Transcript for: What is new: Trends in Biopharma

Nigel Langley: In the next minute, 250 babies will be born to add to the world's population. In the next 30 years, the world population is expected to reach 10 billion people. These are the 10 billion reasons we do what we do every day. Please join us as we explore innovative pharmaceutical solutions and sustainability and digitalization initiatives that'll help us rise to the challenge.

Hello everyone. My name is Nigel Langley, I'm the host of our new BASF Pharma Solutions, 10 billion Reasons podcast series. The podcast series will consist of short discussions with our experts, highlighting different pharmaceutical technology areas, their applications, and industry learnings. And today it's great pleasure that I have Nadia and Phil joining me today who are both experts in the biologics area. And at the beginning, I'd like just, Nadia and Phil to introduce yourselves, and then we can talk about trends, and your end, or your ideas around trends in the biopharma industry. So, Nadia, you want to go first?

Nadia Morales C...: Absolutely. Thank you very much, Nigel. I'm very happy to be here today. My name is Nadia Morales Cummings, and I am the Global Technical Marketing Manager for the Biopharma Ingredients Platform within, BASF Pharma Solutions.

Nigel Langley: That's great, Nadia, thanks very much. What about Phil, do you wanna have a go?

Phill Butler: Sure. Thanks Nigel. And I'm also happy to be here. My name is Phil Butler, and I'm a Regional Technical Manager at BASF in supporting our Biologic Ingredients Platform.

Nigel Langley: Excellent, Phil. Thank you. And then, so the question, the topic today concerns what the trends are, the current trends in the industry and, and some perception that you might have on that. So maybe I can start with you, Nadia, to, just explore maybe one or two of these areas. And my particular interest that I have is, you know, the messenger RNA technology has also been very recent in our news, of course, with the coronavirus and the vaccine that came using that technology. And I'm just interested in intrigued of what's next with Messenger RNA, because I believe there's been some news recently concerning one of the companies that have been involved. So maybe you could explore a little bit on that topic for us.

Nadia Morales C...: Absolutely So mRNA technologies are incredibly... Obviously, we have all heard about them, right? We all feel that we know them. And one of the key, parts of that, those kinds of technologies is that it's very easy to change about, right? So we actually learned through all, all of us who lived through the pandemic, we learned that once the companies that are working in these areas had the

genetic information, they were able to make vaccines in a relatively fast manner. And because this, the technology is so easily, transposable, so you can actually take genetic information from different sources and actually use that as the target of the therapeutic. I see this as a very exciting growth area for treatments; cancer treatments are one of the big focuses, but also for some of those more rare diseases as well. So in the next few years, this is going to be a very interesting field to keep an eye on.

Nigel Langley: Yeah, very interesting. I mean, Phil, do you have any insight as well into this topic or? Yeah.

Phill Butler: The one thing that I've noticed just, in reading and, and interactions is also just not from the injectable standpoint, I'm looking at these RNA products or medicines, but also looking at small molecules that the, this, all this interest in RNA right now is developed, is looking at development in different areas and looking at using small molecules to impact how RNA works in, making some, stopping them from making these proteins that can cause these disease conditions. So I think wouldn't be happening if all the other activities weren't going on in the RNA field as well.

Nigel Langley: And very interesting. Sorry, Phil. Go on.

Phill Butler: And Nigel, I wanted to make sure that we got your opinion as well. So we wanted to inquire with you what you thought was going on in this field too.

Nigel Langley: Yeah, I think it's really quite exciting. I mean, I've obviously been reading a little bit about what's been in the public domain, with cancer therapy, with the Keytruda product and Moderna's vaccine. I mean, that's, that's public knowledge of course. And yeah, they're very excited. I mean, they got some very interesting phase two results and it seems that that will transfer hopefully into phase three fairly soon. And then, let's see. I mean, cancer is such a distressing disease, and it's all, it's 200 or so different forms. You know, the impact of that into the industry was, could be tremendous.

Phill Butler: Yeah-

Nigel Langley: So-

Phill Butler: ... Nadia and I have-

Nigel Langley: ... yeah, I'm exciting. Yeah.

Phill Butler: Nadia and I talked about that too, how the focus on started with the vaccine, right? And COVID and just how it could explode into so many different areas and is amazing and, and the disease conditions that it can target is, is kind of cool.

Nigel Langley: Yeah. And the, the other, the other approach of course that certainly Moderna has stated on communicated is that basically they're using the same nano particle, lipid nanoparticle formulation approach as a sort of platform that can

actually potentially be used in all these types of new vaccines in the future. So, I sense that some of the hard work that's all has already been done in this. You know, over the last 20 years or so of developing these formulation approaches. And, of course, probably that's where BASF would be interested potentially in the future. I know that we're not currently in involved there, but you know, with the lipids and then the novel excipients, we're very strong in novel excipients of course, and have been. There's innovation potentially there that we could, contribute probably as well as other companies of course, into this area, into this field.

So, yeah, very exciting. And another exciting area, of course, is, you know, taking the monoclonal antibodies that have been developed over several years as well as new ones that are being developed and which are administered intravenously, of course, as a route of administration. And, and there is a drive and a real drive to actually make this a little bit more patient-friendly in so far as that if you can actually deliver these subcutaneously, you've got the potential in the future of, having patients being able to self-administer or at least, let us start that. The injection time is much shorter than an intravenous infusion.

And so, I know that the industry is working very actively into this, this particular area. And of course, excipients play a very, very important role in, stabilizing and, potentially reducing the viscosities of some of these very highly viscous, products that you would then administer by different way, not just intravenous, but intramuscular or subcutaneous. I don't know whether you have any insight into that particular trend. Nadia and and Phil, maybe Nadia, you can start if you have some thoughts.

Nadia Morales C...: I think from my perspective as, as a person who actually has been affected, by different... I have family members who actually have to get administration of these kinds of therapies, and it is such a... It's a production, right? So you have to take the day, it takes several hours. This patient, the patient I'm talking about, it's my mom. So it makes it, bothersome for her, and she can't understand why is it that she has to do this several times a year. So for patients like her, having this kind of breakthrough excipient and new kinds of formulations that would allow for one, high concentration, right, so that we can actually concentrate that, antibodies. So the amount of doses are less, and also for it to be administered in a more, you know, in a more efficient way, I think it would actually make a great impact on, patients that receive these kinds of therapies. I think it would and, I think at the end, help increase compliance, right? Because when we make it approachable and easier to use, patients are more likely to stick to it to with it.

Phill Butler: Yeah, I agree definitely from that compliance and then as well as the cost, right, brings the cost down too, with having to reduce the visit to a hospital if you're, if you're doing an infusion from that standpoint. But both that compliance and cost factor. And then from, I guess an, from the excipient or an ingredient supplier perspective, I think it's exciting just from the ability to see what ingredients surfactants, that we might have that could play into some of that

new formulation that's gonna go on to meet this need, I think is interesting as well.

Nigel Langley: Yeah, and there's also an additional thing that, I think companies are working on as well is potentially combination products. So you're taking more than one monoclonal antibody, in at a one dose, if that makes sense. And then the challenge is, also there, of course, with the formulation part because you know, if you've got two antibodies together, how can you ensure that they're both stable, and how can you ensure that they can be delivered in that way? So I sense there's quite a lot of activity around there and more on the future aspects of formulation. Traditionally, excipients such as polysorbate and polymer are used, aren't they, as to stop aggregation of these very large molecules and-

Phill Butler: Yep.

Nigel Langley: And, maybe in the future they will still be there, but maybe there's an opportunity for new excipients as well. With this combination approach you know, that might be a driver as well. So I think this, particular area is very interesting and I think, you know, with the patient in mind, compliance is clearly a driver. Convenience is also a driver, where you can administer potentially a home. Personal medicine of course, is also a driver, isn't it, in generally in the industry. So, yeah, very, very interesting areas. Are there any other-

Phill Butler: Yeah.

Nigel Langley: ... trends, that, or are there those, the, some of the two big ones or are there anything else that, you would say is really, state-of-the-art as a trend currently in the industry?

Phill Butler: It's interesting that you bring up personalized med- not interesting, but you bring up personalized medicine because it's a term we've heard over the years, right, over the past years. And I really see it coming into play now, right? It's becoming, an important part of, of how we're treating disease states and, the mRNA, the messenger RNA part, and then also the cell and gene therapy area, I think is, a big trend that you're seeing now as well. And some of the topics that you talked about from a formulation perspective and the manufacturing perspective on how we bring, innovations to that I think are, are something that customers are looking for as well.

Nadia Morales C...: Yeah, I mean, for the cell gene therapy, it seems... , so Phil and I had the opportunity of attending, some trade shows in the fall of 2022. And it was very interesting to see the amount of CMOs that are now, operating in the cell and gene therapy space. And it goes again, more, wondering more about what you were saying, Nigel, regarding a personalized medicine. This is exactly in that area where gene therapy operates, and where it actually brings, treatments to sometimes rare diseases, orphan diseases, diseases that are not as common. And now there is actually a gateway in where we can make these kinds of medicines, they can get approvals, right? So we have had about 20 approvals in

the last five to seven years of this type of therapies. So it's, and many, producers have figured out ways of doing, of producing these kinds of treatments. So it is actually a really exciting time to see how that is going to continue to grow.

Nigel Langley: Yeah, and, and that's another interesting point. As, as you know, from, I think our perspective as well, as a supplier and, and manufacturer of excipients, pharmaceutical excipients,there's the opportunity, I'm, in these areas to sort of design specific excipients for the need in each of these examples. And, so it's an excitement, not just the innovation of the therapeutic, but also the formulation part as we said, potentially having new ingredients as well to actually make these things work most, most efficiently.

Phill Butler: I think.

Nigel Langley: Yeah.

Phill Butler: I'm sorry, I'm sorry, Nigel.

Nigel Langley: No, no. The, the only thing I was also going to add that the convenience of obviously a conventional tablet would have, people, you know, just take that generally without really thinking too much of the complexity that's actually been put into making a tablet, a drug product in that form. If theses biologics can get to a similar stage, maybe not a tablet, but something that's much more convenient to administer, then I think the whole acceptance as well would actually drive that. So, then, you know, it would be a leveler in that respect for the patient, wouldn't it? But I sense also that, you know, these things, these materials and these products are very complex and highly, there's a high cost associated with them currently, reflecting seriously on the extent of investigation that's required.

But it could be that these more personalized medicine approach would be restricted, unfortunately, in the short term, probably to the developing world. but, you know, that's a dilemma that's another discussion on the dilemma based that situation then.

Phill Butler: Great. And to build on that a little bit, I think it leads us to the other trend where with some of these technologies being newer and being introduced, there is a lot of focus, and Nadia brought it up talking about CMOs and CDMOs in refining the processes. So all these viral vectors that have been introduced during the, for the manufacturer, some of these, cell and gene therapy applications, the AAV, the Lentivirus, the gene editing applications are all being refined. I think, to help bring down that cost or to help reign that in as well as, to opt- not just to optimize the process, but get it to the patient in a better format as well. So, yeah, and could it result in opportunities for new ingredients from an ingredient supplier as well as these processes get refined.

Nigel Langley: Sure, well, I think I'd like to thank you. I mean, this actually now finishes our podcast today. Giving you some insight into some of the trends that are actually

now very, very important and will be for a number of years in the future. And with that, I'd like to thank Nadia and Phil for your excellent contribution and stay tuned. There will be a, a series of web, podcast coming on this topic and other topics within the drug development area. And we appreciate your attention and interest and thank you very much.

Phill Butler: Thanks, Nigel.

Nadia Morales C...: Thank you, Nigel. Bye-bye.

Nigel Langley: Bye-bye.

Speaker 4: BASF, we create chemistry