

Drug Delivery Technology: Revolutionizing CNS Therapies

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Abstracts

Use the incisive analysis, commentary, opinions and forecasts provided in this note to:

gain an in-depth understanding of the technology landscape for invasive, minimally invasive and non-invasive delivery of CNS therapeutics and regenerative therapies

assess the options available for the invasive delivery of small molecules, peptides, proteins, gene therapies and stem cells now & in the future

assess the potential delivery options available for emerging non-invasive formulations including transdermal, intranasal, oral and buccal melts

evaluate the use of ultrasound and convection enhanced delivery as alternative methods for CNS delivery

gauge the current & future technology requirements of pharma, biotech & medical device companies developing CNS products & devices

analyze how the market is evolving & the influence that drug delivery may have on pharma CNS pipelines

identify key pharma & delivery companies focusing on the improved delivery of existing & novel CNS agents

KEY FINDINGS:

2006 global CNS market worth over US\$100 billion

The CNS market has attracted attention of specialty pharma and big pharma players such as Abbot, Astellas, AstraZeneca, Biogen, Boehringer Ingelheim Bristol-Myers Squibb, Dianippon Sumitomo, Eisai, Eli-Lilly, Forest Laboratories, GlaxoSmithKline, Lundbeck, Johnson & Johnson, Merck & Co., Novartis, Otsuka, Pfizer, sanofi-aventis, Schering AG, Merck Serono, Shire, Takeda, Tanabe, UCB and Wyeth

Challenges remain to ensure the efficient and targeted delivery of agents across the blood brain barrier by invasive and non-invasive delivery methods to a provide flexible, reproducible and cost-effective method of managing CNS disorders

Specialists are applying a plethora of platforms to deliver CNS agents and regenerative therapies, including needle free delivery, transdermal, intranasal, pulmonary, oral & buccal delivery

Many new classes of drugs will reach the market over the next 6 years, driving future market growth including small molecules, peptides and regenerative therapies (stem cells and gene therapies). Their success is analyzed in detail and case studies provided to highlight the progress of each technology.

The application of nanotechnologies including micellar nanoparticles, nanoparticles, nanocells and lipobridge systems offers significant opportunities for selective and targeted delivery of CNS products. A number of nano-enabled delivery systems are evaluated in this report.

As the CNS market evolves new approaches to treatment of CNS are emerging utilizing stem cells and gene-based therapies. Several companies are working towards this goal including: Copernicus Therapeutics, Genzyme, Oxford Biomedica, NeuroGeneration and Pharmidex. A number of delivery options are currently being evaluated to optimize the clinical utility of these regenerative therapies and are analyzed in detail in the report.

Introduction

“The World Health Organization has indicated that CNS disorders are the major medical challenge of the 21st Century, yet treatments for most CNS disorders are either inadequate or absent. The CNS is the most challenging frontier for drug discovery largely because of the complexity of the brain and the existence of the BBB”

Alan Palmer, Chief Executive of Pharmidex, UK

The revenue derived from Central Nervous System (CNS) drugs is vast, in that such a large number of diseases and disease processes are grouped under the CNS “umbrella”. These include acute organic conditions, such as infection, pain (both acute and chronic); chronic organic conditions such as neoplasms, seizure disorders; chronic degenerative disorders such as multiple sclerosis, Parkinson's disease, Alzheimer's disease, and other dementias, as well as the range of functional disorders classified as mental illnesses: schizophrenia, affective and anxiety spectrum disorders, attention deficit hyperactivity disorder (ADHD), sleep disorders and addictions.

The CNS has always posed problems in terms of drug delivery, drug efficacy and safety/ tolerability because of the presence of the blood brain barrier (BBB). The BBB is composed of a layer of extremely tightly packed epithelial cells, saturated with enzymes designed to protect the brain by disallowing the entry of noxious substances via the bloodstream. The unfortunate by-product of this has been the problem of delivering beneficial drugs to the CNS in sufficient quantities to effectively treat the targeted condition without causing unacceptable systemic adverse reactions.

Administering drugs directly into the CNS e.g. intrathecally or intracerebrally, is an effective method of delivery but carries significant risks in terms of infection as well as being invasive and unpleasant for the patient. In recent years, methods of by-passing the BBB have been proposed, trialed and are now available, such as osmotic permeability, the use of nanoparticles small enough to penetrate the BBB, ultrasonic adjunctive drug treatment, and stem-cell and gene therapy, which effectively provide a “self-cure” by promoting neuroplasticity and cell regeneration within the central nervous system itself.

Newer delivery methods such as transdermal drug delivery which can employ nanotechnology to increase absorption and bioavailability, as well as being non-invasive and simple to use are on the rise, and seem set to be used for a wide range of CNS disorders, including psychoses, pain and neurodegenerative disorders.

SEVEN QUESTIONS THIS NOTE ANSWERS:

1. How will the drug delivery technology drivers change in the CNS arena during the next decade and beyond?
2. What are the key delivery technologies and devices in the CNS field?
3. When are products and medical devices which utilize these key delivery technologies likely to reach the market?
4. Which drug delivery technologies are likely to win in the near-term and the long-term, and why?
5. Which companies are the winners in each technology category?
6. How are drug delivery technologies evolving to meet the demands of the CNS market?
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COMPANIES MENTIONED:

Aastrom, Ablynx, Abbott Laboratories, Acadia Pharmaceuticals, Actelion, Alkermes, Alseres Pharmaceuticals, Altea Therapeutics, ALZA Corporation, Anesiva, Amarin, Arena, AstraZeneca, ArmaGen Technologies, Astellas, Axonyx, Biogen Idec, Boehringer Ingelheim Bristol-Myers-Squibb, Boston Life Sciences, Brookwood Pharmaceuticals, Cenomed BioSciences, CeNeRx, Ceregene, Clinical Data Online, Inc., Corcept, Cortex Pharmaceuticals, Copernicus Therapeutics, Cyberkinetics, Dainippon Sumitomo, Dermatrends, D-Pharm, DOV Pharmaceuticals, Durect, Elan Corporation, Eli Lilly, EKOS, Endo Pharmaceuticals, Epix, Esai, Fabre-Kramer, Forest Laboratories, GlaxoSmithKline, GPI Pharma, Generex, Genzyme Corporation, Glide Pharma, GW Pharmaceutical, Janssen, Juvantia Pharma, Johnson & Johnson, Inflazyme Pharmaceuticals, Ipsen, Ivax, Intranasal Therapeutics, King Pharmaceuticals, Kurve Technologies, Kyowa Lundbeck, Medtronic, MediciNova, Memory Pharmaceuticals, Midatech, MAP Pharmaceuticals, Medical technologies, Merck & Co., Merck Serono, Migenix, Myriad Genetics, Nabi Pharmaceuticals, Nanopharm, NeuroWave, Neuro3d, Neurocrine, Neurogen, Neurologix, NiTi Medical Technologies,

NeoPharm, NeuroSearch, Neurocrine, Northwest Biotherapeutics, Novartis, NPS, Ono Pharmaceuticals, Otsuka Pharmaceutical, Organon, Ovation Pharmaceuticals, Oxford BioMedica, Pain Therapeutics, Pharmidex UK, Pharms, Perfusion Technology, Pfizer, Phase 2 Discovery, Potomac Pharma, Predix Pharmaceuticals, Prescient, Repligen, Roche, Saegis Pharmaceuticals, sanofi-aventis, Schering-Plough, Schering AG, Schwarz Pharma, Sepracor, Servier, Shire Pharmaceuticals, New River Pharmaceuticals, SK Pharmaceuticals, Solvay Pharmaceuticals, Sosei, Spherics, SurModics, Tanabe, Takeda, Teikoku Pharmaceuticals, Tissue Repair Cell Technology, Transpharma Medical, Targacept, Tetragenex, Teva Pharmaceuticals, Tikvah Pharmaceuticals, Titan Pharmaceuticals, Torrey Pines Therapeutics, Toyama Chemical, Trans-Tech Pharma, UCB, Valeant Pharmaceuticals, Vanda Pharmaceuticals, Wyeth, Xytis, Zogenix

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