. Therefore, the regulatory environment is going to guide our decisions in regard to Brexit, much more than the business environment. Nonetheless, we do not have any intention to relocate our EMEA headquarters out of the UK. As an

investing Japanese company, we do not simply have a commercial hub here in the UK, we have a research hub and a manufacturing hub. Although this makes us unique, it also presents assets we cannot simply move around on a whim. Our manufacturing plant in the UK is geared towards supplying one of our flagship products going forward, lenvatinib mesylate. From the UK we will export it to Brazil, to China… We are hence well positioned and the reasons to stay in the UK become straightforward.

The UK government has put in place the Life Sciences Industrial Strategy (LSIS) to ensure the UK remains a top destination for life sciences business in post-Brexit times. What is your take on this paper?

GH: Eisai had access to the report early on as we sit on the board of the working group which Sir John Bell first presented the LSIS to. I had the opportunity to make comments to him and Secretary of Health & Social Care Jeremy Hunt concerning the content. We think the LSIS is very positive and we support it. In a way, it seems to have been modeled on Eisai and its presence and ambitions in the UK: important inward investment, extensive research, strong manufacturing. All goals reprised by the LSIS.

Nick Burgin (NB): Brexit is a challenge for the market and the government, but it also poses the opportunity for change. Improving the NHS would make the UK more attractive and this will drive investment from the government's side, and this is what the LSIS puts forward.

How would you assess the general ease of market access in the UK and what experiences has Eisai made in its collaboration with the various stakeholders?

NB: The UK's Health Technology Assessment (HTA) body NICE can be praised for its clear and structured processes that define precisely what NICE expects from industry. However, NICE has had issues with slow turnaround times and been challenged by a recent budget twist. Moreover, it has proven difficult for NICE to constitute its own ERG (Evidence Review Group).

Without a NICE recommendation, obtaining reimbursement from the NHS —the UK's single payer—is very difficult and its standards are world renown. But NICE cannot master the number of applications submitted in a timely manner. Recently, NICE has addressed those capacity concerns, involving industry earlier in the process. Eisai has developed a positive relationship with NICE as the body has become more accessible over time.

Our relationship with the NHS has been somewhat more complicated. The industry as a whole has had to bear the consequences of the NHS' budget struggles and their cost driven strategy, posing the challenge of affordability. Within the NHS we also identify an important duplication in assessments, further contributing to delayed uptake.

While the UK is an excellent market and a company like Eisai will always retain an interest to invest in it, regardless of challenges such as Brexit, this truth does not apply to the domain of research. If

in clinical trials you do not have appropriate comparators because they cannot be accessed, then you cannot execute clinical development properly and this will ultimately result in retracted investment.

GH: Echoing this, we have definitely seen NICE improve but we still see more room for improvement. We would like to see more flexibility in assessment processes and that the bodies take more components into consideration than just cost effectiveness.

Our relationship with the NHS has to improve significantly, from both sides. Ultimately, they are the payer and not NICE, but often in the UK, we focus on the HTA and not the NHS. Because of the NHS' decentralized nature we see it as not very accessible and perhaps there's an almost natural barrier between the NHS and industry. At the end of the day, industry wants to charge the highest possible price while the NHS wants to pay the lowest possible. Hence, the barrier. Somehow, we have to overcome this barrier, as this is in the interest of patients. Eisai is very willing to invest more resource in talks with the NHS to improve the situation for all stakeholders.

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I think that what the industry hopes for is better access but not only in relation to price. As pharmaceutical companies, we are often pinpointed on the fact that we charge high prices for our drugs. I on the contrary see us adopting a flexible attitude in negotiations as well as a willingness to compromise. In the UK, we provide access through clinical trials and early access programs, but we may not be able to pursue these in the future. This would unfortunately deny patients' access to innovative drugs that could extend or sustain their life for up to three years.

We are looking forward to Brexit as an opportunity for something to happen, a shift to occur in the current process. Something positive will come from this, as with any major change.

How would you define the overall strategic importance of the EMEA region to Eisai globally?

GH: While Japan is crucial to Eisai as its home market and original R&D is driven out of it, the EMEA region's contribution to global sales is in the high single digit range. In terms of value, the US market will be the big driver. Nevertheless, the price ratio between us and the US is one to five. Thus, we significantly punch above our weight when it comes to units and volume. For Halaven® alone, the EMEA region contributes 48 percent of global volume in terms of absolute number of units, and we outpace the US in number of patients treated.

How does the EMEA region contribute to a sustainable research pipeline at Eisai?

NB: As a medium-sized company, Eisai has to collaborate in order to achieve real grandeur. We have three main research centers, one in Japan, one in the US and one here in Hatfield. The Japan development site leverages on these three.

GH: We pursue an open innovation strategy. Here in the UK we have a long and successful

collaboration with UCL (University College of London). This collaboration even resulted in a drug discovery program for our epilepsy drug perampanel -an exceptional result. Our collaboration continues in the field of neurodegenerative diseases.

EMEA further contributes importantly to research through clinical trials. In a recent kidney cancer phase III study, patient recruitment in Spain was higher than in the US. In Central and Eastern European countries, we also regularly see patient over-recruitment because patients are difficult to reach through commercial routes as budgets in that region are often extremely tight.

What are you currently most excited about for Eisai's research development?

GH: Eisai is a specialist pharma company with a focus on Alzheimer's and oncology mainly as we are striving towards inventing drugs that make a significant difference. The first ever drug combatting Alzheimer's was Aricept®, developed by our scientists in Japan. Today, those same scientists work on the next generation of Alzheimer's drugs.

The challenge in Alzheimer's disease is to treat the disease in a way thathas never been done before. The antibody treatment we collaborate on with Biogen does not target symptoms but the cause of the disease and aims at modifying the course of it. Luckily, we have four assets in total in our Biogen alliance, and hence four shots at goal for Alzheimer's. Witnessing a breakthrough in just one of these would be highly rewarding.

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We do not have the scale to compete with big pharma and therefore choose to partner with them. In this collaboration and especially in the oncology segment—for which I hold a role of global commercial responsibility—, we see synergies on the commercial and research level. We have just recently entered into a partnership with MSD. On our own, we see ourselves capable of making lenvatinib mesylate into a USD-one-billion-asset- with MSD, we believe we can multiply this by five.

What would you like the international readers to know about Eisai's approach to the future?

GH: We see Brexit as a glass half full. If we prepare for a hard Brexit, it is only because we do not want to see our lead times waste away during the transition period. We think that Brexit can help us create a better commercial environment for inward investment from the government and for commercial return.

Luckily, we are a smaller and more agile player and can adapt quicker as we have a smaller portfolio than huge corporations and can make decisions quickly.

NB: As the Brexit process is one of negotiation, it is currently difficult to know what exactly will happen – and as it cannot be worse than a hard Brexit, we prepare for that. However, we of course hope for mutual recognition that would cover pharmacovigilance, clinical trial access portals and batch release testing. While the created supplementary cost would still be important, this would

pose the practical base we could build upon moving forward. Without the agreement, we risk delays and long lead times for manufacturing, which are not in the interest of patients. Finally, we are ideally in favor of a no tariff agreement!

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