Low-grade glioma - Market Insights, Epidemiology and Market Forecast- 2032

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Report description:

DelveInsight's " Low-grade glioma - Market Insights, Epidemiology and Market Forecast- 2032" report delivers an in-depth understanding of the LGG, historical and forecasted epidemiology as well as the LGG market trends in the United States, EU-5 (Germany, Spain, Italy, France, and the United Kingdom) and Japan.
LGG market report provides current treatment practices, emerging drugs, and market share of the individual therapies, current and forecasted 7MM LGG market size from 2019 to 2032. The report also covers current LGG treatment practice/algorithm, and unmet medical needs to curate the best of the opportunities and assesses the underlying potential of the market.
Geography Covered
- The United States
- EU-5 (Germany, France, Italy, Spain, and the United Kingdom)
- Japan
Study Period: 2019-2032

Low-grade glioma Disease Understanding and Treatment Algorithm

Low-grade glioma Overview
Low-grade glioma (LGGs) are a diverse group of primary brain tumors that often arise in young, otherwise healthy patients and generally have an indolent course with longer-term survival in comparison with high-grade glioma. Moreover, in this type of brain tumor with a relatively good prognosis and prolonged survival, the potential benefits of treatment must be carefully weighed against potential treatment-related risks.
Low-grade astrocytic tumors include diffuse astrocytoma, pilomyxoid astrocytoma, and pleomorphic xanthoastrocytoma (WHO grade II), as well as subependymal giant cell astrocytoma (SEGA) and pilocytic astrocytoma (WHO grade I tumors).
IDH1 and IDH2 are the most commonly mutated genes in low grade glioma, with mutations estimated to occur in > 70% of cases. BRAF V600E point mutations are occasionally observed in pilocytic astrocytoma; the mutations are also observed in nonpilocytic pediatric low-grade glioma, including ganglioglioma, desmoplastic infantile ganglioglioma, and approximately two-thirds of pleomorphic xanthoastrocytomas.

Low-grade glioma Diagnosis

Diagnosis of LGGs is made through a combination of imaging, histopathology, and molecular diagnostic methods. On computed tomography scans, LGGs appear as diffuse areas of low attenuation. In conventional magnetic resonance imaging (MRI), which is currently the imaging modality of choice, LGGs are often homogeneous with low signal intensity on T1-weighted sequences and hyperintensity on T2-weighted and Fluid-Attenuated Inversion Recovery (FLAIR) sequences. Calcifications may be evident as areas of T2 hyperintensity/T1 hypointensity in up to 20% of lesions, including oligodendrogliomas and astrocytomas, and are particularly suggestive of oligodendrogliomas. Glioma, in general, infiltrate the surrounding parenchyma despite apparent radiographic margins observed on T2/FLAIR sequences.

Low-grade glioma Treatment

There are no marketed drugs for the treatment of LGG. Low-grade glioma (LGG) are usually treated with a combination of surgery, observation, and radiation. If the tumor is located in an area where it is safe to remove, then the neurosurgeon will attempt to remove it as much as possible.

Low-grade glioma Epidemiology

The disease epidemiology covered in the report provides historical as well as forecasted epidemiology segmented by total incident population of primary brain cancer, total incident population of low-grade glioma, grade-specific, age specific, type-specific cases of low-grade glioma, and the further segmentation is based on molecular alterations and enhancing/non-enhancing low-grade glioma in the 7MM market covering the United States, EU-5 countries (Germany, France, Italy, Spain, and United Kingdom) and Japan from 2019 to 2032.

Key Findings

This section provides glimpse of the LGG epidemiology in the 7MM

Country Wise- Low-grade glioma Epidemiology

- The epidemiology segment also provides the LGG epidemiology data and findings across the United States, EU-5 (Germany, France, Italy, Spain, and the United Kingdom) and Japan.
- The total incident population of LGG in the 7MM comprised of 9,078 cases in 2021 and are projected to increase during the forecast period.
- The total incident population of glioma in the United States is 3,654 in 2021.
- The United States contributed to the largest incident population of LGG, accounting for ~ 40% of the 7MM in 2021.
- In the EU-5 countries, the diagnosed prevalence of LGG was found to be maximum in Germany followed by France. While, the least number of cases were found in Spain, in 2021.
- In Japan, the total incident population of LGG is 814 in 2021 and is anticipated to rise during the forecast period.
- In 2021, 2,958 patients accounted for IDH mutation, and 251 accounted for BRAF V600E cases in the United States.
- In 2021, the Grade II non-enhancing LGGs accounted for 1,819 cases in the United States.
- In the United States, there were number of Grade 2 glioma cases are higher than the Grade I cases in 2021.
- In the US, based on age, the maximum cases are in the age group of <18 years i.e. 1,253 followed by 18-44 years, 45-59 years, 60-74 years, and least in ?75 years in 2021.
- Based on the molecular alterations the incident population of LGG is segmented into diffuse astrocytoma, oligodendroglioma, oligoastrocytic tumors, pilocytic astrocytoma, ependymal tumors, and unique astrocytoma variants. In 2021, the diffuse astrocytoma and oligodendroglioma in the United States accounted for 1,161 and 689, respectively.

LGG Drug Chapters

The drug chapter segment of the LGG report encloses the detailed analysis of LGG mid and late stage pipeline drugs. It also helps to understand the LGG clinical trial details, expressive pharmacological action, agreements and collaborations, approval and patent details of each included drug and the latest news and press releases.

Marketed drug

Trametinib + Dabrafenib: Novartis Pharmaceuticals

Novartis Pharmaceuticals is developing trametinib + dabrafenib which is an oral small-molecule inhibitor Inhibits MAPK pathway

and inhibits cell growth of various BRAFV600E positive tumors. Currently, the company is conducting Phase II trials on children and adolescent patients with BRAF V600 mutation-positive relapsed or refractory HGG or BRAFV600 mutation-positive LGG. Recently in August 2022, Novartis announced that the US FDA has granted accelerated approval to Tafinlar (dabrafenib) + Mekinist (trametinib) for the treatment of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options.

Note: Detailed Current therapies assessment will be provided in the full report of LGG.

Emerging drugs

DAY101: Day One Biopharmaceuticals

Tovorafenib is an investigational, oral, brain-penetrant, highly selective type II pan-RAF kinase inhibitor designed to target a key enzyme in the MAPK signaling pathway and may offer an important alternative for people with primary brain tumors or brain metastases of solid tumors. DAY101 has been granted Breakthrough Therapy designation by the US FDA for the treatment of patients with pLGG harboring an activating RAF alteration who require systemic therapy and who have either progressed following prior treatment or who have no satisfactory alternative treatment options. The FDA has also granted Rare Pediatric Disease Designation to DAY101 for the treatment of low-grade gliomas harboring an activating RAF alteration that disproportionately affects children. DAY101 has also received Orphan Drug designation from both the FDA and the European Medicines Agency (EMA) for the treatment of malignant glioma. The trial is being conducted in collaboration with the Pacific Pediatric Neuro-Oncology Consortium (PNOC) and is designed to support the regulatory approval of DAY101. Initial data from pivotal FIREFLY-1 study with tovorafenib (DAY101) in relapsed pediatric low-grade glioma (pLGG) expected in August 2022. In May 2022, the company announced to initiate pivotal Phase III FIREFLY-2 clinical trial evaluating tovorafenib as a first-line therapy in pLGG in the second quarter of 2022.

Vorasidenib: Servier

Servier is developing Vorasidenib an investigational, oral, selective, brain-penetrant dual inhibitor of mutant IDH1 and IDH2 enzymes. The drug is currently being evaluated in the registration-enabling Phase III INDIGO study as a potential treatment for patients with residual or recurrent grade 2 low-grade glioma with an IDH1 or IDH2 mutation (NCT04164901). In August 2021, the company announced promising Phase I data for Vorasidenib in IDH mutant low-grade glioma. The study data demonstrated a median progression-free survival of 36.8 months (3.1 years) for patients with non-enhancing low-grade glioma and demonstrated a favorable safety profile. This drug is also being evaluated in a Phase I trial for grade II/III glioma with an IDH1 R132H mutation (NCT03343197).

AB-218: AnHeart Therapeutics

AnHeart Therapeutics is currently studying AB-218 in patients with IDH1 mutant Glioma AB-218 is a novel, potent, highly selective mutant IDH-1 inhibitor, which has high permeability of the blood-brain barrier and has demonstrated encouraging safety and efficacy signals in a Phase I trial of glioma patients. The company has initiated a Phase II trial in participants with recurrent or progressive histologically confirmed IDH1 mutant WHO Grade 2/3 glioma for which the recruitment has not yet started. The drug was originally developed by Daiichi Sankyo but in 2020 AnHeart therapeutics acquired this drug. The Phase I clinical trial of AB-218 in glioma patients have demonstrated promising efficacy and safety profiles in 12 non-enhancing and 35 enhancing glioma patients. The objective response rate (ORR) was 33% and 17.1% in non-enhancing and enhancing patients, respectively.

Mirdametinib: SpringWorks Therapeutics

SpringWorks Therapeutics, a clinical-stage biopharmaceutical reported the initiation of a Phase I/II clinical trial to evaluate Mirdametinib, an investigational MEK inhibitor, for the treatment of children, adolescents, and young adults with low-grade glioma (LGG). Mirdametinib is an oral, allosteric, brain-penetrant small molecule designed to inhibit MEK1 and MEK2, which are proteins that occupy pivotal positions in the MAPK pathway.

Note: Detailed emerging therapies assessment will be provided in the final report.

LGG Market Outlook

At present, the therapeutic landscape of LGG is devoid of approved treatment, and there is a substantial unmet need for a therapy to slow its worsening. The pathophysiology of LGG is poorly understood. The low-grade glioma segment is anticipated to be a

highly lucrative segment in the near future due to more treatment options available and early detection of tumor of this grade. LGGs progress into HGGs over a period, so there is an urgent need for upcoming therapies to stop the progression of LGG into HGG, especially in the Grade 2 stage.
There is more focus on high-grade glioma than low-grade glioma as patients with low-grade glioma typically lives longer than those with high-grade glioma. Traditional outcome measures in clinical cancer research have been confined to overall survival, progression-free survival, and radiological response to treatment. Palliation and the maintenance or improvement of quality of life are also important, and this recognition has resulted in that health-related quality of life.
Many pharmaceutical companies are working to develop a novel approach to treat this condition. Key players like Day One Biopharmaceuticals (DAY101), AnHeart Therapeutic (AB-218), SpringWorks Therapeutics (mirdametinib), Servier (vorasidenib [AG-881]), and others are focusing on indications like LGG to fulfill the gap of this high unmet need..
Key Findings
This section includes a glimpse of the Low-grade glioma7MM market.
- The total market size of low-grade glioma (LGG) in the 7MM USD 969 million in 2021 and is projected to grow during the forecast period (2022-2032).
- According to the estimates, the highest market size of LGG is from the United States in 2021.
- Among the EU5 countries, Germany has the maximum revenue share followed by France in 2021 while Spain has the lowest market share.
- The market size of LGG in Japan is USD 83 million in 2021 which is expected to rise during the forecast period (2022-2032).
- The upcoming therapies of LGG are expected to combat the current unmet needs faced by the patients with LGG.

The United States Market Outlook
The total market size of LGG in the United States is expected to increase with a CAGR of 4.2% during the study period (2019-2032).

EU-5 Market Outlook
The total market size of LGG in EU5 is expected to increase with a CAGR of 2.6% during the study period (2019-2032).

Japan Market Outlook
The total market size of LGG in Japan is expected to increase with a CAGR of 1.6% during the study period (2019-2032).
Analyst Commentary
- The current emerging market of LGG possesses an intermediate pipeline. There are three emerging therapy in the higher stage i.e., Novartis Pharmaceuticals (Trametinib + Dabrafenib), Day One Biopharmaceuticals (DAY101), and Servier (Vorasidenib); however, a few potential emerging players are investigating their product candidates in lower phase clinical developmental stage, namely, AnHeart Therapeutics (AB-218) and SpirngWorks Therapeutics (Mirdametinib).
- Since there are no approved therapies for LGG, the market is mainly dominated by the use Surgery, chemotherapy, and radiation either alone or in combination.
- Given the compartmentalization of the market competition, companies are looking at biomarker-specific drugs, indicating a commercial possibility in LGG sub segments.
- In August 2022, Novartis presented the Phase II/III results of trametinib + dabrafenib in BRAF mutated patient population. The results were positive and if approved can be beneficial for the treatment based on the unmet needs it is addressing.

LGG Drugs Uptake
This section focusses on the rate of uptake of the potential drugs expected to get launched in the market during the study period 2019-2032. The analysis covers LGG market uptake by drugs; patient uptake by therapies; and sales of each drug. For example- DAY101 (tovorafenib) is an investigational, oral, brain-penetrant, highly selective type II pan-RAF kinase inhibitor designed to target a key enzyme in the MAPK signaling pathway, which may offer an important alternative for people with primary brain tumors or brain metastases of solid tumors. Based on the initial FIREFLY-1 data, the company plans to expand the development of

tovorafenib as a front-line therapy for patients newly diagnosed with pLGG and anticipates reporting topline data from this trial in the first quarter of 2023, and if the data are supportive, the company expects to file an NDA to FDA, in first of half 2023. The drug is expected to launch in 2024 in the US as second line and in 2025 as first line treatment of LGG. As per our analysis, DAY101 drug uptake in the US is expected to be medium- fast in both lines with 85% probability of success in second line and 60% in first line and an estimated peak share of 34% and 12% respectively.

LGG Pipeline Development Activities
The report provides insights into different therapeutic candidates in Phase II, Phase III and Phase I stage. It also analyzes key players involved in developing targeted therapeutics.

Pipeline Development Activities
The report covers the detailed information of collaborations, acquisition and merger, licensing and patent details for LGG emerging therapies.
KOL- Views
To keep up with current market trends, we take KOLs and SME's opinion working in the domain through primary research to fill the data gaps and validate our secondary research. Some of the leaders are - M.D., senior vice president, Center for Neuroscience and Behavioral Medicine, and director, Brain Tumor Institute, Children?s National Hospital and Senior Associate Scientist Emeritus at The Hospital for Sick Children Toronto, Canada. Their opinion helps to understand and validate current and emerging therapies treatment patterns or LGG market trend. This will support the clients in potential upcoming novel treatment by identifying the overall scenario of the market and the unmet needs.
Competitive Intelligence Analysis
We perform competitive and market Intelligence analysis of the LGG market by using various competitive intelligence tools that include-SWOT analysis, PESTLE analysis, Porter?s five forces, BCG Matrix, Market entry strategies, etc. The inclusion of the analysis entirely depends upon the data availability.
Scope of the Report
- The report covers the descriptive overview of LGG, explaining its causes, signs and symptoms, pathogenesis and currently available therapies.
- Comprehensive insight has been provided into the LGG epidemiology and treatment.
- Additionally, an all-inclusive account of both the current and emerging therapies for LGG are provided, along with the assessment of new therapies, which will have an impact on the current treatment landscape.
- A detailed review of LGG market; historical and forecasted is included in the report, covering the 7MM drug outreach.
- The report provides an edge while developing business strategies, by understanding trends shaping and driving the 7MM LGG market.
Report Highlights
- In the coming years, LGG market is set to change due emerging therapies in the pipeline, and incremental healthcare spending across the world; which would expand the size of the market to enable the drug manufacturers to penetrate more into the market.
- The companies and academics are working to assess challenges and seek opportunities that could influence LGG R&D. The therapies under development are focused on novel approaches to treat/improve the disease condition.
- As per DelveInsight?s analysis, LGG can be divided into two grades, namely, Grade I and Grade II gliomas.
- The report also encompasses other major segments, i.e., age-specific, type-specific cases of low-grade glioma, incident pool based on molecular alterations, and enhancing/non-enhancing.
- Expected Launch of potential therapies, Day One Biopharmaceuticals (DAY101), Servier (Vorasidenib), and AnHeart Therapeutics (AB-218) might change the landscape in treatment of LGG.
- Tafinlar + Mekinist is the only approved drug in the market for LGG and current standard treatment mainly depends on surgery, chemotherapy and radiation.

LGG Report Insights

LGG Report Insights
- Patient Population
- Therapeutic Approaches
- LGG Pipeline Analysis
- LGG Market Size and Trends
- Market Opportunities
- Impact of upcoming Therapies

LGG Report Key Strengths
- Eleven Years Forecast
- 7MM Coverage
- LGG Epidemiology Segmentation
- Key Cross Competition
- Highly Analyzed Market
- Drugs Uptake

LGG Report Assessment
- Current Treatment Practices
- Unmet Needs
- Pipeline Product Profiles
- Market Attractiveness
- SWOT
- Attribute Analysis

Key Questions
Market Insights:
- What was the LGG market share (%) distribution in 2019 and how it would look like in 2032?
- What would be the LGG total market size as well as market size by therapies across the 7MM during the study period (2019-2032)?
- What are the key findings pertaining to the market across the 7MM and which country will have the largest LGG market size during the study period (2019-2032)?
- At what CAGR, the LGG market is expected to grow at the 7MM level during the study period (2019-2032)?
- What would be the LGG market outlook across the 7MM during the study period (2019-2032)?
- What would be the LGG market growth till 2032 and what will be the resultant market size in the year 2032?

Epidemiology Insights:

- What is the disease risk, burden and unmet needs of LGG?
- What is the historical LGG patient pool in the United States, EU5 (Germany, France, Italy, Spain, and the UK) and Japan?
- What would be the forecasted patient pool of LGG at the 7MM level?
- What will be the growth opportunities across the 7MM with respect to the patient population pertaining to LGG?
- Out of the above-mentioned countries, which country would have the highest incident population of LGG during the study period (2019-2032)?
- At what CAGR the population is expected to grow across the 7MM during the study period (2019-2032)?

Current Treatment Scenario, Marketed Drugs and Emerging Therapies:

- What are the current options for the treatment of LGG? What are the current treatment guidelines for the treatment of LGG in the US and Europe?
- What are the LGG marketed drugs and their MOA, regulatory milestones, product development activities, advantages, disadvantages, safety and efficacy, etc.?
- How many companies are developing therapies for the treatment of LGG?
- How many emerging therapies are in the mid-stage and late stage of development for the treatment of LGG?
- What are the key collaborations (Industry-Industry, Industry-Academia), Mergers and acquisitions, licensing activities related to the LGG therapies?
- What are the recent novel therapies, targets, mechanisms of action and technologies developed to overcome the limitation of existing therapies?
- What are the clinical studies going on for LGG and their status?
- What are the key designations that have been granted for the emerging therapies for LGG?
- What are the 7MM historical and forecasted market of LGG?

Reasons to buy
- The report will help in developing business strategies by understanding trends shaping and driving the LGG.
- To understand the future market competition in the LGG market and Insightful review of the key market drivers and barriers.
- Organize sales and marketing efforts by identifying the best opportunities for LGG in the US, Europe (Germany, Spain, Italy, France, and the United Kingdom) and Japan.
- Identification of strong upcoming players in the market will help in devising strategies that will help in getting ahead of competitors.
- Organize sales and marketing efforts by identifying the best opportunities for LGG market.
- To understand the future market competition in the LGG market.

Table of Contents:

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