



# With FDA approval, Cobenfy is set to make inroads into the schizophrenia treatment pathway

Market Event Summary

Prakhar Saxena; Himanshu Jain | October 2024

# Cobenfy is the first FDA-approved drug in schizophrenia with a novel mode of action in more than 30 years.

On **September 26, 2024**, Bristol Myers Squibb's **Cobenfy** received FDA approval in schizophrenia, nearly nine months after the company acquired the drug developer Karuna Therapeutics for \$14 billion.

Key opinion leaders interviewed by Clarivate are excited for a novel drug in schizophrenia. **Key positives** for Cobenfy are:

- **A novel mechanism of action:** Cobenfy combines **xanomeline**, an M1/M4 muscarinic receptor agonist, with **trospium chloride**, a muscarinic antagonist, to minimize cholinergic side effects outside the brain.
- **Promising clinical efficacy:** In the Phase 3 EMERGENT-2 and -3 clinical studies, it significantly improved PANSS total scores versus placebo from **8.4 points to 9.6 points** at week five (with a **high effect size [0.6]** comparable to the effects demonstrated by the efficacious antipsychotics olanzapine and risperidone in their respective studies).
- **Low risk for the usual side effects of antipsychotics:** The drug has no atypical antipsychotic class warnings, precautions, or boxed warnings (e.g., extrapyramidal symptoms, weight gain, somnolence).

**However**, Cobenfy has the following potential **shortcomings**:

- **Twice-daily dosing** and **anticholinergic side effects** (could be as concern for psychiatrists because of schizophrenia patients' generally poor adherence to oral drugs).
- **Lack of approval for specific schizophrenia patients with high unmet need**, such as treatment-resistant patients, patients with negative symptoms, or those with cognitive impairment.



## Clarivate's takeaways

### Expected positioning of Cobenfy in schizophrenia

- Because of its novel mechanism of action, it would be beneficial for schizophrenia patients (as a monotherapy or adjunctive therapy) who do not respond to dopamine-acting drugs and/or who cannot tolerate side-effects of current antipsychotics. In early lines, it will have limited use because of the competition from generically available antipsychotics.
- Owing to its potential for an early onset of action, psychiatrists will likely prescribe it in hospitalized acutely psychotic patients and will continue the drug in the treatment-responsive patients in the outpatient setting.

### Commercial potential in schizophrenia

- As a first-in-class drug, Cobenfy is expected to benefit from its **first-mover advantage**. We forecast that the drug will achieve blockbuster sales in the United States.

### The road ahead for Cobenfy

- It **will remain the only drug in its class for at least the next 3 years** (we expect that other emerging agents in the same class [e.g., Neurocrine Biosciences' NBI-1117568, AbbVie's emeraldine] will not launch before 2027; they may offer once-daily dosing and a better tolerability profile).
- Cobenfy's **potential label expansions** for inadequately responding schizophrenia patients and for psychosis associated with Alzheimer's Disease will boost its commercial potential.

## About the authors



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## Clarivate coverage of schizophrenia

- [Disease Landscape & Forecast: Schizophrenia \(G7\)](#), providing comprehensive market intelligence insights
- [Epidemiology](#): diagnosed incidence and prevalence data for various population segments of schizophrenia across the G7 and emerging markets
- [Current Treatment: Detailed, Expanded Analysis \(US and EU5\)](#), exploring prescribing trends among U.S. and EU5 psychiatrists
- [Current Treatment: Treatment Algorithms | Schizophrenia \(US\)](#), exploring prescribing trends via claims data analysis
- [Unmet Need: Schizophrenia \(Positive Symptoms, Negative Symptoms, Cognitive Impairment\) \(US / EU\)](#), including an Excel-based target product profile simulator
- [Access & Reimbursement: Schizophrenia \(US\)](#), providing insights on the impact of payer policy on prescribing behavior in schizophrenia



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