



Study on the potential of Antipsychotic drugs (Schizophrenia Disease) and identify launch opportunity in US market.



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Project Objective

- To assess the potential of Antipsychotics (Schizophrenia Disease) for US market
- To identify a launch opportunity in Antipsychotics for US market

Methodology

- Data was collected by doing secondary research from clinical studies, research articles and websites

Methodology

- **Data was collected by doing secondary research from clinical studies, research articles and websites**
- **Type of Research:** Secondary Research
- **Setting:** Organisation setting (PharmaAce Innovations LLP)
- **Duration of study:** 3 Months
- **Type of study:** Observational study

Review of Literature

Title	Authors	Conclusion
Non-pharmacological interventions for schizophrenia-analysis of treatment guidelines and implementation in 12 Southeast European countries	Idija Injac Stevović, Nikolina Jovanović	The study on schizophrenia treatment guidelines in Southeastern European countries revealed that while medication-focused guidelines were prevalent, non-medication treatments were recommended in some countries. However, the evidence supporting these treatments was limited, and their implementation within mental health services was found to be low. Family therapy and psychoeducation were commonly recommended, but the overall adoption of non-medication treatments was limited, indicating a gap between guidelines and actual practice in the region.
The acute efficacy of antipsychotics in schizophrenia: a review of recent meta-analyses	Peter M. Haddad and Christoph U. Correll	In conclusion, antipsychotic medications have demonstrated effectiveness in reducing symptoms and improving various aspects of functioning in schizophrenia patients. First-episode patients tend to have better treatment responses compared to those with multiple episodes. Lack of response or symptom worsening after 2 weeks of treatment indicates the need for treatment modification. Clozapine stands out as an effective option for treatment-resistant schizophrenia. However, individual response and symptom domains vary, highlighting the need for personalized approaches and the development of new medications that target specific symptoms and consider patient characteristics.
Exploratory analyses of efficacy data from schizophrenia trials in support of new drug applications submitted to the US Food and Drug Administration	Ni A Khin, Yeh-Fong Chen, Yang Yang, Peiling Yang, Thomas P Laughren	To summarize, antipsychotic medications have shown effectiveness in alleviating symptoms and enhancing functioning in schizophrenia patients. Initial treatment response is generally better among individuals experiencing their first episode of psychosis. If symptoms do not improve or worsen after two weeks of treatment, adjustments to the treatment plan may be necessary. Clozapine is particularly effective for treatment-resistant schizophrenia cases. However, given the variability in individual responses and symptom profiles, there is a need for tailored approaches and the development of novel medications targeting specific symptoms and individual patient characteristics.
Schizophrenia Primary Research (KOL's Insight) Competitive Intelligence Market Analytics & Forecast 2030	Mellalta Meets LLP	In conclusion, the growth of the diagnosed prevalence of schizophrenia is expected to drive sales growth in the therapy market, with an estimated annual increase across major pharmaceutical markets. The adoption of second-generation treatments and emerging therapies will play a significant role in the overall expansion of the schizophrenia market by 2030. Although there is no cure for schizophrenia, a combination of medication and psychological interventions is recommended for managing the chronic disorder. Ongoing research aims to address the limitations of current treatments and improve schizophrenia management. However, it is crucial to address the treatment gap and ensure that all individuals with schizophrenia receive appropriate healthcare.
Schizophrenia Drugs in Development by Stages, Target, MoA, RoA, Molecule Type and Key Players, 2022 Update	Global Markets Direct	In conclusion, Global Markets Direct's "Schizophrenia - Drugs In Development, 2022" pipeline guide provides a comprehensive overview of the therapeutics being developed for Schizophrenia in the CNS. It offers valuable insights into the stage of development, drug targets, mechanisms of action, and routes of administration of these therapeutics. The guide reviews key players in the field and includes information on dormant and discontinued projects. It serves as a valuable resource for identifying emerging players, understanding their portfolios, and making informed decisions in the competitive Schizophrenia market. The guide is regularly updated to capture the latest developments in the field.



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ANTIPSYCHOTICS

Classification, Applications, Diagnosis, Market size

D

SCHIZOPHRENIA DISEASE OVERVIEW

Epidemiology, Causes, Symptoms, Prognosis, Population at risk, Market size

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Phase 2 and above, Class

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Year 2021- 2031 (Molecule- Evenamide), Epidemiology flow

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Antipsychotics– Overview

Antipsychotics

- Antipsychotic drugs (**also called neuroleptics or major tranquilizers**) are used primarily to treat **schizophrenia (biologic illness)**, but they are also effective in other **psychotic states**, including **manic states** with psychotic symptoms such as grandiosity, paranoia, and hallucinations, and delusions
- Antipsychotic drugs are **not curative and do not eliminate the chronic thought disorder**, but they often **decrease the intensity of hallucinations and delusions** and permit the person with schizophrenia to function in a supportive environment

Classification

Typical Antipsychotic

- Haloperidol
- Loxapine
- Thioridazine
- Molindone
- Thiothixene
- Fluphenazine
- Mesoridazine
- Trifluoperazine
- Perphenazine
- Chlorpromazine

Atypical Antipsychotic

- Aripiprazole
- Clozapine
- Ziprasidone
- Risperidone
- Quetiapine
- Olanzapine

Therapeutics Applications

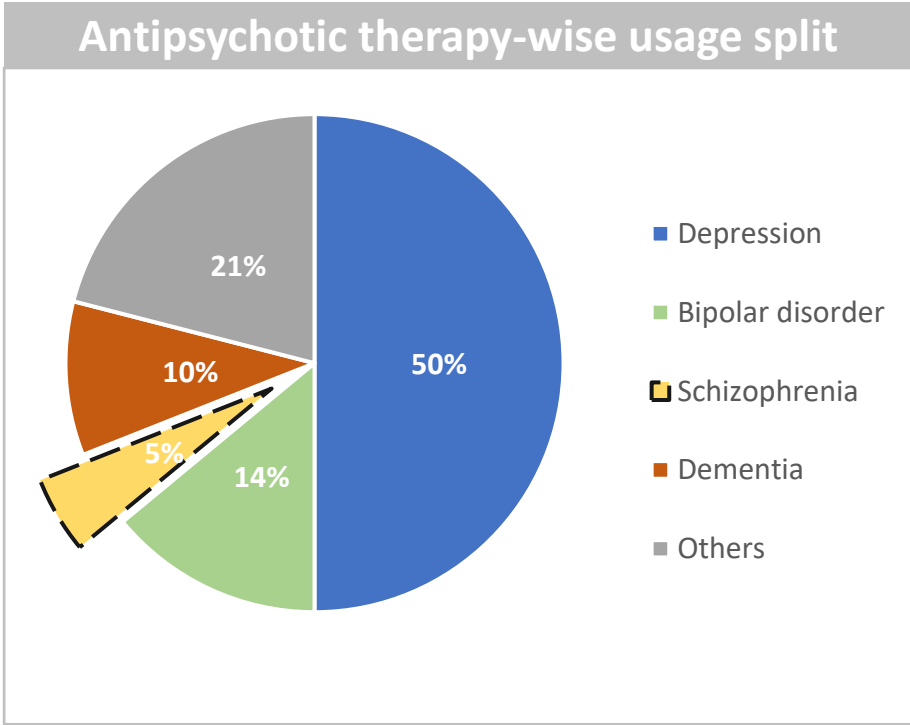
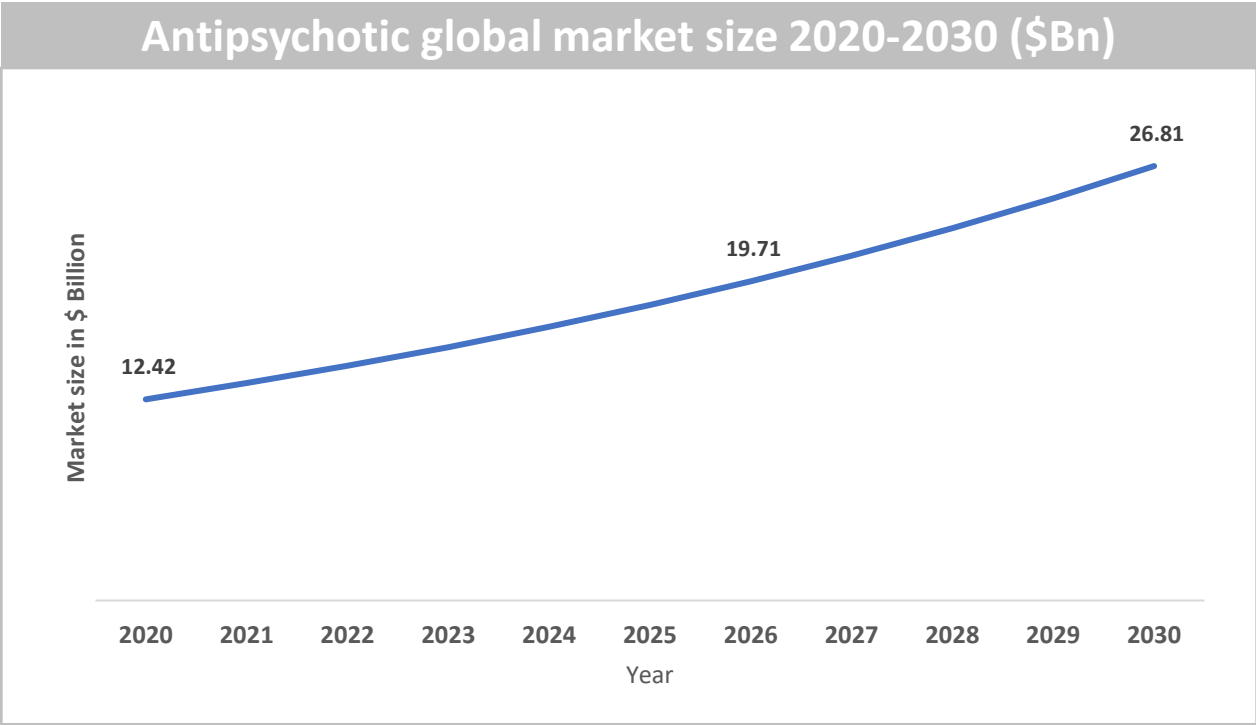
- ☒ Schizophrenia
- ☐ Parkinson's
- ☐ Bipolar disorder
- ☐ Dementia
- ☐ Alzheimer's disease
- ☐ Attention Deficit Hyperactivity Disorder (ADHD)

Diagnosis

- ☐ MRI
- ☐ CT SCAN
- ☐ Cognitive testing
- ☐ Personality testing
- ☐ Open-ended or projective testing
- ☐ PANSS
- ☐ SANS and SAPS
- ☐ BPRS

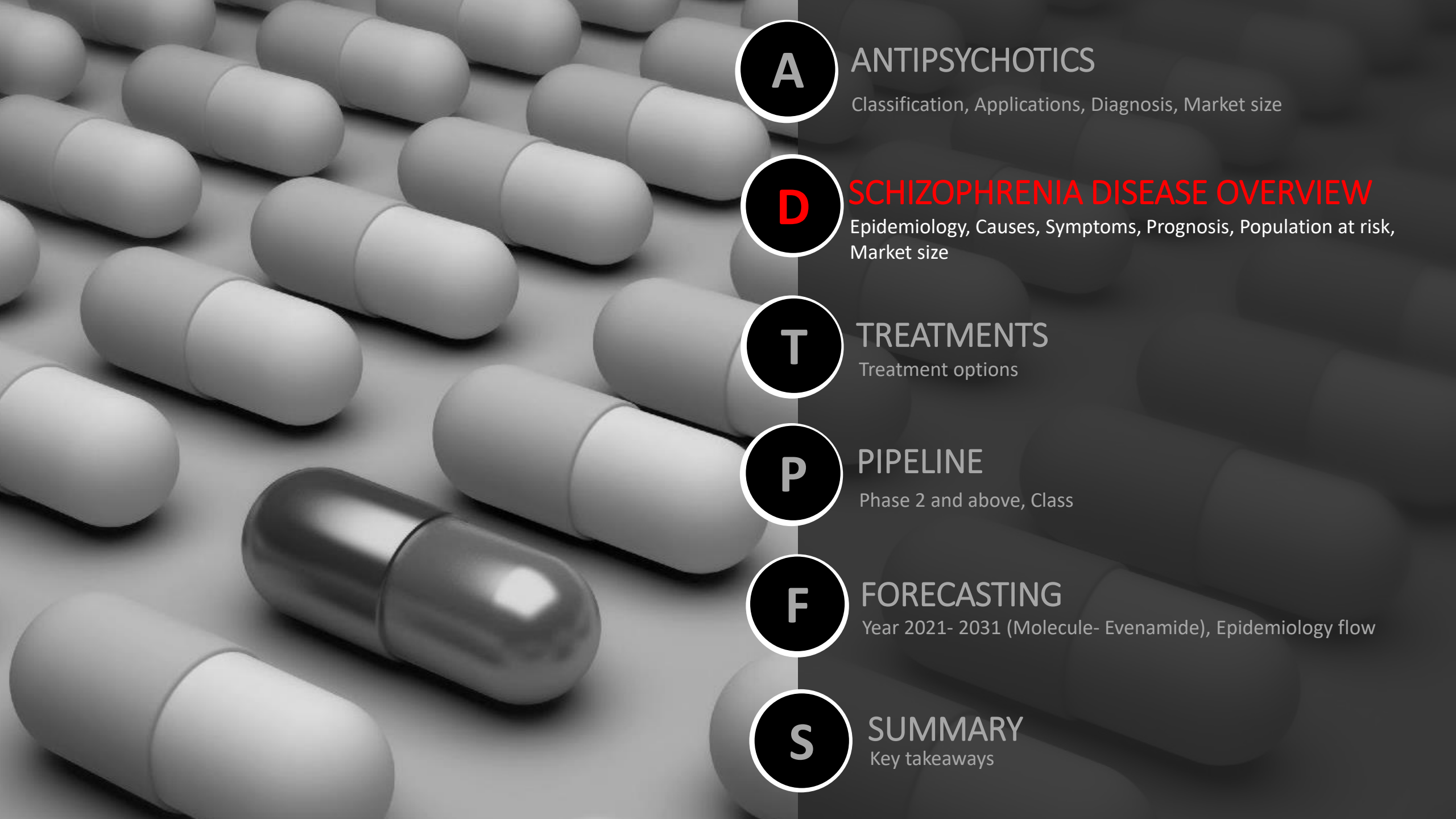
Antipsychotics- Market Size

- The global market for antipsychotic drugs is anticipated to witness positive growth trends, owing to strong increase in prevalence of psychotic disorders
- Rise in geriatric population, and growth in awareness program regarding mental health drive also contribute to market growth



Top Antipsychotics by 2026 Forecasted Worldwide Sales

Brand name	Generic Name	Company	Mechanism of action	2026 Sales
Invega	Paliperidone palmitate		5-HT2 antagonist, D2 antagonist	\$4856 m
Vraylar	Cariprazine hydrochloride		5-HT2A antagonist, 5-HT 1A partial agonist, D2 agonist, D3 agonist	\$1307 m
Abilify	Aripiprazole		5-HT2 antagonist, 5-HT1A partial agonist, D2 partial agonist	\$1,080 m
Rexulti	Brexipiprazole		5-HT2 antagonist, 5-HT1A partial agonist, D2 partial agonist	\$852 m
KarXT	Trospium chloride; xanomeline		Selectively activate muscarinic acetylcholine receptors in the brain to improve the therapeutic potential of xanomeline	\$746 m
Caplyta	Lumateperone tosylate		Unknown, but efficacy could be mediated through a combination of antagonist activity at central serotonin 5-HT2A receptors and post synaptic antagonist activity at central dopamine D2 receptors	\$705 m



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Schizophrenia– Overview

PREVALENCE RATE

- 24 million people worldwide
- 2.8 million adults in the United States aged 18 or older

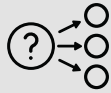
SYMPTOMS

- Delusions and hallucinations
- Alterations of the senses
- An inability to sort and interpret incoming sensations, and an inability therefore to respond appropriately
- An altered sense of self
- Changes in emotions, movements and behaviour

POPULATION AT RISK

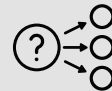


More common in Oceania, Middle East and East Asia



CAUSES

- Genetics (heredity)
- Brain chemistry and circuits
- Brain abnormality
- Environment
- Pregnancy and birth complications
- Taking mind-altering (psychoactive or psychotropic) drugs during teen years and young adulthood



Unmet need

- Lack of efficacy and negative side effects with the existing treatment
- High discontinuation rate



PROGNOSIS

- Ten years after initial diagnosis, approximately 50% of people diagnosed with schizophrenia are either noted to be completely recovered or improved to the point of being able to function independently
- 25% percent are improved which require strong support network, and an additional 15% remain unimproved and are typically hospitalized
- 10% of the affected population ends up committing suicide



More common in males (39.8 per 100,000) than females (22.4 per 100,000)

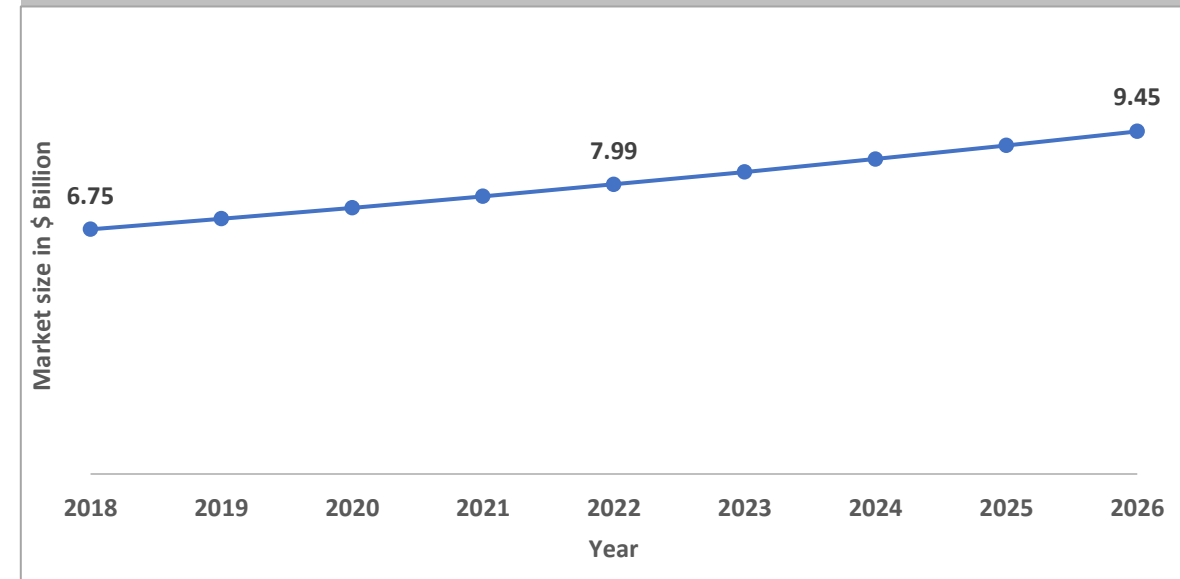


Individuals aged 55 years and older will soon account for 25% or more of the total population of patients with schizophrenia worldwide

Schizophrenia- Market Size

- The growth of the global Schizophrenia Drugs Market growth is majorly driven by the increase in prevalence of mental disturbances & schizophrenia and rise in awareness about mental health
- In addition, surge in mental health awareness programmes by government and non-government organizations drives the growth of market
- Rise in number of geriatric population drives the growth of market. The old age people are more prone to mental disorders

Schizophrenia global market size 2020-2026 (\$Bn)





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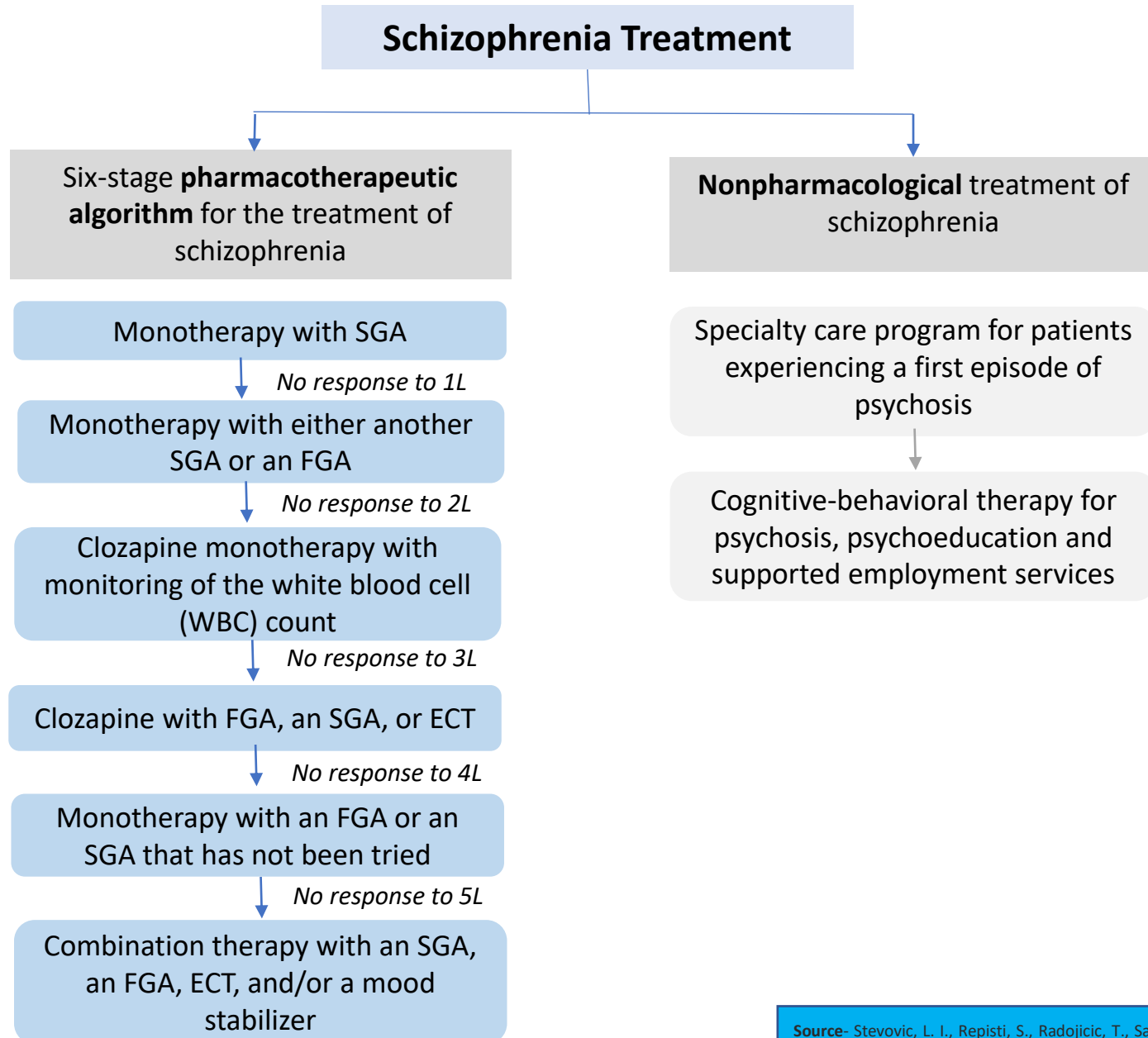
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Treatment Algorithm



FDA Approved Drugs for Schizophrenia

- Aripiprazole
- Asenapine
- Brexpiprazole
- Cariprazine
- Clozapine
- Lioperidone
- Lurasidone
- Olanzapine
- Paliperidone
- Quetiapine
- Lybalvi (Olanzapine & Samidorphan)
- Dexmetomidine

Source- Stevovic, L. I., Repisti, S., Radojicic, T., Sartorius, N., Tomori, S., Kulenovic, A. D., & Jovanovic, N. (2022), non-pharmacological interventions for schizophrenia-analysis of treatment guidelines and implementation in 12 Southeast European countries. *Schizophrenia*, 8(1), 1-1., Chokhawala, K., & Stevens, L. (2021). Antipsychotic medications. In StatPearls, StatPearls Publishing, Journal of Psychosocial Nursing and Mental Health Services



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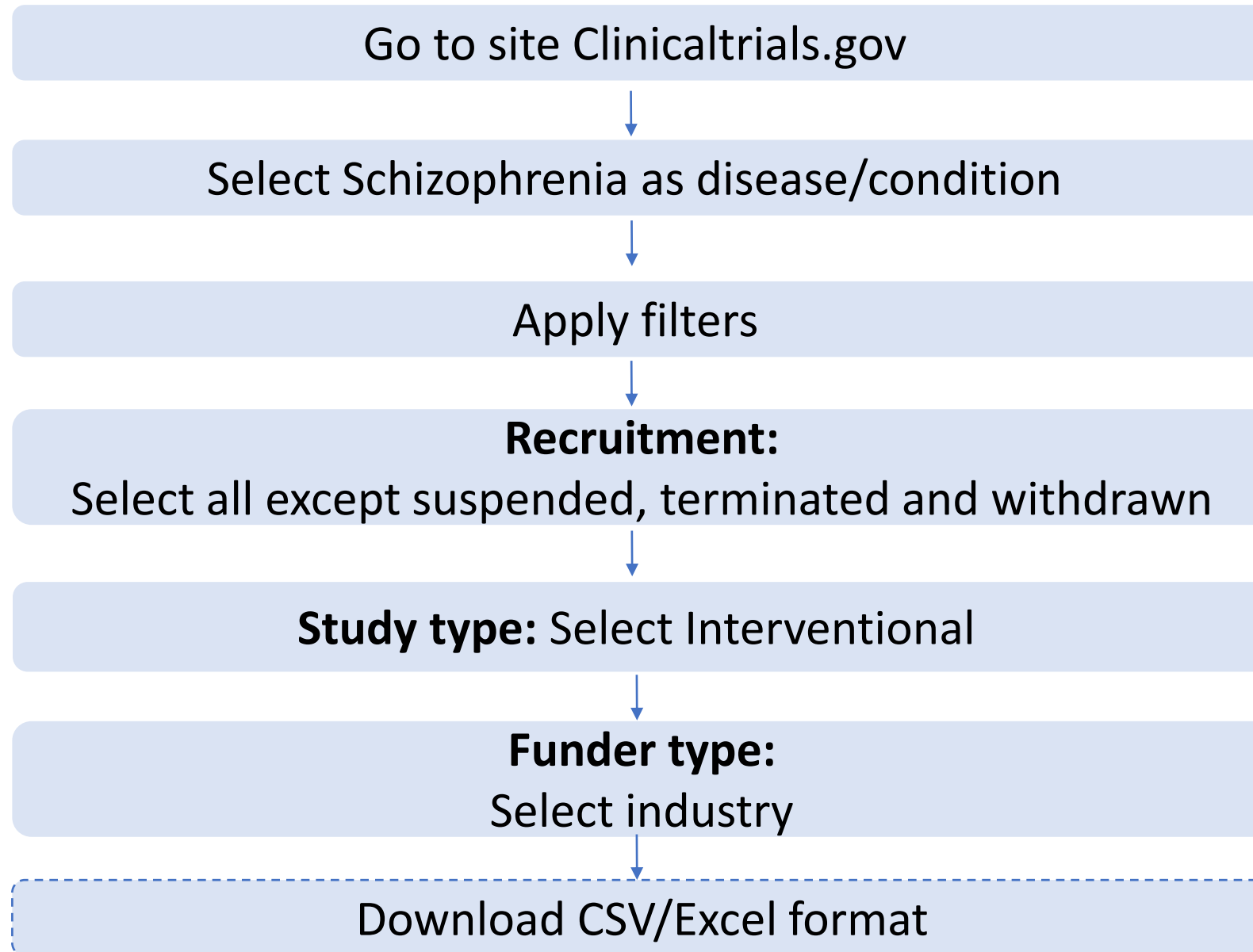
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Methodology for extracting pipeline drugs



Pipeline for Schizophrenia (Phase II and above)- US Market

Phase - 2

Phase - 3

cerevel

Emraclidine
(Muscarinic M4 receptor modulators)



Evenamide*
(Glutamate modulation and voltage-gated sodium channel blockade)

Deudextromethorphan
(Norepinephrine plasma membrane transport protein inhibitor, Serotonin plasma membrane transport protein inhibitor, NMDA receptor antagonist)

AVANIR

Pfizer

PF- 6412562
(Dopamine-1 receptors partial agonist)

SyneuR

NaBen
(D amino acid oxidase inhibitors)

Ulotaront
(Serotonin 1A receptor agonists, Trace amine-associated receptor 1 agonists)

sunovion

RECOGNIFY
LIFE SCIENCES

RL 007
(Cholinergic receptor modulators)



Dexmedetomidine
(Alpha 2 adrenergic receptor agonists)

Boehringer
Ingelheim

Osoresnontrine
(Phosphodiesterase 9A inhibitors)



Doria
(Dopamine D2 receptor antagonists, Serotonin 2A receptor antagonists)

Roluperidone*
(Alpha-1a adrenergic receptor antagonists; Serotonin 2A receptor antagonists; Sigma-2 receptor antagonists)

MINERVA
NEUROSCIENCES

Takeda

Luvadaxistat
(Potent inhibitor of DAAO enzyme)

Alkermes

ALKS 3831
(Antagonist of Dopamine D1 & D2, Opioid mu and Serotonin 2A receptors)

Brilaroxazine
(dopamine (D)/serotonin (5-HT) modulator)

Reviva
PHARMACEUTICALS

MERCK

MK - 8189
(PDE10A inhibitor)

ACADIA
Pharmaceuticals

Pimvanserin
(Serotonin 2A receptor antagonists; Serotonin 2A receptor inverse agonists)

KarXT
(M1/M4 preferring muscarinic agonist)

KARUNA
THERAPEUTICS

Route of administration

* Drug under Pre-registration

● Oral
● Intramuscular



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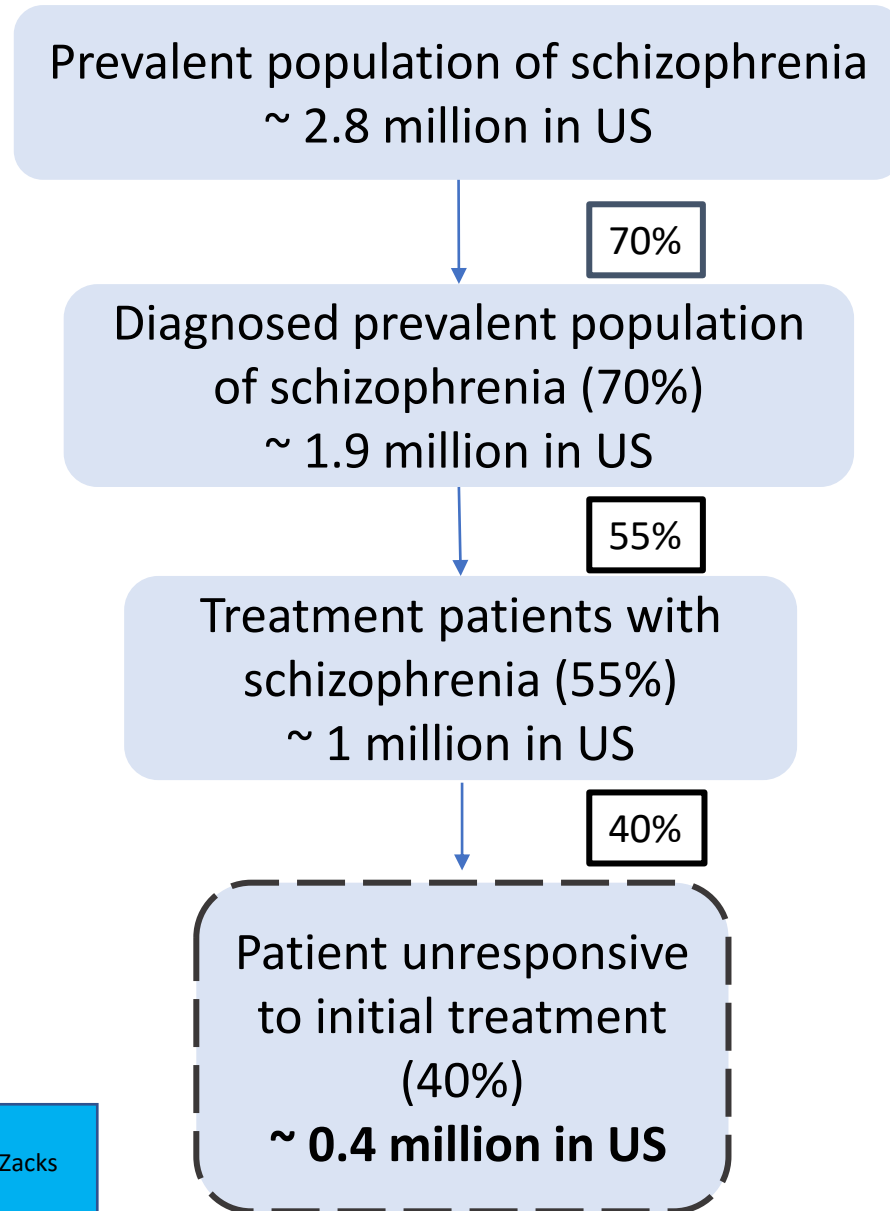
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Epidemiology Flow



Source

1. V, John D., CFA (2021, January13), Reviva Pharmaceutical Holdings, Zacks Small-Cap Research

2. Schizophrenia, Primary Research (KOL's Insight), Competitive Intelligence, Market Analytics & Forecast 2030

Forecasting

--	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Schizophrenia prevalence	28,00,000	28,56,000	29,13,120	29,71,382	30,30,810	30,91,426	31,53,255	32,16,320	32,80,646	33,46,259	34,13,184	34,81,448
Diagnosis rate	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%
Treatment rate	55%	55%	55%	55%	55%	55%	55%	55%	55%	55%	55%	55%
Unresponsive patient rate	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%
Eligible pool*	4,31,200	4,39,824	4,48,620.5	4,57,592.9	4,66,744.7	4,76,079.6	4,85,601.2	4,95,313.3	5,05,219.5	5,15,323.9	5,25,630.4	5,36,143.0
Market Share of <u>Evenamide**</u>	0%	0%	0%	0%	0%	2%	5%	7%	9%	11%	14%	16%
Patients treated with <u>Evenamide***</u>	-	-	-	-	-	10,882	22,199	33,964	46,191	58,894	72,086	85,783
Cost of therapy per year (in USD)#	-	-	-	-	-	4,946	5,045	5,146	5,249	5,354	5,461	5,571
Gross revenue****	-	-	-	-	-	5,38,26,598	11,20,02,385	17,47,90,923	24,24,69,968	31,53,32,193	39,36,85,937	47,78,55,990

*Eligible Pool (number of patients) = (Schizophrenia prevalence in US * Diagnosis Rate * Treatment Rate * Unresponsive Rate)

**Market share = Calculated by using linear forecast considering 0% before launch and 16% in peak year 2031

***Patients treated with Evenamide = Market share * Eligible pool of Evenamide

****Gross revenue (in USD) = Patients treated with Evenamide * Cost of therapy per year (in US \$)

#Cost of therapy per year is taken from Newron analyst report and forecasted with rise of 2%

Diagnosis, treatment and unresponsive patient rate have been kept constant for forecasted period (2020-2031)



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Conclusion

The inline treatment algorithm for schizophrenia is extensive, with multiple lines of therapy and treatment modalities available for each line of therapy. Drug resistance poses a significant challenge to adherence and compliance with medical treatment which is an important unmet need.

However, Newron plans to launch a potential drug (Drug X) to overcome drug resistance, which has shown promising results and holds the potential for capturing a market share. Currently, there are no approved drugs targeting drug resistance in the pipeline, providing a unique opportunity for Evenamide.



It is recommended that if ABC Company wants to expand its pipeline portfolio in the neuro specialty area, specifically in antipsychotics, there is a high market competition in US, the company can plan the business development in a different geography .



If the company X wants to continue with their idea of portfolio expansion in the same therapeutic area within US, it is suggested that they should consider a commercial partnership with Newron, which could be a strategic move to further enhance their position in the market.



Thank You