Interview: Terry O'Regan – Vice President and Managing Director, Biogen UK and Ireland



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Terry O'Regan, VP and managing director at Biogen UK and Ireland, discusses the company's longstanding commitment to the UK, market access issues, and why Biogen is staying the course with developing Alzheimer's products at a time when many MNCs are winding down their neurology programs.

How would you describe Biogen's longstanding presence within the UK marketplace?

This year we are celebrating Biogen's 40th anniversary and for the majority of those years, we have maintained a legal entity here in the UK. This is an indication of how Biogen holds the UK market in great esteem. Indeed, one of our founding fathers, Sir Kenneth Murray, a Nobel Prize winner was from Scotland, so we have a British perspective embedded in our roots. Our footprint extends far beyond the commercialization of our leading MS portfolio and the potential first DMT in the UK for Spinal Muscular Atrophy. Our overriding aim in this country has always been to pioneer in neuroscience and to be a good corporate citizen. We invest in community projects every year, as well as partner with key academic institutions to pioneer new breakthroughs in neuroscientific research. 70 percent of Biogen's clinical trial programs are conducted in the UK. Our ambition is to be positioned right at the sharp end of scientific progress and to successfully translate that into meaningful medicines in areas of high unmet need.

We place the patient at the heart of everything we do; striving to ensure that UK and Irish patients

get access to these transformative medicines.

We strive to add such value that, should we not be present, we would be sorely missed in the area of neuroscience as well as in our community.

How strategically significant, then, is the UK affiliate relative to Biogen's other EU-wide operations?

There can be little doubt that the UK market is of global strategic relevance. This is partly down to the way in which the UK remains very much a leader in life sciences. I think it is fair to say that the Life Sciences sector constitutes one of the big remaining bastions of British industry. Many of the other traditional heavyweight industries have been gradually hollowed out, often being relocated to other parts of the globe. With life sciences, however, the hub remains implanted in the UK.

When you consider that the UK boasts quite a unique ecosystem – a national health service that is universal and free at the point of delivery, one of the most advanced health data sets and some of the foremost academic institutions globally – then it is hardly surprising that the UK has achieved worldwide acclaim for its innovation in early phase drug discovery. Looking ahead, the Life Sciences Industrial Strategy (LSIS), recently presented to the UK government, is a positive package with a range of measures that could bring benefits to the UK environment. The Accelerated Access Pathway could also contribute to driving a more conducive environment. We are supportive of the intention to ensure that the UK is in the top quartile of comparator countries, both for the speed of adoption and the overall uptake of innovation.

The size and depth of Biogen's local footprint reflects these underlying realities. We have assembled a multifunctional, in-country workforce of around 300 personnel. This includes experts that we have brought in from around the world: there are some 25 different languages spoken in this site alone. Moreover, our operations span beyond simply the role of a UK affiliate. Firstly, we serve as the marketing authorization holders for Europe. Secondly, the UK has participated in around 70 percent of our global clinical trials run over the past five years. Thirdly, we leverage our physical proximity to the EMA to conduct a substantial portion of our Europe-wide pharmaco-vigilance and data analysis functions here.

To what extent do Brexit and the relocation of the EMA to Amsterdam threaten to upend all of this?

Quite frankly it is very difficult to predict the full implications of Brexit at this time. There is still far too much political uncertainty to properly assess the impact. Under the best-case scenario, nothing really changes except the address of the EMA to Amsterdam, retaining some of the existing skillset in the UK. Our hope is very much that the current tight knit relationship between the MHRA and EMA can survive intact. The UK has, after all, contributed so very much to the design of regulatory reform and health technology assessment (HTA) mechanisms

We are certainly encouraged by some of the noises coming out of the government and UK Government and Parliament. Just the other day, Prime Minister May delivered a very strong and clear speech in which she called for Britain to essentially remain within the EMA. Likewise, the government has already committed to matching, and in some cases even surpassing, any scientific research funding and grant-monies that will be surrendered as Britain relinquishes EU membership. [Featured_in]

Personally, I can't imagine the UK losing its prowess in life sciences anytime soon. The UK will remain a fantastic arena for understanding genomics and undertaking early drug discovery. Biogen, for its part, remains steadfast in its commitment to the local market. We have heavily invested in the UK economy, highlighting our commitment to the life science sector. However, we don't feel our job is done. We are strident in our mission to find a cure for diseases like multiple sclerosis and find treatments for ALS and other neurodegenerative diseases, notably Alzheimer's Disease. We are confident that harnessing British infrastructure and expertise is an effective way will get us closer to materializing these ambitions.

What are the highlights of your local portfolio?

We are immensely proud to possess one of the most comprehensive portfolios for treating multiple sclerosis. Biogen feels that having a breadth of therapies is especially important for a complex disorder of this kind where heterogeneity appears intrinsic to the disease and patient choice is fundamental to positive treatment outcomes. As MS affects different patients in markedly different ways, a one-size-fits-all solution is unrealistic. Instead, we have assembled a full spectrum of products including the leading oral medication Tecfidera® (dimethyl fumarate), which can be deployed upfront as a first-line therapy, a PEGylated Interferon with an administration protocol of every two weeks and a monoclonal antibody, Tysabri® (natalizumab), that has been very effective in highly active MS.

Meanwhile, we are in active dialogue with UK health services to bring Spinraza® (nusinersen) to UK patients with spinal muscular atrophy (SMA), a rare neuromuscular disorder that has a significant impact on survival and quality of life. In Autumn 2016, Biogen opened one of the largest global expanded access programs in rare disease, even before marketing authorization was granted. This program is open for children with the highest unmet clinical need, those with infantile-onset SMA (most likely to develop Type 1). To date we have provided all eligible children in the UK with nusinersen free of charge via this program.

It appears that it is taking much longer than initially forecast to place Spinraza® on the British market. Why is this? Is it just a question of price and affordability?

We certainly have been disappointed with the unexpected delays in the process so far. England is now significantly behind the rest of Europe in reviewing nusinersen. The major delay was the

decision around the appropriate appraisal route. However, the decision to appraise via the single technology appraisal (STA) route has now been made by NICE and so we don't want to look back but forward.

However, it's important to recognize that the bottlenecks that we are experiencing transcend the issue of price for this significant therapeutic advancement. There are broader challenges associated with assessing a medicine such as nusinersen via the STA route, such as long term data uncertainty for example.

Also, it's useful to note that there are more practical considerations as evidenced during the introduction of the expanded access program, where despite the provision of free drug, infrastructure and capacity challenges still needed to be overcome before patients could receive it. It was, quite frankly, seriously heartbreaking to hear that a breakthrough therapy with the potential to fundamentally change the course of disease was not immediately available, but, resolution was found, and many children are now being treated through this program.

We remain resolute in our commitment to ensure that all eligible patients who could potentially benefit from treatment have access. We are open to discussing innovative commercial proposals for nusinersen with the NHS and are hopeful that we can quickly come to an arrangement that is acceptable to both parties. We urge all parties to begin such negotiations immediately to mitigate any possible delays, and we are encouraged by a recent meeting in which NICE agreed for a managed access agreement to be developed in parallel with the STA appraisal, which means that negotiations may happen much earlier in the process than usual.

What, then, is your candid assessment of the ease of market access in Britain?

The numbers speak for themselves. The office of health economics reports that, of all the rare disease therapies approved within the European Union, which comes in at around 143 approvals, a mere 68 were available on the NHS in 2016. That means that only around 50 percent are making it through. Equally concerning, it takes on average 2.5 years for that approval to be attained which is a long time for patients to be waiting. I want to emphasize that this transcends just issues of pricing. It is important to note, that the list price is different to the price the NHS ultimately pays as the majority of therapies will have a 'patient access scheme' in place which has been agreed in parallel to the NICE process.

If you return to the issue of securing approval for nusinersen, it becomes immediately apparent that the UK's commissioning process requires flexibility when it comes to innovative and rare disease medicines. The UK was the last of the EU member countries to decide on a commissioning pathway for nusinersen. This commenced in March, nearly a year after receiving our marketing authorization. Clearly, a mature, well-developed affluent economy like the UK should be doing much better.

I would go as far as to say that there's a bit of a contradiction within the British life sciences realm. When it comes to upstream activities we stand out as being excellent in drug discovery and translational medicine. However, when it comes to the downstream tasks of medicines assessment and access to new innovative medicines, we lag behind Europe.

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With respect to the latter functions, the Scottish Medicines Consortium has a different approach. They have introduced a new system specifically designed for the assessment of ultra-orphan and orphan therapies which also brings patient and clinician views to the heart of the process. Furthermore, they are reinvesting funds received from the pharma industry PPRS rebate to fund new innovative medicines through its Medicines Fund. It reflects the direction of travel for existing process and demonstrates the need for new approaches as the landscape continues to evolve.

Continuing with the example of Spinraza®, can you please elaborate upon how the British reimbursement process is not yet fit-for-purpose for this kind of therapy?

Currently there are two appraisal routes under the NICE framework: a Single Technology Appraisal (STA) for general medicines and a Highly Specialized Technology (HST) for very rare diseases. We have always said that neither HST nor STA routes are entirely appropriate for the whole patient population covered by the marketing authorization.

The assessment is currently being undertaken through the STA route, which is not designed for rare diseases, it is the standard route within which all new medicines are reviewed – such as another hypertensive for example. Previous cases have shown that a rare disease medicine is highly unlikely to gain recommendation via the STA route.

In this disease area, there are major challenges associated with producing the type of data that NICE would need to see for an STA appraisal. For example, measuring quality of life in a young pediatric population (many SMA patients) is very difficult, and yet it is a major determining factor of cost effectiveness. Other challenges include the uncertainty around long-term health outcomes that inevitably comes with a world first medicine – whilst the data we have so far is extremely compelling, there are only so many years of data available, which makes calculating cost effectiveness difficult. The STA also requires a comparator as part of the cost effectiveness analysis, which does not exist in SMA as nusinersen is the first and only treatment.

Due to the potential of nusinersen as well as the significant unmet need, the EMA reviewed nusinersen under accelerated assessment, and the trials were stopped early as the results were so compelling. This was fantastic in terms of the regulators recognizing the clinical value of nusinersen, however it presented a double-edged sword as some health technology assessment bodies require a long-term picture of how the medicine will work, which of course, is challenging with medical innovations such as this.

NICE and NHSE responded favorably to our request to sit around the table and decide on a workable solution in the interests of patients. The fruit of these discussions was a common agreement on how to move forward. The critical issue now is to prevent any clock stoppages along the way. I am, however, genuinely optimistic about how everything is panning out. We are witnessing an unprecedented degree of flexibility being shown by the authorities and that, in itself, appears to herald a new dawn.

Unlike some of MNCs that have been winding down their neurology programs after high profile phase III blowouts, Biogen appears to be staying the course when it comes to developing new products against Alzheimer's. How come?

Right now, we have six molecules under development. Some of the best research is being generated in Biogen as we have focused our resources and expertise in pioneering in neurodegenerative diseases. Scientists know much less about the brain than any organ in the human body and therefore, logically, you literally have to go into it with everything that you have got.

We remain optimistic about our Alzheimer's program because indicators are signaling that we have found an effective way to remove amyloid plaques early within the disease pathway before the real damage is done.

Again, the UK is at the forefront of medical progress in this domain. We are also proud to invest in the UK Dementia Discovery Fund, which is a specialist venture capital fund that invests in novel science to create meaningful new medicines for dementia.

What is your final message to our international readers?

Here in the UK, Biogen has an opportunity to not only wield a significant impact with regard to improving patient outcomes, but we can also be instrumental in helping to reform access policies and processes so that UK patients can be some of the first in the world to have access to new and innovative medicines in areas of high unmet need.

We are deeply committed to the UK market on multiple levels and resolute in our desire to be pioneers in neuroscience, partners to government and other stakeholders as well as good corporate citizens.

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