

# Global Claudin 18.2 Targeted Therapy Market Opportunity & Clinical Trials Insight 2028

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## Abstracts

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Global Claudin 18.2 Targeted Therapy Market Opportunity & Clinical Trials Insight 2028  
Report Findings & Highlights:

First Claudin 18.2 Targeting Antibody Commercial Launch By H1 2024

Claudin 18.2 Targeted Drugs In Clinical Trials: > 60 Drugs

Global Claudin 18.2 Current Market Trend & Developments

Global Claudin 18.2 Drugs Clinical Trials By Company, Indication & Phase

Insight On Technical & Clinical Platforms For Developing Claudin 18.2 Therapy

Claudin 18.2 Targeted Therapy Development Approaches: CAR T Cell Therapy, Bispecific Antibodies, Antibody Drug Conjugates

Cancer is marked by the presence of numerous biomarkers, many of which are being used as targets for precision medicine. Among the various promising cancer proteins, Claudin-18 (CLDN18) has become a compelling option with considerable therapeutic promise. Particular attention has been aroused by the emergence of CLDN18.2, a variation of CLDN18. The expression pattern of CLDN18.2 is distinct and it is mostly present in the gastric mucosa. This variant has gained prominence due to its association with certain malignancies. As investigations into the therapeutic potential of

CLDN18 continue, its impact on the pharmaceutical domain is poised to be substantial, potentially revolutionizing the way we treat some cancers.

CLDN18, a protein that is largely linked with tight junctions in epithelial cells, has received a lot of interest recently because of its potential as a therapeutic target. One of its key advantages is that it is expressed in a variety of tumors, including pancreatic, gastric and lung cancers. Because of this selective expression, it is an appealing target for precision medicine, enabling the creation of targeted medicines that protect healthy tissues while destroying malignant tissues. Therefore, CLDN18 overexpression in diverse malignancies offers a unique opportunity in the realm of cancer pharmaceuticals.

In addition, the usage of CLDN18.2 as a cancer therapeutic target has also showed promise in terms of lowering drug resistance. Resistance mechanisms are less likely to develop when the exact protein responsible for the cancer is specifically targeted, boosting the effectiveness of treatment. Therefore, loaded with several benefits, the potential of CLDN18 and CLDN18.2 has not clearly not gone unnoticed by the pharmaceutical sector.

Zolbetuximab, a first-in-class investigational monoclonal antibody designed to target the CLDN18, is being developed for the first-line treatment of patients with gastric or gastroesophageal junction cancer that is CLDN18.2-positive HER2-negative. Astellas, the developer of Zolbetuximab, announced in July 2023 that the FDA had approved their biologics license application (BLA) for Zolbetuximab, also granting it a priority review. If approved, Zolbetuximab will become the first CLDN18.2-targeted drug to become available in the US for these patients. In addition, Astellas has also filed applications for Zolbetuximab approval in Japan, Europe and China. The drug is being evaluated in multiple late-phase clinical trials in gastric and gastroesophageal junction adenocarcinoma and pancreatic adenocarcinoma.

Apart from antibodies like Zolbetuximab, chimeric antigen receptor T-cell (CAR-T) therapies targeting CLDN18.2 are also under development. These cell-based therapies represent a cutting-edge approach to combating cancers that express CLDN18.2. CAR-T therapy involves the genetic modification of donor or patient-derived T cells to recognize and attack cancer cells, and when applied to CLDN18.2-expressing cancers, the therapy holds great promise. For instance, the Affiliated Hospital of Qingdao University is conducting a clinical trial with 9 participants to assess the safety and tolerability of iPD-1-Claudin18.2-CAR-T therapy, XKDCT086, in recurrent or refractory gastric cancer expressing Claudin18.2. This novel approach not only highlights the

adaptability of Claudin18.2 as a therapeutic target but also underscores the evolving nature of precision medicine in the treatment of cancer.

CLDN18.2-targeted therapies have also aided the growth of personalized therapies in cancer treatment. Treatments customized to the patient's CLDN18.2 levels could improve treatment outcomes significantly. In addition, therapies that target CLDN18 or CLDN18.2 can potentially be used in combination with current therapies to boost their efficacy. For instance, pairing CLDN18-targeted therapies with immunotherapies represents a powerful cancer treatment strategy that requires further investigation.

Pharmaceutical companies are heavily spending on CLDN18 research, realizing its market upheaval potential. CLDN18-focussed ventures may be appealing to investors looking for prospects in the pharmaceutical sector. Small pharmaceutical companies working on CLDN18-targeting therapies are also becoming more visible in the pharmaceutical market. KYM Biosciences, for example, announced a global license agreement with global pharma giant AstraZeneca in February 2023 for its CLDN18.2 targeting antibody-drug conjugate CMG901, the first of its kind. AstraZeneca will be responsible for the global research, development, manufacturing and commercialization of CMG901. According to the agreement, AstraZeneca will pay KYM an upfront payment of US\$ 63 million upon closing of the transaction, as well as another US\$ 1.1 billion on further research and sales-related milestones.

Therefore, CLDN18 and its variant CLDN18.2 are a ray of hope in the pharmaceutical industry, especially cancer therapy. Its prevalence in numerous cancers as well as encouraging outcomes from research investigations and clinical trials have continuously highlighted its importance. CLDN18 has a fascinating potential as a therapeutic target and could potentially alter the way we approach cancer therapy.

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