# Lytix Biopharma focuses on immuno-oncology future

Authored by Karl Simpson (uk.linkedin.com/in/simpsonkarl).

01 September 2014

Liftstream was able to recently interview Unni Hjelmaas, CEO of Lytix Biopharma, a privately owned Norwegian company. Lytix Biopharma is developing one drug candidate for immunotherapy in cancer and one drug in topical infections. Our conversation was a great opportunity to explore the plans Lytix Biopharma has for the future and what it hopes to do with its assets. At a time when cancer immunotherapy is showing some significant progress, we were pleased to have this opportunity to explore one of Norway's prominent biotechnology companies working in the field of immuno-oncology.

Unni Hjelmaas is an executive with high energy and lots of enthusiasm for her company and its mission. She offered a very pragmatic view of the dynamics of the Norwegian pharmaceutical sector, views informed by being Chairman of the Board of the Norwegian Pharma Industry Association between 2003 and 2009, as well as co-Chair since. An experienced industry professional with a successful international career at Roche culminating in a position as General Manager of Roche, Norway.

Firstly, we wanted to give an overview of the two significant assets that Lytix Biopharma is developing and which form the basis for strategic decisions about the company's future.y pragmatic view of the dynamics of the Norwegian pharmaceutical sector, views informed by being Chairman of the Board of the Norwegian Pharma Industry Association between 2003 and 2009, as well as co-Chair since. An experienced industry professional with a successful international career at Roche culminating in a position as General Manager of Roche, Norway.

**LTX-315**

- LTX-315 is a novel intratumoral immunotherapy
- Intratumoral injection kills cancer cells, releases tumour-associated antigens and triggers innate immune responses. Complete tumour regression and protective immune respons is achieved in murine models in single and two/three-tumour models
- The Mechanism of Action is synergistic to anti-CTLA4 / PD-1 / PD-L1 approaches
- The drug is equally effective against resistant and wild-type cancer cells
- It is active against a range of experimental tumours, including highly treatment-resistant cancer stem cells
- The drug candidate has completed initial Phase 1, and is currently recruiting in an enlarged exploratory Phase I/IIa study
- Lytix Biopharma has extensive research collaboration with leading groups in cancer immunology (NCI, IGR, Norwegian Cancer Institute)
- Lytix Biopharma clinical advisors include leading American and European oncologists and immunologists, working within immunoncology
- for LTX-315 the company is aiming for a co-development agreement, preferably with a global oncology focused company

**LTX-109**, is a topical, fast acting bactericidal antimicrobial drug

- Broad spectrum of activity
- Low propensity for resistance development
- Effective against multi-drug resistant bacteria
- Effective against biofilm
- The drug candidate has finished recruitment in a randomised placebo controlled phase II Impetigo- trial
- LTX-109 has a potential in many topical indications. It removes bacteria in the nose (nasal decolonisation) and has PoP in an animal wound healing model
- For LTX-109 the ambition is to licence the product candidate to one global (alternatively regional) infectious disease or dermatology focused company/s.

Unni Hjelmaas is quite specific about how she sees the future of the company. It will be a company focused on immune-oncology, therefore LTX-109 is an asset for which she actively seeks to find a licence or development partner who wants to take the asset on and take it beyond the current Phase II status*. Having conducted 4 clinical studies for the product with good results, the company actively seeks to find a suitable partner interested in licensing the product, leaving the company the opportunity to focus entirely on immuno-oncology and asset LTX-315.

LTX-109 - The following clinical trials are completed:

A first in man Phase I study to investigate tolerability and safety of topical LTX-109 in healthy subjects (Study C08-109-01);

A Phase I/IIa study to evaluate the safety, tolerability and efficacy of topical LTX-109 in subjects nasally colonized with methicillin-resistant/-sensitive Staphylococcus aureus (MRSA/MSSA; Study C10-109-02)

A Phase IIa pilot study to evaluate the safety, tolerability and efficacy of LTX-109 in patients with uncomplicated, Gram-positive, skin infection (Study C10-109-03)

A Phase II, randomised, double-blind, placebo-controlled study to evaluate the efficacy and safety of two doses of LTX-109 (1 % and 2 %) versus placebo in impetigo (Study C12-109-04)

*Figure above details clinical studies for LTX-109

With LTX-315, Lytix Biopharma are also seeking a co-development partner. The basis for this decision is driven by two factors, bringing new capital funding to the company as well as the competence to develop a therapy in immune-oncology. Having seen some very good results in animal models, the company is now focused on getting the first human clinical studies set up for LTX-315. The company introduced the product to potential partners last year at BIO-2013 after the finalisation of the first dose ranging trial. They continue to progress these avenues of opportunity.

Unni Hjelmaas says “that with LTX-315, Lytix has seen ‘very encouraging effects’ in animal studies and now the company aims to see if those same effects can be seen in human studies.” The initial results from the exploratory Phase I/IIa open study will give an indication by the Autumn 2014 given patients are treated for 33 weeks and patients with immunotherapy take some time to respond. In the laboratory, LTX-315 has shown to work across all tumours including chemo-resistant cancers and cancer stem-cells respond. The company now needs to learn in humans where this drug asset has the most clinical benefit and thereby define the development strategy. They are currently planning the expansion phase of the study to look at groups of patients within different indications.

There are many strategic options in deciding the indication, partly informed by present treatment options, the competitive landscape and also the population of patients and their current treatment options. Hjelmaas, who’s industry background is with Roche, cites Avastin as an example of how products with a mechanism of action which works across tumour types can be developed sequentially. Admitting it is too early to tell if this is the case with LTX-315, however, it is clear that they are encouraged by the early data.

This validation of the potential of LTX-315 also comes from experts in the field. The Company has an ongoing collaboration with Laurence Zitvogel who is a leading expert on the interaction between the immune system and cancer. Zitvogel`s group is investigating the immunological signature of LTX-315 alone and in combination with checkpoint blockade inhibitors. A further collaboration with Professor Guido Kroemer, one of the world’s leading experts in mechanisms of cancer cell death, has recently been initiated too. Kroemer`s group will investigate the cytocidal mode of action of LTX-315.

Lytix’s collaboration with Zitvogel is particularly encouraging according to Hjelmaas. She has found some effects of LTX-315 which Lytix was not aware of an also some very synergistic effects with the checkpoint inhibitors.

**Competence in Norway**

Unni Hjelmaas, herself an industry veteran with international experience, pinpoints competence as a particular challenge for the company, as well as the region. She accepts that Norway’s ability to attract the necessary high quality competence on a permanent basis is limited by several factors, including the country’s tax regime. However, she says ‘to commute to Oslo is perfectly possible in Europe and they have to be flexible in this regard’.  She continues, “finding professionals locally with drug development or even international regulatory experience is incredibly difficult and this extends to functions like business development”.  “Norway is strong from an affiliate perspective but does not have

the international HQ functions".

Hjelmaas has taken an innovative approach to maximise resources, choosing to rent expertise with other companies in their cluster, making it possible to maximise the value of pooled resources.

**Funding in Norway**

As CEO of Lytix Biopharma, Hjelmaas has inherited a company with 210 shareholders with many 'small shareholders'. Liftstream believes she may have to accept cleaning up the capital structure as this may be necessary to make it a more investable company.

Looking internally within Norway, Hjelmaas sees considerable limitations for funding biotechnology companies in the country. With a history of investing in other industries such as shipping and oil, and the lack of Norwegian Pharma locomotives the competence of a broad base of local investors need to be built in the science sector.

**Public Framework in Norway**

Hjelmaas has good oversight of the Norwegian public sector support for the country's biotech industry. As CEO of Lytix, a beneficiary of several grants, she sees first-hand the particular workload this imposes on small innovators. While these grants are valuable and important, she advocates a far more integrated or joined up approach to funding from the public sector. This would allow a more stepped approach tied to success factors and the sequential distribution of further funding upon achieving the company's goals, without having to begin a whole new application process.

Equally, she looks to places like the UK which has the 'patent box' and believes that the political system in Norway now needs to implement similar tax advantages for research and development if the country's political class are to deliver on their promise of early access of the leading drug therapies for citizens.

**Outlook at Lytix Biopharma**

Today Lytix Biopharma is a company of 15 people, 4 of which are based in the north in Tromso, where the company is originating from, this location has also been beneficial for public funding. The affiliate in Oslo, houses the rest of the employees. The company uses a typical network of virtual resources too.

Hjelmaas, like almost any biotech CEO sees the funding of the company as a particular strategic focus over the next 12 months. It is envisaged that this funding will need to be secured by Q4 2014. She sees the need to build competence in certain areas of the company as they move forward in the clinic and execute the strategic ambitions of the company. To accomplish this she understands that finding practical immuno-oncology experience in drug development will prove a challenge, needing a flexible and international perspective.

Hjelmaas is a passionate and astute leader with a very clear sense for the strategy she wants to implement. Her positivity about the future is checked by

pragmatism but she remains highly focus on successful execution of turning Lytix into a successful drug development company in immuno-oncology.

**Readers who read this article also read:**

Immunotherapeutics biotech Nordic Nanovector demonstrates progress (../../nordic-nanovector-oslo.html#.VASi4_ldV8E)

Oslo Cancer Clusters Biotech Ambition: The Strategic Vision (../../oslo-cancer-cluster-p1.html#.VASgrPldV8E)

Oslo Cancer Cluster: Innovation, Funding and the Future (../../oslo-cancer-cluster-p2.html#.VASiLPldV8E)

Adaptive Licensing Begins to Shape EU medicine regulation for better access (../../adaptive-licensing-europe.html#.VASiXPldV8E)