

Schizophrenia - Pipeline Insight, 2021

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Abstracts

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DelveInsight's, "Schizophrenia – Pipeline Insight, 2021," report provides comprehensive insights about 70+ companies and 70+ pipeline drugs in Schizophrenia 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

Schizophrenia Understanding

Schizophrenia: Overview

Schizophrenia is a chronic brain disorder that affects less than one percent of the U.S. population. When schizophrenia is active, symptoms can include delusions, hallucinations, disorganized speech, trouble with thinking and lack of motivation. Schizophrenia does not mean split personality or multiple-personality. Most people with schizophrenia are not any more dangerous or violent than people in the general population. However, with treatment, most symptoms of schizophrenia will greatly improve and the likelihood of a recurrence can be diminished. The symptoms of schizophrenia generally fall into the following three categories: Psychotic symptoms, Negative Symptoms, cognitive symptoms. Symptoms of schizophrenia usually first appear in early adulthood and must persist for at least six months for a diagnosis to be

made. Men often experience initial symptoms in their late teens or early 20s while women tend to show first signs of the illness in their 20s and early 30s. More subtle signs may be present earlier, including troubled relationships, poor school performance and reduced motivation. While there is no cure for schizophrenia, research is leading to innovative and safer treatments.

'Schizophrenia - Pipeline Insight, 2021' report by DelveInsight outlays comprehensive insights of present scenario and growth prospects across the indication. A detailed picture of the Schizophrenia pipeline landscape is provided which includes the disease overview and Schizophrenia treatment guidelines. The assessment part of the report embraces, in depth Schizophrenia 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, Schizophrenia 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 Schizophrenia R&D. The therapies under development are focused on novel approaches to treat/improve Schizophrenia.

Schizophrenia Emerging Drugs Chapters

This segment of the Schizophrenia report encloses its detailed analysis 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.

Schizophrenia Emerging Drugs

SEP-363856: Sunovion Pharmaceuticals

SEP-363856 is a TAAR1 agonist with 5-HT_{1A} agonist activity. The therapy is under trial for the treatment of schizophrenia and other psychiatric conditions. Sunovion is running a global Phase III development program for schizophrenia (DIAMOND) with additional

indications under consideration.

Roluperidone (MIN-101): Minerva Neurosciences

Roluperidone is meant to block a specific subtype of serotonin receptor called 5-HT_{2A}. When 5-HT_{2A} is blocked, certain symptoms of schizophrenia, such as hallucinations, delusions, agitation, and thought and movement disorders, as well as the side effects associated with antipsychotic treatments, can be minimized. Additionally, blocking 5-HT_{2A} promotes slow-wave sleep, a sleep stage often disrupted in patients with schizophrenia. It is currently in phase 3 of clinical trials and in December 2020 Minerva Neurosciences announces its intention to request a pre-NDA meeting with the US FDA for planned NDA submission of Roluperidone for Schizophrenia.

BI 425809: Boehringer Ingelheim

BI 425809 is a glycine transporter inhibitor that is being developed for the treatment of schizophrenia in Phase III stage of development. The rationale behind this approach is that abnormalities in glutamatergic signaling downstream of neuronal NMDA receptors contribute to cognitive impairment in both these diseases, hence boosting NMDA receptor function might benefit synaptic plasticity and cognition. BI 425809 is proposed to increase glycine levels and its ability to modulate NMDA receptor function. On 25 May, 2021 Boehringer Ingelheim announced that its BI 425809 product had been granted Breakthrough Therapy Designation (BTD) by the US Food and Drug Administration (FDA) for cognitive impairment associated with schizophrenia (CIAS).

TV-46000: Teva Pharmaceuticals

TV-46000 is an extended-release subcutaneous risperidone injection, an investigational once-monthly or once-every-two-months injectable formulation of the well-characterized and widely used atypical antipsychotic risperidone for the treatment of schizophrenia. The investigational subcutaneous risperidone injection utilizes a novel polymer delivery platform that allows the product to be delivered subcutaneously. The polymer delivery platform, in combination with risperidone, allows for control of the rate and duration of drug release and a range of dosing options. The investigational subcutaneous risperidone injection has been studied extensively in non-clinical and clinical studies, including a global Phase 3 clinical development program with two pivotal studies

evaluating investigational subcutaneous risperidone injection in schizophrenia. Teva Pharmaceutical intends to submit NDA application for Schizophrenia.

KarXT: Karuna Therapeutics

Karuna therapeutics product candidate, KarXT, selectively activates muscarinic acetylcholine receptors in the brain to unlock the therapeutic potential of xanomeline, which previously demonstrated significant benefits in Phase 2 studies in schizophrenia and Alzheimer's. M1 and M4 muscarinic receptors are the receptor subtypes believed to mediate the antipsychotic, procognitive and analgesic effects of xanomeline and other muscarinic agonists. Results from preclinical studies and clinical trials conducted by third parties support the hypothesis that xanomeline can reduce psychosis and improve cognition. The drug is currently being evaluated in Phase III clinical to treat Schizophrenia.

AVP-786: Avanir Pharmaceuticals

This investigational therapeutic is a deuterated, second-generation version of AVP-923/Nuedexta, a fixed-dose combination of two approved drugs. AVP-786 is a combination of deudextromethorphan hydrobromide (d6-DM) and quinidine sulfate (Q), a CYP2D6 inhibitor. Deuteration was observed to significantly reduce susceptibility to cytochrome P450 (CYP2D6) enzyme metabolism thereby increasing the bioavailability of d6-DM. It is being investigated in Phase II/III clinical trial to treat Schizophrenia.

MK-8189: Merck sharp & Dohme

MK 8189 is an orally administered, phosphodiesterase 10A (PDE10A) inhibitor, being developed and investigated in Phase III stage of development by Merck Sharp & Dohme, for the treatment of schizophrenia.

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

Schizophrenia: Therapeutic Assessment

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

Major Players in Schizophrenia

There are approx. 70+ key companies which are developing the therapies for Schizophrenia. The companies which have their Schizophrenia drug candidates in the most advanced stage, i.e. Phase III include, Sunovion Pharmaceuticals.

Phases

DelveInsight's report covers around 70+ 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

Schizophrenia 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

Monoclonal Antibody

Peptides

Polymer

Small molecule

Gene therapy

Product Type

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

Schizophrenia: Pipeline Development Activities

The report provides insights into different therapeutic candidates in phase II, I, preclinical and discovery stage. It also analyses Schizophrenia 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 Schizophrenia drugs.

Schizophrenia Report Insights

Schizophrenia Pipeline Analysis

Therapeutic Assessment

Unmet Needs

Impact of Drugs

Schizophrenia 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 Schizophrenia drugs?

How many Schizophrenia drugs are developed by each company?

How many emerging drugs are in mid-stage, and late-stage of development for the treatment of Schizophrenia?

What are the key collaborations (Industry–Industry, Industry–Academia), Mergers and acquisitions, licensing activities related to the Schizophrenia 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 Schizophrenia and their status?

What are the key designations that have been granted to the emerging drugs?

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Schizophrenia Key Products

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