Commentary: Richard Goodfellow

Why we want to work with patient advocacy groups

Sometimes, as a biotech CEO, when most of the stakeholders in the business are seeking commercially significant results as soon as possible, it's easy to forget the most important stakeholder of all – the patient.

An innovative and productive way of ensuring that patients are central to corporate thinking is to work with patient advocacy groups. They help patients, their families, and their caregivers, navigate the cancer landscape, in the US especially. Patient advocacy groups have also evolved into powerful organisations that interact with pharmaceutical companies, biotechnology companies, regulatory authorities, doctors, carers, academia and all those involved in improving the lives of patients.

One such, The Addario Foundation, was founded by the advanced-stage lung cancer survivor Bonnie Addario in 2008. It has since raised millions of dollars to increase awareness of the importance of treating this often stigmatised condition and encourage research into new approaches to treatment. An estimated 1.8 million people worldwide are diagnosed with some form of lung cancer every year and 150,000 people will die from this disease in the US alone. Addario and its partner, the Addario Lung Cancer Medical Institute (ALCMI), overcome barriers to progress via a world-class team of investigators from 25 institutions in the US, UK and Europe, supported by dedicated research infrastructures such as centralised project management and biorepositories and data systems.

In Europe, lung cancer was predicted to cause almost 274,000 deaths in 2016 which is more than 20% of total cancer deaths. Tobacco smoking is still the main cause, but lifestyle, diet, passive smoking and occupational exposure also contribute to risk. The assumption that most lung cancer is self-induced has stigmatised the disease, an obstacle that Addario hopes to overcome.

A few years ago it was rare to see a patient with metastatic lung cancer live for more than a year. Nowadays some patients can live for three years or even more. In the future many experts believe that combination therapy could be the answer to further progress – with immunotherapy as one of the key components of the regimen.

It is with this in mind that our company Scancell has forged a unique collaboration with the ALCMI to accelerate the US development of our lung cancer vaccine, SCIB2, which is being prepared for first-in-man clinical trials in combination with a checkpoint inhibitor.

Many cancer vaccines have failed in the past as they do not stimulate T cells with sufficient avidity to kill tumour cells. Our DNA technology platform enhances the uptake and presentation of cancer antigens to generate high avidity T cell responses that can eliminate tumour cells. The platform is illustrated by the lead product SCIB1, which has been evaluated in a Phase 1/2 clinical trial in patients with malignant melanoma. SCIB1 induced strong T cell responses, objective tumour responses and improved survival rates well beyond established norms. SCIB2 is the second product and it targets the cancer testis antigen NY-ESO-1, which is expressed on a number of tumour types, including non-small cell lung cancer. Mice immunised with SCIB2 showed high frequency and, more importantly, high avidity T cells that were capable of killing NY-ESO-1 positive tumour cells *in vitro*. These responses were significantly higher than those induced by an NY-ESO-1 peptide vaccine or peptide-pulsed dendritic cells. In a murine tumour model PD-1 blockade potentiated the activity of SCIB2, with the SCIB2/checkpoint inhibitor combination resulting in 100% of the animals surviving and showing significant enhancement of survival relative to each agent given alone.

The next step will be to see whether SCIB2, in combination with a checkpoint inhibitor, will deliver the same results in patients. The deal with Addario will mean that Scancell will be able to tap into the medical institute's international network of clinical investigators as well as the foundation's patient support programmes to find suitable trial candidates – which should allow the trial to be completed much faster than otherwise.

Pharmaceutical companies have been slow to see the huge potential of the next generation of cancer vaccines due to the tendency of some to plan the future whilst keeping an eye on the rear-view mirror, for it is true that many of the older cancer vaccines failed to deliver a beneficial outcome. However, the mood music is beginning to change. For example Genentech, one of the leaders in pharmaceutical cancer research and development, recently wagered $310 million in up-front and near-term milestones for access to BioNTech AG's mRNA cancer vaccine platform.

The Addario/Scancell collaboration offers us the opportunity to gather convincing clinical data in highly regarded US institutions that will hopefully confirm the role that cancer vaccines could play in future clinical practice, especially in combination with checkpoint inhibitors. In practical terms, ACMLI will help with planning, assembling a high quality core investigator group, liaising with pharmaceutical companies and assisting with many other aspects of the clinical trial process. From Addario's point of view, the collaboration is expected to bring new treatment options to lung cancer patients more quickly.

As a direct result of our evolving relationship with Addario, we have started reaching out to other US patient advocacy groups with an interest in melanoma, breast cancer, childhood cancers and so on. Each group has a different approach and something different to offer. At this stage in our development our interest is to gain access to the pre-clinical and clinical expertise and networks that these groups offer with a view to making progress faster and better – and it's a constant reminder of why we are in business – for the benefit of patients.

This article was written by Richard Goodfellow, chief executive officer of Scancell Holdings Plc of the UK.