BiTE
THE ENGAGER

AN EDUCATIONAL RESOURCE
ON THE BiTE® IMMUNO-ONCOLOGY PLATFORM

WE’RE BRINGING BiTE TO THE FIGHT™

BiTE, Bispecific T Cell Engager.

AMGEN®
Oncology
Advancing oncology at the speed of life™
Despite recent advancements in immuno-oncology, not enough patients benefit from current treatments. Therefore, additional immuno-oncology options are needed to address both hematologic malignancies and solid tumors.

Amgen is committed to advancing the field of immuno-oncology.
BiTE® technology is designed to engage the natural power of T cells

The BiTE® molecule is designed to activate the cytotoxic potential of T cells with the goal of eliminating cancer cells.6

- Recruitment of a T cell to a cancer cell leads to the formation of a cytolytic synapse, triggering T-cell activation and the release of perforin and granzymes6
- Fusion of perforin with the cancer cell membrane allows granzymes, released by the cytotoxic T cell, to enter the cancer cell to induce apoptosis6

The goal of BiTE® technology is to eliminate detectable cancer cells

Once T cells are activated by a BiTE® molecule, the T cells may induce further T-cell proliferation and cytokine production.6,7

- Following cancer cell apoptosis, activated T cells release cytokines and produce additional perforin and granzymes that may allow T cells to target surrounding cancer cells, potentially resulting in the serial lysis of multiple cancer cells by a single T cell8
- Sustained activation of a single activated cytotoxic T cell theoretically results in local proliferation and expansion of polyclonal memory T cells2,6

Cytotoxic T cells play an important role in the body’s immune defense by identifying and eliminating cancer cells; however, cancer cells can develop mechanisms to evade T cell recognition and destruction.2,5

BiTE® technology is designed to overcome cancer cells’ evasion of the immune system by engaging patients’ own T cells to directly target cancer cells. BiTE® molecules are engineered from two flexibly linked, single-chain antibodies, with one that is specific for a selected tumor antigen and the other that is specific for CD3 found on T cells.2,4

CD, cluster of differentiation.
The BiTE® immuno-oncology platform offers versatility to potentially target any tumor-specific antigen

The CD3-targeting domain is designed to bind to the T cell, while the other domain can be engineered to target tumor-specific antigens across both solid and hematologic malignancies. This approach is being studied across a wide range of settings:

- In patients with high and low tumor burden
- In patients with rapidly progressing disease
- Across different treatment lines

The BiTE® immuno-oncology platform is designed to bring T cell innovation to more patients:

- Designed to target tumor-specific antigens
- Being investigated across a broad range of solid and hematologic malignancies
- Designed to lead to off-the-shelf therapies without the need for ex-vivo manipulation of patient’s cells
- Investigated for use as monotherapies and in combination with other treatments

The BiTE® immuno-oncology platform offers potential for off-the-shelf therapies

BiTE® molecules under clinical investigation include the following targets:

- BCMA, B-cell maturation antigen
- CD19
- CD33
- DLL3, delta like canonical Notch ligand
- EGFRvIII, epidermal growth factor receptor variant III
- FLT3, FMS-like tyrosine kinase 3
- PSMA, prostate-specific membrane antigen

The goal of the BiTE® immuno-oncology platform is to make innovative T cell therapies available to more healthcare providers and their patients.
The BiTE® immuno-oncology platform has been studied in thousands of patients, many of whom have been followed for up to 5 years.\textsuperscript{11}

\textbf{Amgen is committed to developing innovative medicines that address important unmet needs}

Amgen is a pioneer in immuno-oncology and developed the first approved BiTE® molecule. The BiTE® immuno-oncology platform continues to be investigated across multiple different hematologic malignancies and solid tumors.\textsuperscript{8}

With the BiTE® immuno-oncology platform, Amgen is driven to push the boundaries of science to transform the standard of care for patients with cancer by:

- Leveraging innovative trial designs\textsuperscript{12,13}
- Investigating clinically relevant endpoints and outcomes such as MRD negativity and long-term survival\textsuperscript{14-16}

\textbf{BiTE® therapies are being investigated for use as monotherapies and in combination with other treatments\textsuperscript{7,8,10}}

AML, acute myeloid leukemia; GBM, glioblastoma; NHL, non-Hodgkin lymphoma; SCLC, small cell lung cancer.

Investigational cancers being targeted by the BiTE® platform\textsuperscript{7}
The BiTE® platform has the potential to bring hope to patients, including those with rare and aggressive diseases.
BiTE: THE ENGAGER™

Designed to close the space between T cells and tumors

The BiTE® immuno-oncology platform:

- Engages patients’ own T cells to identified tumor-specific antigens, with the goal of activating the cytotoxic potential of T cells to fight cancer\(^2,4,7,8\)

- Is being investigated in more than a thousand patients and continues to be investigated across multiple different hematologic malignancies and solid tumors\(^9,11\)

- Pioneered by Amgen, who continues to accelerate the investigation of BiTE® technology with the goal of enhancing patient experience and therapeutic potential\(^7,8\)

Learn more at amgenoncology.com