

S22. Anti-Nicotine Vaccination: Where Are We?

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Nicotine is the main substance responsible for dependence on tobacco containing products. They have a tremendous negative impact on the public health of developed as well as non-developed countries by being a main etiologic factor for the induction of tobacco related cancer and other tobacco associated diseases.

A vaccine against nicotine induces antibodies against the nicotine molecule, which intercept the nicotine on its way to its specific receptors. The binding of the antibody to nicotine in turn significantly diminishes the nicotine concentration in the brain shortly after smoking. This approach therefore interrupts the vicious circle between smoking and nicotine related gratification. The low price and long action of the vaccine, as well as the fact, that a vaccine is not dependent on the daily application of a patient suffering from withdrawal symptoms, make this approach particularly interesting.

At the end of 2003, three companies are in early clinical development of an antinicotine vaccine: Xenova

(TA-NIC), Nabi (NicVAX) and Cytos (Nicotine-Qbeta). The carrier molecules are recombinant cholera toxin B (TA-NIC), an especially selected carrier protein (Nabi) and a virus-like particle VLP (Cytos). An other carrier is additionally used by Chilka in an advanced preclinical model, which showed superiority to cholera toxin B carrier.

So far, results of reported Phase I trials showed no unexpected toxicities and Phase II trials are about to start in Switzerland (Cytos). Cytos has successfully completed a Phase I study with 40 healthy non smoking volunteers: they were divided in 4 dosage groups of 10. Two of the participants of each group received placebo. The other 8 in each group showed high levels of nicotine specific antibodies and only significant reversible local side-effects at the injection side were documented.

This short overview will summarize the latest results of the ongoing trials as much as they are available.