+44 20 8123 2220
info@marketpublishers.com

US Orphan Drug Pipeline Analysis

https://marketpublishers.com/r/U947E346F68EN.html
Date: October 2013
Pages: 880
Price: US$ 1,800.00 (Single User License)
ID: U947E346F68EN

Abstracts

Please note: extra shipping charges are applied when purchasing Hard Copy License depending on the location.

In recent years, the pharmaceutical industry has been experiencing a paradigm shift. While a large pool of patients was considered as a major source of revenue for pharma companies in the past, the focus is now gradually shifting to small sections of patients suffering from rare disease. In US, this pool of patients is gradually growing and orphan drugs are becoming an extremely attractive business proposition for the pharmaceuticals industry. With close to 30 million people in the US having some kind of rare disease complaints, the increasing activities around the development of orphan drugs only imply that the appropriate treatments for unmet needs are increasing, thus increasing the profit margins in the future.

“US Orphan Drug Pipeline Analysis” by PNS Pharma gives comprehensive insight on the various orphan designated drugs being developed for the treatment of rare disease. Research report covers all the orphan designated drugs being developed in various development phases. This report enables pharmaceutical companies, collaborators and other associated stake holders to identify and analyze the available investment opportunity in the US Orphan Drug market based upon development process.

Following parameters for each vaccine profile in development phase are covered in “US Orphan Drug Pipeline Analysis” research report:

Drug Profile Overview

Alternate Names for Drug

Active Indication

+44 20 8123 2220
info@marketpublishers.com

Phase of Development

Mechanism of Action

Brand Name

Patent Information

Orphan Designation by Indication, Country & Organisation

Country for Clinical Trial

Owner / Originator/ Licensee/Collaborator

Administrative Route

Drug Class

ATC Codes

US Orphan Drug Pipeline by Clinical Phase:

Research: 4

Preclinical: 54

Phase-I: 68

Phase-I/II: 62

Phase-II: 169

Phase-II/III: 15

Phase-III: 93

Preregistration: 28

+44 20 8123 2220
info@marketpublishers.com

Registration: 18

Marketed: 137

+44 20 8123 2220
info@marketpublishers.com

Contents

+44 20 8123 2220
info@marketpublishers.com

+44 20 8123 2220
info@marketpublishers.com

About

Arbaclofen - Seaside Therapeutics

(GABA-B) agonist, for the treatment of social withdrawal (and possibly other core impairments) associated with fragile X syndrome (FXS) and autistic disorder. These disorders are believed to be caused by excessive activation of glutamate signalling, and abnormally high ratios of excitatory to inhibitory neurotransmission in the brain. Arbaclofen is designed to inhibit glutamate signalling, thereby inhibiting excessive metabotropic glutamate receptor (mGluR)-mediated protein synthesis. It may also optimise the ratio of excitatory to inhibitory neurotransmission. Studies in preclinical models of fragile X syndrome and autistic disorder have shown this agent to be efficacious. Phase III development of capsule and fast-dissolving tablet formulations are underway in patients with autistic disorder in the US. Phase III clinical development in fragile X syndrome is also in progress in the US.

Autistic disorder (also called autistic spectrum disorders or ASD) is used to describe a group of complex developmental brain disorders that are caused by a combination of genetic and environmental disorders. It is marked by the presence of markedly abnormal or impaired development in social interaction and communication and a markedly restricted repertoire of activity and interest. Manifestations of the disorder vary greatly depending on the developmental level and chronological age of the individual. There are currently are no US FDA-approved therapeutics to treat the core impairments of autistic disorder.

Acetylcysteine Injection - Cumberland Pharmaceuticals

Cumberland Pharmaceuticals has developed an intravenously injectable formulation of acetylcysteine (Acetadote®) for the treatment of paracetamol overdose. Acetylcysteine is used in emergency departments to prevent or lessen the liver damage that results from paracetamol overdose. This product was the first injectable treatment available in the US for this potentially lethal overdosing occurrence. It has also been launched in Australia and New Zealand for use in paracetamol poisoning. A supplemental NDA (sNDA) has been submitted to the US FDA seeking approval for use of Acetadote® in patients with non-paracetamol-related acute liver failure. Phase II/III trials of acetylcysteine for the prevention of radiocontrast-induced nephropathy are underway in the US.

+44 20 8123 2220
info@marketpublishers.com

In January 2013, the US FDA approved InnoPharma's ANDA for acetylcysteine intravenous injection for the prevention or lessening hepatic injury following paracetamol overdose. Fresenius Kabi USA will sell, market and distribute the product under the agreement with InnoPharma. The ANDA approval provides for the first generic alternative to Acetadote® injection. Acetylcysteine injection was launched by Fresenius Kabi in January 2013. Perrigo also launched a generic version of acetylcysteine.

Cumberland's competitors in the paracetamol overdose market are those companies selling orally administered N-acetylcysteine; this includes (but is not limited to) Geneva Pharmaceuticals, Bedford Laboratories (a division of Ben Venue Laboratories), Roxane Laboratories, and Hospira.

+44 20 8123 2220
info@marketpublishers.com

I would like to order

Product name: US Orphan Drug Pipeline Analysis
Product link: https://marketpublishers.com/r/U947E346F68EN.html
Price: US$ 1,800.00 (Single User License / Electronic Delivery)

If you want to order Corporate License or Hard Copy, please, contact our Customer Service:
info@marketpublishers.com

Payment

To pay by Credit Card (Visa, MasterCard, American Express, PayPal), please, click button on product page https://marketpublishers.com/r/U947E346F68EN.html

To pay by Wire Transfer, please, fill in your contact details in the form below:

First name:
Last name:
Email:
Company:
Address:
City:
Zip code:
Country:
Tel:
Fax:
Your message:

**All fields are required

Custumer signature _____

Please, note that by ordering from marketpublishers.com you are agreeing to our Terms & Conditions at https://marketpublishers.com/docs/terms.html

To place an order via fax simply print this form, fill in the information below and fax the completed form to +44 20 7900 3970