NANO-BASED ONCOLOGICAL DRUG DELIVERY

MARIANNE ASHFORD, Senior Principal Scientist, Pharmaceutical Sciences, Innoative Medicines Biotech Unit, **AstraZeneca**

Marianne is Senior Principal Scientist in Advanced Drug Delivery, Pharmaceutical Sciences within Innovative Medicines Biotech Unit at AstraZeneca. In this role, Marianne in responsible for applying drug delivery approaches to improve therapeutic index of medicines and is working to enable novel targets via successful intracellular delivery of new modalities such as nucleic acid and peptide drugs. This is achieved both via internal research programs and through external collaborations. Marianne has initiated a number of collaborations, which has resulted in the introduction of nanomedicines into our Oncology development portfolio. She is a member of the global Pharmaceutical Sciences and Oncology Science Leadership teams.

CONSTANTIN-C. COUSSIOUS, Director, Oxford Institute of Biomedical Engineering, & Director, **Oxford Centre for Drug Delivery Devices**

Professor Constantin Coussios is the the Director of the Oxford Institute of Biomedical Engineering. He received his BA, MEng and PhD in Engineering from the University of Cambridge and was elected to the first statutory chair in Biomedical Engineering at the University of Oxford in 2011, with special responsibility for drug delivery and non-invasive therapies. He founded and heads the Biomedical Ultrasonics, Biotherapy and Biopharmaceuticals Laboratory (BUBBL) and recently launched the £10m Oxford Centre for Drug Delivery Devices (OxCD3) under a 5-year programme grant by the UK's Engineering and Physical Sciences Research Council. The author of over 100 peer-reviewed publications and 16 patents, Prof. Coussios received the UK's Institute of Acoustics' Young Person's Award for Innovation in Acoustical Engineering in 2007, was elected as Secretary-General of the International Society for Therapeutic Ultrasound between 2006-2010 and was honoured with the Society's Fred Lizzi award in 2012.

Do you think that more nanomedicines will be used in other therapeutic areas?

MA: Yes, I think that they will be. I think that currently many people are focused on oncology because of the obvious challenges that the therapeutic index presents and that has driven many of the examples currently in use. I do think that as more modalities are coming through, and we're seeing a lot more nucleic acids and peptides, this will open up the drug target space in other areas as well as the need for a more targeted delivery. I think that we will see this a lot more in different therapeutic areas.

Most of the nanomedicines that you have mentioned are intravenously delivered, what about other routes of administration?

MA: Again, I think that we will see this more in other routes of administration, but I think that this will be particularly in terms of Cell CarT, intra muscular, and also some of the long acting preantrals. I really think that this is an under exploited area for nanomedicines and I think that by understanding the bio-distribution which is unlikely to be into the systemic circulation, it will be important. I think that we will see it used a lot more in combination with therapy, surgery, and interventional medicine when nanoparticles are used. In oncology I think that we will see a lot more local delivery which will allow us, as we diagnose diseases earlier, to deliver to many different sites in the body It will also impact respiratory, inflammation, and auto-immune areas and these are the areas that we will perhaps see more local delivery of nanoparticles to the lung which will change the distribution within the lung.

Are there limitations to the indications and anatomical locations which such device and drug approaches can be deployed?

CC: Each of the modalities has different limitations. Ultrasound only really feels air and bone which means that it would be able to treat pretty much any soft tissue indication or any prostate, head, or neck, skin indication but treating the gut or inside the skull is a lot more challenging. However, what ultrasound and shockwaves cannot do, magnetic fields can do. So, for example, magnetic fields can delivery some of these benefits in the lung where ultrasound cannot be used. It can also be used within the brain cavity more generally.

What do you know about the regulatory pathway for these device and drug approaches in Europe and in the US?

CC: There are essentially two approaches here, one where the drug is combined or re-formulated in a liquid or nanomedicine form and one where the drug is co-administered with a nanoparticle that responds mechanically. The second situation is very interesting because in Europe these known drug carrying drug particles and micro particles tend to be classified as medical devices. This means that it may be possible to access a broad range of indications through a C marking route than a more conventional pharmaceutical route. In the US, of course, they will always be seen as a combination product by the FDA, but which side of the FDA might actually lead these studies will depend on whether the additional component is purely a device or is actually a novel drug or a novel drug formulation. I think that is the important distinction between the re-formulated drugs and the co-administered drugs with some of these stimulus responses in nanomedicines.

This is an excerpt from the free webinar, 'Nano-based Oncological Drug Delivery'.
The full recording is available on our website at: www.formulation-congress.com/webinar-recordings/