N4 Pharma Oncology programme initial pilot study – summary of findings

N4 Pharma has successfully completed an *in vivo* confirmatory oncology study which reinforces the results from an earlier pilot study designed to test the ability to use a monodispersed Nuvec® formulation in an *intravenous* ("i.v") route of administration using a DNA plasmid (pDNA) encoding TNF alpha, to assess the tolerance of different doses and to look at tumour regression.

The confirmatory study incorporated the following control and test groups: TNF alpha pDNA alone, unloaded Nuvec®, Nuvec® loaded with 50ug of the TNF alpha pDNA and Nuvec® loaded with 20ug of TNF alpha pDNA. The study involved injecting tumour bearing mice at regular intervals for 2 weeks and monitoring tumour growth.

In untreated animals, the tumour continued to grow, while in animals treated with Nuvec® and pDNA, there was suppression of tumour growth.

The animals receiving Nuvec® loaded with 20ug of DNA gave the best results, showing a clear inhibition of tumour progression when compared to animals treated with unloaded Nuvec® or the TNF alpha plasmid alone. Figure 1 shows the complete suppression of the tumour during the treatment phase. The tumour only started to grow once treatment with TNF alpha and Nuvec® was ceased.

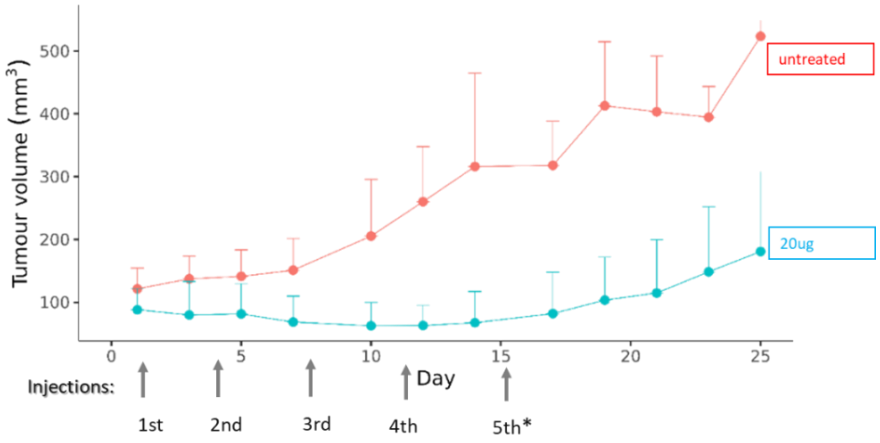

Figure 1

In addition, the use of 20ug TNF alpha loaded on Nuvec® was shown to improve animal survival rates in the life of the study [Figure 2].

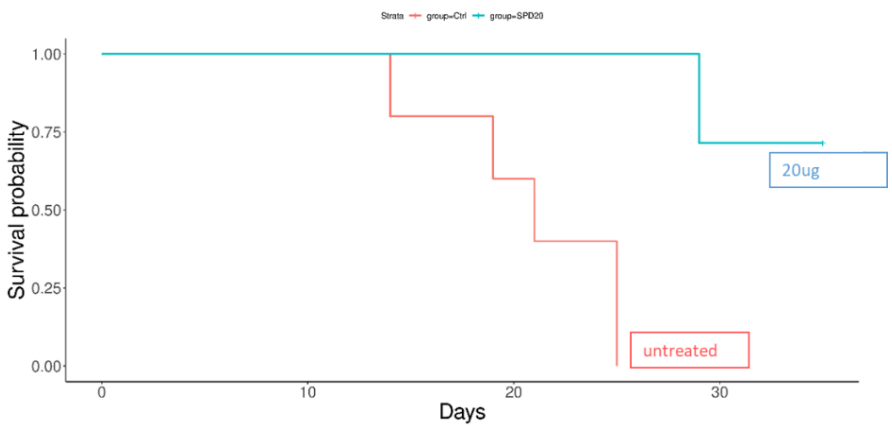

Figure 2

These results confirm the *in vivo* ability of Nuvec® to deliver a plasmid DNA to appropriate cells and to effect transfection and release of a clinically relevant product, in this case TNF alpha.