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Amyotrophic Lateral Sclerosis - Pipeline Insight, 2021

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Abstracts

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DelveInsight's, "Amyotrophic Lateral Sclerosis – Pipeline Insight, 2021," report provides comprehensive insights about 100+ companies and 100+ pipeline drugs in Amyotrophic Lateral Sclerosis pipeline landscape. It covers the pipeline drug profiles, including clinical and nonclinical stage products. It also covers the therapeutics assessment by product type, stage, route of administration, and molecule type. It further highlights the inactive pipeline products in this space.

Geography Covered

Global coverage

Amyotrophic Lateral Sclerosis Understanding

Amyotrophic Lateral Sclerosis: Overview

Amyotrophic lateral sclerosis (ALS) is a rare neurological disease that primarily affects the nerve cells (neurons) responsible for controlling voluntary muscle movement (those muscles we choose to move). Voluntary muscles produce movements like chewing, walking, and talking. The disease is progressive, meaning the symptoms get worse over time. Currently, there is no cure for ALS and no effective treatment to halt or reverse the progression of the disease. ALS belongs to a wider group of disorders known as motor neuron diseases, which are caused by gradual deterioration (degeneration) and death of motor neurons. Motor neurons are nerve cells that extend from the brain to the spinal cord and to muscles throughout the body. As motor neurons degenerate, they stop sending messages to the muscles and the muscles gradually weaken, start to twitch,

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and waste away (atrophy). Eventually, the brain loses its ability to initiate and control voluntary movements. Early symptoms of ALS usually include muscle weakness or stiffness. Gradually all voluntary muscles are affected, and individuals lose their strength and the ability to speak, eat, move, and even breathe. Most people with ALS die from respiratory failure, usually within 3 to 5 years from when the symptoms first appear. However, about 10 percent of people with ALS survive for 10 or more years.

There is no single test that provides a definitive diagnosis of ALS. It is primarily diagnosed based on a detailed history of the symptoms observed by a physician during physical examination, along with a review of the individual's full medical history and a series of tests to rule out other diseases. A neurologic examination at regular intervals can assess whether symptoms such as muscle weakness, muscle wasting, and spasticity are progressively getting worse. There is no treatment to reverse damage to motor neurons or cure ALS. However, treatments can help control symptoms, prevent unnecessary complications, and make living with the disease easier.

'Amyotrophic Lateral Sclerosis - Pipeline Insight, 2021' report by DelveInsight outlays comprehensive insights of present scenario and growth prospects across the indication. A detailed picture of the Amyotrophic Lateral Sclerosis pipeline landscape is provided which includes the disease overview and Amyotrophic Lateral Sclerosis treatment guidelines. The assessment part of the report embraces, in depth Amyotrophic Lateral Sclerosis commercial assessment and clinical assessment of the pipeline products under development. In the report, detailed description of the drug is given which includes mechanism of action of the drug, clinical studies, NDA approvals (if any), and product development activities comprising the technology, Amyotrophic Lateral Sclerosis collaborations, licensing, mergers and acquisition, funding, designations and other product related details.

Report Highlights

> The companies and academics are working to assess challenges and seek opportunities that could influence Amyotrophic Lateral Sclerosis R&D. The therapies under development are focused on novel approaches to treat/improve Amyotrophic Lateral Sclerosis.

Amyotrophic Lateral Sclerosis Emerging Drugs Chapters

This segment of the Amyotrophic Lateral Sclerosis report encloses its detailed analysis

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of various drugs in different stages of clinical development, including phase II, I, preclinical and Discovery. It also helps to understand clinical trial details, expressive pharmacological action, agreements and collaborations, and the latest news and press releases.

Amyotrophic Lateral Sclerosis Emerging Drugs

AMX0035: Amylyx Pharmaceuticals

AMX0035 is an investigational product comprised of two complementary active agents, sodium phenylbutyrate (PB) and taurursodiol (TURSO), which were combined in a co-formulation to reduce neuronal death and dysfunction. AMX0035 was specifically co-formulated and manufactured by Amylyx to ensure proper absorption, exposure, and quality. AMX0035 targets endoplasmic reticulum and mitochondrial dependent neuronal degeneration pathways in ALS and other neurodegenerative diseases. The company has submitted a New Drug Submission (NDS) to Health Canada for AMX0035 (sodium phenylbutyrate (PB)-taurursodiol (TURSO)) for the treatment of ALS.

BIIB067: Biogen

BIIB067 (tofersen) is thought to reduce the production of SOD1 protein and is being evaluated in Phase III clinical trial to see if it can potentially slow the fatal progression of SOD1-ALS. Tofersen (BIIB067) previously called IONIS-SOD1Rx is an investigational therapy to slow the progression of familial amyotrophic lateral sclerosis (ALS). The therapy was developed in a collaboration between Ionis Pharmaceuticals and Biogen but is now being developed solely by Biogen.

Masitinib: AB Sciences

Masitinib is currently the only tyrosine kinase inhibitor in late-stage development for ALS. Masitinib distinguishes itself from other ALS developmental drugs by exerting neuroprotection in both central and peripheral nervous systems. Masitinib appears exceptional among other ALS-developmental drugs, exerting neuroprotection in both central nervous system and peripheral nervous system via selective kinase inhibition that modulates the functionality of different cells implicated in ALS pathogenesis. In recognition of the critical need for new treatments, masitinib received orphan drug

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designation for ALS from both the European Medicine Agency (EMA) and the U.S. Food and Drug Administration (FDA).

Ravulizumab: Alexion Pharmaceuticals

Ravulizumab is the first and only approved long-acting C5 complement inhibitor. It is administered intravenously every eight weeks or every four weeks for pediatric patients less than 20 kg, following a loading dose. ULTOMIRIS works by inhibiting the C5 protein in the terminal complement cascade, a part of the body's immune system. The terminal complement cascade, when activated in an uncontrolled manner, plays a role in severe ultra-rare disorders. ULTOMIRIS is approved in the U.S., Japan, and the EU as a treatment for adults with PNH and in the U.S. for aHUS to inhibit complement-mediated thrombotic microangiopathy (TMA) in adult and pediatric (one month of age and older) patients. The drug is being evaluated in Phase III clinical trial to treat patients with ALS.

Autologous MSC-NTF cells: BrainStorm Cell Therapeutics

BrainStorm has entered into agreements with Dana-Farber Cancer Institute (Dana-Farber) in Boston, Massachusetts and the City of Hope National Medical Center in Duarte, California to provide clean room facilities for production of autologous MSC-NTF cells. The company has completed a phase III clinical trial of autologous MSC-NTF cellular therapy in Amyotrophic Lateral Sclerosis (ALS).

Further product details are provided in the report……..

Amyotrophic Lateral Sclerosis: Therapeutic Assessment

This segment of the report provides insights about the different Amyotrophic Lateral Sclerosis drugs segregated based on following parameters that define the scope of the report, such as:

Major Players in Amyotrophic Lateral Sclerosis

There are approx. 100+ key companies which are developing the therapies for Amyotrophic Lateral Sclerosis. The companies which have their Amyotrophic Lateral Sclerosis drug candidates in the most advanced stage, i.e. Preregistration include,

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Amylyx Pharmaceuticals.

Phases

DelveInsight’s report covers around 100+ products under different phases of clinical development like

Late stage products (Phase III)

Mid-stage products (Phase II)

Early-stage product (Phase I) along with the details of

Pre-clinical and Discovery stage candidates

Discontinued & Inactive candidates

Route of Administration

Amyotrophic Lateral Sclerosis pipeline report provides the therapeutic assessment of the pipeline drugs by the Route of Administration. Products have been categorized under various ROAs such as

Oral

Parenteral

Intravenous

Subcutaneous

Topical

Molecule Type

Products have been categorized under various Molecule types such as

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- Monoclonal Antibody
- Peptides
- Polymer
- Small molecule
- Gene therapy
- Product Type

Drugs have been categorized under various product types like Mono, Combination and Mono/Combination.

Amyotrophic Lateral Sclerosis: Pipeline Development Activities

The report provides insights into different therapeutic candidates in phase II, I, preclinical and discovery stage. It also analyses Amyotrophic Lateral Sclerosis therapeutic drugs key players involved in developing key drugs.

Pipeline Development Activities

The report covers the detailed information of collaborations, acquisition and merger, licensing along with a thorough therapeutic assessment of emerging Amyotrophic Lateral Sclerosis drugs.

Amyotrophic Lateral Sclerosis Report Insights

- Amyotrophic Lateral Sclerosis Pipeline Analysis
- Therapeutic Assessment
- Unmet Needs
- Impact of Drugs

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Amyotrophic Lateral Sclerosis Report Assessment

- Pipeline Product Profiles
- Therapeutic Assessment
- Pipeline Assessment
- Inactive drugs assessment
- Unmet Needs

Key Questions

Current Treatment Scenario and Emerging Therapies:

- How many companies are developing Amyotrophic Lateral Sclerosis drugs?
- How many Amyotrophic Lateral Sclerosis drugs are developed by each company?
- How many emerging drugs are in mid-stage, and late-stage of development for the treatment of Amyotrophic Lateral Sclerosis?
- What are the key collaborations (Industry–Industry, Industry–Academia), Mergers and acquisitions, licensing activities related to the Amyotrophic Lateral Sclerosis therapeutics?
- What are the recent trends, drug types and novel technologies developed to overcome the limitation of existing therapies?
- What are the clinical studies going on for Amyotrophic Lateral Sclerosis and their status?
- What are the key designations that have been granted to the emerging drugs?

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