

Ziccum AB: senior Astra Zeneca vaccine & biopharmaceutical strategist to be new Board member

(Stockholm, 9 May 2019) Few people know the special risks and rewards of working with vaccines and biopharmaceuticals better than Astra Zeneca's VP Mikaela Bruhammar. From 2012-2015 she led the team that launched and grew Astra Zeneca's unique inhalable LAIV flu vaccine in Europe and US. Now she will bring her biologics/ vaccine expertise and broad pharma commercial experience to the Board of Ziccum AB. She will be proposed as new Board Member at the company's Annual General Meeting on May 20.

"The rewards can be great, but the risks can too. Vaccines aren't like other pharmaceuticals. For some companies they can be scary". She should know. From 2012 to 2015 Astra Zeneca's current Vice President of Nordic-Baltic Business Unit in Respiratory, Inflammation and Autoimmune disease (RIA), was the Global Head of Astra Zeneca's Vaccine Franchise—successfully developing and commercializing Fluenz (Europe) / FluMist (the US), its inhalable Flu vaccine for children.

"The business model for vaccines is significantly different to other pharmaceuticals. Vaccines are heavily policy-driven. They demand a long-term commitment from developers and government—you can't change or adjust your vaccine programs every other year. The extensive collaboration needed between commercial forces, the WHO and governments is unique. It requires a level of commitment that 'new-to-vaccines' pharma companies can find scary. You have to ask yourself 'can you commit to continue supplying this vaccine for the next 50 years?'"

Bruhammar and her team faced all these challenges, and more serious ones, when commercializing Fluenz. Yet they launched successfully in just three years, an exceptionally short period. How did they 'achieve the impossible'? And what can it teach Ziccum?

VACCINES: MAKING THE IMPOSSIBLE POSSIBLE

"It's true we had a really challenging product", says Bruhammar. "It was a live vaccine, a weakened version of the flu virus itself. Once thawed from its frozen form it only had a shelf life of 16 weeks. So you can imagine the logistics. On paper it was an impossible product to sell. But the thing is it was highly efficacious, highly potent, and

it was a needle-free, nasal spray vaccine aimed at kids – who don't like injections. Plus children are highly infectious carriers of flu in the general population. So if you can successfully immunize your paediatric population you get a powerful knock-on effect on your overall population, in fact you only need to inoculate 30% of children in order to have a population-wide impact. So that was the package of benefits. There was a triple win. For us, the developer; for NGOs and governments; and crucially, for patients. Everyone got a clear win out of it. And because of that, all of a sudden stakeholders were willing to be flexible to get over the 16week shelf life, for instance the EU regulatory agency agreed to an



annual tailor-made approval process for this specific vaccine, a key enabler for the EU launch. And in the UK the NHS trained special vaccinators to administer Fluenz to millions of school-children during 1-2 months every fall."

WHAT DOES IT TEACH ZICCUM?

"I see a lot of the same excitement and potential with Ziccum right now as I saw with the Fluenz project back then," says Bruhammar. "It's super-exciting to be joining at such an interesting phase. As Fluenz shows, you have to paint the big opportunity in such a way that people get it immediately. I see that connection with Ziccum. You can tell Ziccum's dry vaccines and biologics story in two sentences and people get it. There's a momentum that has already built up around Ziccum, and a big picture. Now I want to see that momentum accelerate. And as I said, the triple win—showing clearly how the technology solves key problem for pharma developers, NGOs and governments—and patients, is crucial.

"For example, dry powder formulation solves the cold chain challenge, but how would it be for patients and clinics? For conditions that require multiple administrations many clinics want the patient to self-administer. They don't want large patient traffic or a logistics chain in-clinic. So a nurse having to reconstitute and rehydrate large batches of dry vaccines back into liquid solution might not be a win for them. But if an autoinjector reconstituted the dry powder back into solution for the patient, in the pen or device, with sterile water behind a seal that remixed the solution with a couple of shakes—then you're back in the game. And as Fluenz shows, if the solution is a win for everybody people will solve challenges. For large investors, being able to make major cold chain savings could make it well worth solving other challenges. Whilst for big-volume vaccinations like standard flu shots or MMR vaccine (measles, mumps and rubella that most children get at 1 and 3 years), if the clinic knows it has to administer 20 shots in the afternoon, and needs to reconstitute a batch in the morning, that's still a saving that lets them administer more shots, because the price of the shots is lower, thanks to cold chain costs having been cut drastically. So dry formulation would obviously be a big benefit there. But it's all about the real clinical setting and what Ziccum's dry formulation capabilities actually look like in the end reality.

2000 POTENTIAL PROJECTS

"There are 2000 potential projects Ziccum technology could add value to. Applying Ziccum technology into the context of the real patient journey, making it real for patients *and* producers, is key to deciding which to prioritize and tackle first. It's not until we see how the technology fits into the patient's life and journey that we find the real value drivers and value points.

"A great partnership or collaboration scenario is where everybody wins. So it comes down to priorities. What is the scale we dare to grow to? Do we dare to dream big? The Fluenz case shows that even seemingly 'impossible' challenges can be overcome when you can demonstrate clearly how everyone wins. I drove forward commitment to vaccines within a company that was not really focussed on vaccines. It was a pivotal experience for me and gave me really great lessons in how to focus an organisation on vaccines and what to prepare for when moving towards developing vaccines.

"Plus, if we expand the definition of vaccines a little to include let's say peptides genes or biologics which could be an on- or off- switch for an autoimmune disease say, then the opportunities are even bigger. There are some really promising auto switches for airway inflammation. What if you could switch-off asthma early on or stop COPD progression? For asthma and COPD – which are horrific diseases – these could stop that process, so people would not need to suffocate to death.

"I'm super-passionate about driving business and delivering results. I never hesitate to try, fail and try again. I believe dry formulations have a big part to play in vaccines and biologics, and I think that in inhaled biologics for sure there is a very visible lead or opportunity for the technology. With vaccines—there is currently human commitment from many of the most influential and progressive organizations on the planet. These groups and organisations have their eyes clearly on this, so maybe with

their backing we can afford to think and dream bigger. I'm looking forward hugely to this journey."

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About Ziccum

Ziccum AB (publ) develops new patented formulations of biological drugs where sensitivity to temperature differences, especially during transportation, currently limits medical and so commercial potential. The company's patented technology, LaminarPace, develops dry powder formulations of drugs and vaccines that currently only exist in liquid form. By doing so Ziccum can increase the availability of drugs and vaccines in existing markets—and open up new ones.