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The acute myeloid leukemia (AML) market across the seven major countries (7MM) of the US, France, Germany, Italy, Spain, the UK, and Japan, will more than triple from $406 million in 2016 to over $1.5 billion by 2026, representing a compound annual growth rate of 14%, according to research and consulting firm GlobalData.

The company's latest report states that major drivers of the AML market will include the launch of premium-priced therapies, an increasing branded drug treatment rate, a growing desire to develop targeted therapies to treat AML patients with specific driver mutations, and a rising number of elderly incident cases of AML.

Volkan Gunduz, Ph.D., Senior Healthcare Analyst at GlobalData, explains: "Although AML is a rare disease, the high levels of unmet need create ample opportunities for players with effective therapies. However, drug development has been exceedingly challenging, predominantly due to the heterogeneity and aggressive nature of the disease, and many promising drugs have failed in randomized studies.

"Although the biology of AML is still poorly understood, there has been progress towards identifying actionable targets for treatment. With the approval of Novartis' Rydapt and the anticipated approvals of other FMS-like tyrosine kinase 3 gene inhibitors (FLT3 TKIs) and isocitrate dehydrogenase (IDH) 2 inhibitor enasidenib, AML patients are starting to benefit from the targeted therapies that have revolutionized the treatment of most other cancers."

Players hoping to enter the space are aware of the issues that have plagued AML drug development, so are designing larger, randomized Phase II trials to confirm a strong efficacy signal, before proceeding with a Phase III study.

Gunduz continues: "Although AML affects a relatively small number of patients, there are sixteen drugs in late stage clinical development. These drugs are primarily indicated for AML patients who respond poorly to standard cytarabine-based induction chemotherapy, including newly diagnosed elderly patients, relapsed/refractory patients, and patients with FLT3 mutations."

By 2026, the branded AML market leader will be Venclexta, with estimated total sales of $179 million in the 7MM. Other branded therapies with leading sales include Daiichi Sankyo's quizartinib, Astellas' gilteritinib, and Jazz's Vyxeos.