ARE BIOMARKERS FOR EARLY DETECTION OF CANCER FINALLY COMING OF AGE?

ANDREA MURRAY, Chief Operational Scientist, **Oncimmune Ltd.**

Andrea Murray is Chief Operational Scientist at Oncimmune Ltd. She has a PhD in Pharmaceutical Sciences, the focus of which was the development of monoclonal antibodies for diagnosis of cancer. Andrea dedicated her post-doctoral research to working on the manufacture and optimisation of monoclonal antibodies for various applications including cancer diagnosis and therapy. When she joined Oncimmune in 2004 as Senior Director of Assay Development, she was one of the company's first employees and has since led the development of the EarlyCDT® platform and the subsequent development of autoantibody diagnostic assays for the diagnosis of lung, liver and various other cancers, becoming a leading expert in cancer diagnostics.

Your talk a little while ago was about biomarkers for early detection and prognosis. Why do you think there is such a push towards biomarkers for early cancer diagnosis at the moment?

I think everyone is now recognising the potential positive impact early detection can have on both patient outcomes and the costs of treatment. Biomarkers are going to be very important for this because they are cost effective, minimally invasive and provide good information on cancer biology. Therefore, I think biomarkers are a key part of the solution. The government has released its target for detecting 75% of patients at early stage disease rather than later stage, so I think the industry and conferences like this really need to address the early detection challenge.

Early detection is particularly crucial in oncology. Are there other therapeutic areas that would benefit particularly from early detection?

Oncology is definitely the main area we are focusing on, however early detection with autoantibody assays is not just important in cancer; there are approximately 80 different diseases such as rheumatoid arthritis, lupus or type 1 diabetes where early intervention will benefit the patient.

So how does your company's platform for early detection work?

Oncimmune's biomarker platform measures autoantibodies in blood. When normal cells transform into cancer cells, the DNA is disrupted and they start expressing abnormal proteins. The immune system sees those as being foreign and mounts an antibody response. That response is what our tests at Oncimmune detect. We have shown that autoantibodies are released very early in the carcinogenic process, so they are excellent markers for early detection.

Are there any recurrent challenges you have been coming across with this?

The challenges are all really in the amount of time and resource it takes to fully develop and validate biomarkers as commercial assays. In order to validate a test for cancer screening you need to conduct very large prospective randomised controlled trials and they take a long time and require significant investment. This level of investment can be difficult even for the largest of companies, especially as screening tests need to be low cost for them to be economically viable to healthcare payors.

So, as one of the challenges is large- scale trials, do you partner with other organisations to further the research?

We partner with the NHS and other important stakeholders to conduct these trials. For example, we have recently worked with the NHS in Scotland on what is believed to be the largest randomised controlled trial for the early detection of lung cancer using biomarkers. The study recruited over 12,000 patients each of whom was followed up for two years. The primary endpoint is to determine whether the use of EarlyCDT Lung with subsequent x-ray and CT scan reduces the incidence of late stage lung cancer at diagnosis, compared to standard clinical practice. The investigators will be reporting on the trial by the middle of 2019.

We are entering a new area where we are looking at utilising autoantibodies as companion diagnostics. For example to aid in the stratification of patients for the right treatment and we are actively partnering with pharmaceutical and biotech companies at the moment.

An additional area in which we are also looking to partner is with companies who have complementary early detection technologies.

Are there any particular technologies that you are getting excited about at the moment?

There is a huge buzz around circulating tumour DNA at the moment which is an area of technology that could have synergy with autoantibodies. Circulating tumour DNA is evidence of a cancer mutation whilst autoantibodies in the body provide evidence of a patient's immune response to fighting the cancer. No single biomarker alone will be perfect, so we are interested in combining biomarkers of different molecular natures to get the best performance for early cancer detection.

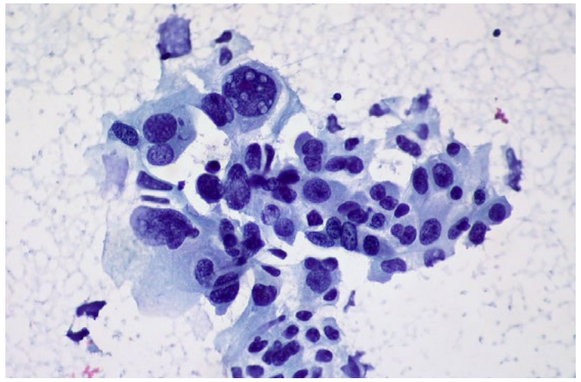
I'm most excited about the potential for combining biomarkers like autoantibodies with circulating DNA or nucleosomes. This has enormous potential to improve diagnostic performance for the benefit patients.

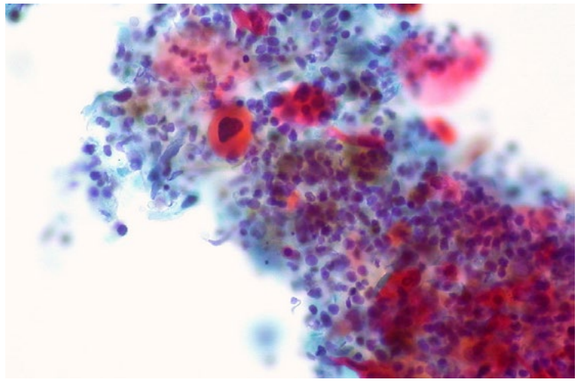
What are the next steps for your research?

We have been doing a prospective study with the NHS in Scotland on our lung cancer early detection biomarker, EarlyCDT Lung, and the results of that study will be published in a few months' time. That is really exciting for us.

What were the key takeaways that you would give for your presentation?

From our presentation at the conference, I am hoping that people will understand that autoantibodies have significant potential as biomarkers for early cancer detection. That the products that we have on the market have been well validated and that there is potential for autoantibody measurements in other areas such as companion diagnostics.





marketing@oxfordglobal.co.uk