

## **OVERVIEW**

Catalyst

Summary

## **EXECUTIVE SUMMARY**

Strategic scoping and focus

Datamonitor insight into the spinal cord injury market

Upcoming reports

## **SPINAL CORD INJURY: PATIENT POTENTIAL**

Key findings

Definition of spinal cord injury

Classification of spinal cord injury

Etiology of spinal cord injury

Road traffic accidents are the leading cause of SCI in developed countries

Pathophysiology of spinal cord injury

Primary injury

Secondary injury

Diagnosis of spinal cord injury

Epidemiology of spinal cord injury

Seven major markets

Rest of the world

Epidemiological trends in spinal cord injury

Economic consequences of spinal cord injury

## **CURRENT TREATMENT PRACTICES AND UNMET NEEDS**

Key findings

Current management of spinal cord injury

Surgery

Methylprednisolone is a pharmacological treatment option for acute spinal cord injury

Rehabilitation

Patient care path

The acute hospital setting is the key intervention point for neuroprotective treatments

For manufacturers of neurorestorative treatments, rehabilitation and community settings are key targets

Further opportunities exist in the management of complications of SCI

Unmet need in spinal cord injury

Neurorestorative treatments

Neuroprotective treatments

Symptomatic treatments

## **MARKET POTENTIAL**

Key findings

Datamonitor's estimate of market potential

## Spinal cord injury: opportunities and threats

Opportunities

Threats

### **PIPELINE ANALYSIS**

Key findings

Clinical trial design in spinal cord injury

ICCP guidelines for the conduct of clinical trials in spinal cord injury

Clinical pipeline overview

Novartis represents the only Big Pharma company in the sparse clinical pipeline for SCI

The pipeline is dominated by neurorestorative treatments for acute SCI

Cethrin (BA-210; Alseres Pharmaceuticals)

Drug profile: intraoperatively administered Rho GTPase protein inhibitor

Development overview

Product positioning

SWOT analysis

XP19986 (arbaclofen placarbil; Xenoport)

Drug profile: GABA<sub>B</sub> receptor agonist in Phase II development for spasticity due to SCI

Development overview

Product positioning

SWOT analysis

ProCord (Proneuron Biotechnologies)

Drug profile: autologous blood-derived macrophage therapy for the treatment of acute SCI

Development overview

Product positioning

ATI355 (reticulon 4 monoclonal antibody; Novartis AG)

Drug profile: first human monoclonal antibody to neutralize Nogo-A

Development overview

Product positioning

Autologous Combination Stem Cell Therapy (TCA Cellular Therapy)

SCI represents the least advanced indication for Autologous Combination Stem Cell Therapy

Astrostem (RNL Bio)

Human clinical study of Astrostem approved by Korean FDA in April 2009

Neu2000 (Neurotech Pharmaceuticals)

Improved locomotor outcomes associated with Neu2000 in rat model of moderate SCI

Cordaneurin (Spinal Cord Therapeutics)

Cordaneurin prevents the formation of growth inhibiting scars

Preclinical pipeline overview

Spinal Cord Therapeutics and SanBio represent key developers in the preclinical SCI pipeline

Initiation of world's first human clinical trial of embryonic stem cell-based therapy is expected in Q3 2010

Neureva is presently seeking a co-development partner for NVA0011 (gacyclidine)

Discontinued pipeline candidates for spinal cord injury

The future of treatment in spinal cord injury

Key opinion leaders view partially restorative therapies to be the most likely advance in the mid-term

Combination treatments offer the greatest potential according to key opinion leaders

Geographical availability of efficacious SCI treatments will be limited by expertise of physicians and cost

## **BIBLIOGRAPHY**

Books and journal papers

Websites

Datamonitor reports

## **APPENDIX**

Contributing experts

Conferences attended

Report methodology

## **TABLES**

Table: ASIA impairment scale

Table: Studies of the incidence of spinal cord injuries in the seven major markets

Table: Incidence of spinal cord injury in the seven major markets, 2010–2020 (actual numbers)

Table: Studies of the incidence of spinal cord injuries in the rest of the world

Table: Incidence of spinal cord injury in the rest of world markets, 2010–2020 (actual numbers)

Table: Average yearly healthcare and living expenses and estimated lifetime costs directly attributable to spinal cord injury

Table: Studies of the prevalence of neuropathic pain in the spinal cord injury population

Table: Results of published studies investigating the efficacy of oral pharmacological treatments in neuropathic spinal cord injury pain

Table: Estimation of the US spinal cord injury market potential

Table: Spinal cord injury market opportunities and threats

Table: Products in clinical development for spinal cord injury, 2010

Table: Cethrin – drug profile, 2010

Table: Key facts: Phase II trial of Cethrin in patients with acute spinal cord injury

Table: XP19986 – drug profile, 2010

Table: ProCord – drug profile, 2010

Table: Key facts: Phase II trial of ProCord in patients with complete spinal cord injury

Table: ATI355 – drug profile, 2010

Table: Key facts: Phase I trial of ATI355 in patients with acute spinal cord injury

Table: Products in preclinical development for spinal cord injury, 2010

Table: Discontinued R&D projects in spinal cord injury, 2002–2010

## **FIGURES**

Figure: Key causes of traumatic spinal cord injury in the US, 2005–09

Figure: Spinal cord injury patient care path

Figure: Key unmet clinical needs in spinal cord injury, 2010

Figure: Comparison of incentives conferred by orphan product policies across the US, EU and Japan, 2010

Figure: Guidelines for the conduct of clinical trials for spinal cord injury as developed by the ICCP panel

Figure: Composition of clinical pipeline for spinal cord injury by stage of development

Figure: Cethrin: Phase I/IIa trial results

Figure: Cethrin: SWOT analysis

Figure: XP19986: Phase II trial results

Figure: XP19986: SWOT analysis

Figure: Autologous activated macrophage therapy: Phase I trial results