



Innovative Solutions For Paralyzed People

SPINALON is a patented combination of “old” drugs (traditionally used for applications other than SCI, MS). It has become the first potent Central Pattern Generator activating drug capable of eliciting powerful walking movements in completely spinal cord-transected mammals. It may therefore constitute the first and only palliative drug treatment dedicated to temporarily restore locomotor functions in chronic SCI and MS patients. It is believed that regular treadmill training sessions (e.g. 3 times a week) induced or facilitated by **SPINALON** will constitute a treatment against health degradation in chronically immobilized and paralyzed individuals.

Proof-of-principal experiments *in vivo* have been successfully conducted in two animal models (mice, turtles). We have shown that a single dose (i.p., s.c. or p.o.) of **SPINALON** can powerfully activate the spinal locomotor networks and, hence, induce locomotor movements in acute or chronic SCI animals. Repeated administration (3 times a week) of SPINALON during 5 weeks led to no detectable systemic side effects and improved a number of health parameters (manuscript in preparation for Nature Biotechnology). A first physician-sponsored **pilot test** has also provided preliminary evidence of **SAFETY** in a monoplegic **patient** (case report published in Spinal Cord).

CLE-106 can elicit seminal emission in SCI animals (mice). SCI is associated with a number of serious complications including infertility and sexual dysfunctions. Given that most SCI patients are young men (80-85%) in their reproductive years, compromised ejaculation and infertility are considered critical issues by this group of individuals. Until now, some approaches (e.g. electrostimulation, vibrostimulation) have been developed to partially restore sexual functions (mainly erection) in chronic SCI patients but only less than 50% have reported having successfully achieved ejaculation with these non-user friendly methods.

Locomotion and ejaculation are controlled by neuronal networks located in the same area of the spinal cord, the lumbar segments. CLE -106 was a small catecholaminergic molecule used separately. However, we recently identified a next-generation product called **VITALON**. Unlike Cle-106, **VITALON** can induce (within 20-40 min) both seminal emission and forceful expulsion (full ejaculatory motor response). It is essentially composed of small molecules (one of which is already sold for hypertension in Europe) that can easily cross the blood-brain-barrier. **Note that SPINALON AND VITALON’s R&D activities have recently been transferred to NORDIC LIFE SCIENCE PIPELINE.**

SPINALON

VITALON

Unique features	Significant advantages	Unique features	Significant advantages
Will allow patients to walk again occasionally in a stable environment such as on a treadmill for approximately one hour	Prevent chronic immobility-related complications	Will allow patients to partially recover normal sexual functions	Will improve quality of life of patients
	Will improve overall health conditions of patients		
	Will improve quality of life of patients and their longevity	Could be used in combination with a phosphodiesterase-5 inhibitor (e.g. Viagra®)	Will improve patient’s psychological status and sexual life
	Will reduce total healthcare costs for these patients		
Active pharmacological products used in Spinalon™ are off-patent and currently commercialized	Will reduce development time, cost and risk	Active pharmacological product used is off-patent and currently commercialized	Will reduce development time, cost and risk
	Drug Master Files exist and could be accessed		Drug Master Files exist and could be accessed
	Abundant literature on safety and cross-reactivity is available		Abundant literature on safety and cross-reactivity is available
Molecules are non-peptidergic	Easy to manufacture	Molecules are non-peptidergic	Easy to manufacture
	Could be orally available		Could be orally available
	Better safety profile		Better safety profile
Product could be administered orally	User friendly	Products could be administered orally	User friendly
	Better patient compliance		Better patient compliance
Could be administered i.p. and s.c.	Flexibility	Could be administered i.p. and s.c.	Flexibility
Patent includes composition, method and utility claims	Strong IP position	Patent includes composition, method and utility claims	Strong IP position
1 st completed pilot test in SCI patient	Provide preliminary evidence of SAFETY in SCI patient		