



Medical Countermeasures for Biodefence

Protexia™ is a recombinant version of human butyrylcholinesterase (BChE), a naturally occurring protein found in minute quantities in blood. BChE functions as a natural bioscavenger, like a sponge, to absorb and degrade organophosphate poisons (e.g., nerve agents) before they cause neurological damage.

Medical Indications

Studies using plasma-derived BChE have shown that increasing BChE concentrations in the blood protects laboratory animals from the toxic effects of nerve agents. Protexia™ is being developed for post exposure (rescue) therapy and military prophylaxis to prevent the toxic effects of nerve agents.

I. Post-exposure Therapy

Protexia™'s post-exposure therapy indication is being developed for casualties on the battlefield or civilian victims of nerve agent attacks. Since the sarin nerve gas attack in the Tokyo subway system in 1995, the vulnerability of North American and European cities to chemical weapons is clear. Following 9/11, the US government has mounted an intensive anti-terrorism campaign and has allocated unprecedented financial resources to develop technologies and products to address these threats. Given the urgent civilian requirement and Protexia™'s demonstrated effectiveness as a countermeasure for chemical weapons, Nexia is planning the development of Protexia™ for strategic stockpiles.



First responders extracting and treating victims of the Tokyo subway chemical attack in 1995.



Military personnel staging a simulated nerve agent attack.

II. Military Prophylactic

The DoD, DND and Nexia intend to develop auto-injectable Protexia™ as a prophylactic (pre-treatment) for warfighters who may come into contact with nerve agents, eliminating the need for expensive, mobility limiting MOPPs gear. Currently there are no true prophylactic drugs that target nerve agents directly to remove them from circulating in the blood.

Chemical Weapon Threat

Nerve agents belong to a class of compounds known as organophosphate (OP) agents. They were first developed in the 1930's to use as insecticides. Their potency was recognized during World War II, and they were developed as nerve agents to use in chemical warfare. In recent history, terrorists have deployed nerve agents as a weapon of mass destruction. OP nerve agents, such as sarin gas or VX, enter the blood stream via inhalation or absorption through the skin. The nerve agents travel in the circulatory system to the brain and muscles causing the nerves to become over stimulated which leads to massive convulsions and death in severe cases.


	Pre-clinical Milestones	Completed
Milestone I	Broad Spectrum - demonstrated effective <i>in vitro</i> binding and neutralization by Protexia™ of a variety of nerve agents, including soman, sarin, VX and tabun.	November 20, 2003
Milestone II	Effective - a series of <i>in vivo</i> challenge studies with nerve agents - demonstrated clearly that Protexia™ was efficacious as a medical countermeasure in animal models.	January 22, 2004
Milestone III	Drug Dynamics - involved pharmacokinetics studies showing that a single injection of Protexia™ resulted in a sustained elevation of blood BChE levels for many hours. Protexia™ concentrates in the blood stream where it bioscavenges nerve agents that principally gain access to the body's nervous system via the blood.	April 13, 2004

The successful completion of these milestones triggers the Protexia™ drug pre-development program including; transgenic herd scale-up, Good Manufacturing Practises (GMP) purification process development and completion of the pre-clinical studies to support the filing of an Investigational New Drug application (IND) with the US FDA. The time to market for Protexia™ could be rapid compared to other biopharmaceuticals. Based on new regulations communicated in 2002 by the US FDA (Federal Register 67 (105) pg 37988-98, May 31, 2002), there is now a clearly established regulatory pathway for FDA approval of medical countermeasures to combat chemical weapons. Products like Protexia™ would likely be required to present pre-clinical "animal efficacy" studies along with human safety data.

Nexia is developing Protexia™ jointly with the USAMRMC under a Broad Agency Announcement (BAA) contract (April 4, 2003) and a Cooperative Research and Development Announcement (CRADA), and a Memorandum of Understanding (March 31, 2003) with Defence R&D Canada Suffield (DRDC Suffield).

Nexia, located near Montréal, Canada, currently employs 60 people at its Headquarters, R&D laboratories and Production Facility. Founded in 1993, Nexia raised CND \$42 million in December, 2000 in Canada's largest life sciences initial public offering. Nexia continues to develop novel, complex recombinant proteins using its proprietary transgenic goat production system.




nexia
BIOTECHNOLOGIES

TSX Symbol:
NXB

Shares
outstanding:
23 M

Market Cap at
04-04-15:
C \$ 35 M

Cash at 03-11-30 :
C \$ 15.4 M

Year End:
August 31

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