

# Global Menin Inhibitor Drugs Clinical Trials & Future Opportunity Insight 2023

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Date: September 2023

Pages: 75

Price: US\$ 3,300.00 (Single User License)

ID: GD574EADE4A2EN

## Abstracts

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Global Menin Inhibitor Drugs Clinical Trials & Future Opportunity Insight 2023 Report Highlights:

Research Methodology

Menin Inhibitors Drugs In Clinical Trials: > 10 Drugs

Highest Clinical Trials Phase: Phase-II

Global Menin Inhibitors Drugs Clinical Trials By Company, Indication & Phase

Clinical Significance Of Menin Inhibitors

Menin Inhibitors Clinical Research Innovation Trends By Region : US, Europe & Canada

Menin represents a new generation of proteins that have found application as a therapeutic target in several prevalent diseases, especially cancer. First linked with benign tumors through the studies on multiple endocrine neoplasia type 1 (MEN1), the menin protein is now being studied for its role in cancer and diabetes, finding potential use in both. This has generated the need for development of menin inhibitors that can be used to treat these diseases. Though no menin inhibitor has received approval yet, the pipeline of menin inhibitors is populated with multiple promising candidates, each

having the potential to become the first-in-class menin inhibitor to receive market approval.

The role of menin inhibitors has been confirmed in multiple cancers, out of which leukemia is dominating the research and development landscape because menin's role in this hematological cancer is the most well characterized out of all indications it has found use in. The menin protein acts as an important cofactor for the fusion proteins of mixed lineage leukemia (MLL) gene, mutations in which are linked to the development of acute leukemia. This association with a prevalent cancer sparked interest in this field and has led to the development of many potential inhibitors.

Several menin inhibitors are now undergoing early phase clinical trials in leukemia, out of which Revumenib, previously known as SNDX-5613, is one of the most promising candidates currently. Revumenib was developed by Syndax Pharmaceuticals, and is a highly potent inhibitor of menin, which has shown a convincing clinical profile in the company's ongoing clinical trials. The ongoing AUGMENT-101 clinical trial is assessing Revumenib as a monotherapy in acute leukemias and the AUGMENT-102 clinical trial is testing Revumenib in combination with chemotherapy to determine the synergized effects of menin inhibitors with established standard of care for leukemia.

The FDA designated Revumenib as a breakthrough therapy in December 2022 the treatment of patients with relapsed or refractory acute leukemia who have a KMT2A rearrangement. In addition, it also has the Fast Track designation from the FDA for the treatment of adults and adolescents with relapsed or refractory acute myeloid leukemia (AML) or acute lymphoblastic leukemia (ALL) with an NPM1 mutation. The fast track designation expedites the review of investigational drugs by the FDA, which puts forth Revumenib as the potential first menin inhibitor to receive marketing approval. Prior to these FDA designations, Revumenib was also granted the orphan drug designation by the EMA in December 2021 for treating acute myeloid leukemia.

Another candidate that has garnered significant attention is BMF-219, a menin inhibitor developed by Biomea Fusion. BMF-219 made name for itself as the first menin inhibitor to enter clinical trials for the treatment of solid cancers. In contrast to other menin inhibitors in the clinical trials, Biomea has expanded the clinical assessment of BMF-219 to KRAS-driven non-small cell lung cancer, pancreatic cancer, and colorectal cancer. The interaction pathways between menin, KRAS and MYC have been established in research studies, which has allowed for this expansion in clinical trials for BMF-219. The trial is still in early clinical phase with the first patient receiving BMF-219 dosage in January this year.

BMF-219 is also an important menin inhibitor in sense that along with solid cancers, it is also the first menin inhibitor to undergo clinical trial for type 2 diabetes mellitus. The candidate showed glycemic control in patients ever after the treatment was stopped, which has been attributed to disruption of menin activity by the drug. In addition, Biomea has also planned a clinical trial to assess BMF-219 in type 1 diabetes. BMF-219 therefore represents a potential force that may be used to improve treatment outcomes of diabetic patients.

Therefore, menin inhibitors represent a significant breakthrough in the management of some prominent diseases marked by high prevalent rates, high mortality rates and a dearth of effective treatments. Ongoing research has been linking menin activities with several other gene products, which can potentially expand the use of menin inhibitors to several other indications. That being said, the global market for menin inhibitors is still in its nascent stage, with companies like Biomea Fusion and Syndax Pharmaceuticals emerging as pioneers of menin inhibitors research. The market holds immense future potential, both clinically and commercially, which needs to be tapped to exploit this newfound commercial opportunity.

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