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N4 Pharma PLC
20 August 2019

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20 August 2019

N4 Pharma Plc
("**N4 Pharma**" or the "**Company**")

Results of University of Queensland Study

N4 Pharma Plc (AIM: N4P), the specialist pharmaceutical company developing Nuvec®, a novel delivery system for vaccines and cancer treatments, is pleased to announce the results of the recent repeat *in vivo* study by the University of Queensland ("UQ") to investigate the use of a reference standard plasmid DNA expressing Ovalbumin ("pDNA OVA"), details of which were announced on 15 April 2019.

Highlights

- Successful repeat of the pDNA OVA study demonstrates that Nuvec® is capable of working *in vivo* when using multiple injections at certain doses
- Together with previously acquired data, these results also confirm that Nuvec® under the appropriate conditions can promote transfection using both DNA and RNA
- N4 Pharma will now focus on improving the Nuvec® loading process to increase the consistency of the *in vivo* results, which, once successful, will allow the Company to move from exploratory collaborations to engage in full licensing discussions
- The Company remains well funded to do this next work

Background to study
The objective of this repeat non-clinical study was: to reconfirm that Nuvec® was capable of generating an effective pDNA OVA antibody response; to extend the Company's knowledge of the factors involved in ensuring a robust and consistent response; and to affirm the precise loading protocol and methodology, in order to properly document the process for successful technology transfer to other contract research organisations ("CROs") and partners.

The study was undertaken by scientists at UQ, who are experts in the field of silica nanoparticles and from whom the Company obtained the licence to develop Nuvec®. The study was conducted using UQ's protocol for loading DNA onto Nuvec® with different DNA:Nuvec® ratios, to try to determine the optimum ratio. In this study, the pDNA was tested at ratios of 50ugDNA/500ugNuvec® (1:10), 50ugDNA/1000ugNuvec® (1:20) and 50ugDNA/1500ugNuvec® (1:30). The ratio is a measure of the number of DNA plasmids bound to Nuvec®. At the lower ratio (1:10) more plasmids are attached to each Nuvec® nanoparticle relative to the higher ratio, but the total DNA that is injected is constant.

In addition, a separate part of the study evaluated the number of injections (one, two or three) at weekly intervals required to obtain a response. The primary response that was being sought was the presence of antibodies to the foreign protein OVA in the murine blood. The level (titre) of antibodies was measured using a standard ELISA methodology.

Results of study

The Company is pleased to announce that analysis of its pDNA OVA findings has again demonstrated that, after three injections, Nuvec® produces an immune response capable of delivering a very clear increase in the number of antibodies specific for OVA in the 1:20 and 1:30 doses, where all test cases (6/6) responded. However, there was only a small response at the 1:10 ratio in 50 per cent. (3/6) of the cases tested.

The evaluation of the response after two injections was compromised by the design of the experiment, where blood samples were taken too soon after the second injection. However, the results did indicate a trend towards the appearance of OVA antibodies in these tests as well.

Analysis after a single injection at a ratio of 1:30 showed a negligible response where only one case responded (1/6). This is in line with previous studies undertaken outside of UQ, where inconsistent results had been observed when the CRO had only used one injection in its study.

These results clearly demonstrate that, under the appropriate conditions and with multiple injections, Nuvec® can promote transfection by plasmid DNA and lead to the production of the relevant circulating antibody. Together with previously acquired data, these results also confirm that Nuvec® under the appropriate conditions can promote transfection using both DNA and RNA.

Next steps

The next steps for the Company will be to improve the process involved in loading DNA onto the particle to establish whether improving dispersion will result in greater *in vivo* consistency. This is seen by the Directors of N4 Pharma as the key step to enable the Company to open commercial licensing discussions in respect of Nuvec®.

To that end, the Company has undertaken a technical review of the processes employed in the manufacture and loading of Nuvec® and has identified steps which require further investigation and refinement to ensure that a highly monodisperse product is consistently produced. A program of CMC and pre-clinical studies has been identified which will culminate in further *in vivo* testing of the improved Nuvec® nanoparticle in vaccine and oncology efficacy models. It is anticipated that this program of work will extend over the next 12 months.

Nigel Theobald, CEO commented:

"The successful repeat of the pDNA OVA study at UQ demonstrates that Nuvec® is capable of working *in vivo* when using multiple injections at certain doses.

"We can now focus on improving the Nuvec® loading process to increase the consistency of the *in vivo* results, which, once successful, will allow us to move from exploratory collaborations to engage in full licensing discussions. We will be in a much stronger position for these discussions once this work has been successfully concluded. The Company remains well funded to do this next work.

"In parallel to this, we continue to evaluate potential acquisitions and/or investments to diversify the Company's asset base whilst this work on Nuvec® remains ongoing."

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About N4 Pharma
N4 Pharma is a specialist pharmaceutical company developing a novel delivery system for vaccines and cancer treatments using its unique silica nanoparticle delivery system called Nuvec®.

N4 Pharma's business model is to partner with companies developing novel antigens for vaccines and cancer treatments to use Nuvec® as the delivery vehicle to get their antigen into cells to express the protein needed for the required immunity. As these products progress through pre clinical and clinical programs, N4 Pharma will seek to receive up front payments, milestone payments and ultimately royalty payments once products reach the market.

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