



# **BiTE** **THE ENGAGER™**

**AN EDUCATIONAL RESOURCE  
ON THE BiTE® IMMUNO-ONCOLOGY PLATFORM**



**THE BiTE® UNIVERSE  
IS EXPANDING**

BiTE, bispecific T-cell engager.

**AMGEN®**

**Oncology**

Advancing oncology at the speed of life™



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THE NEED FOR  
NEW THERAPEUTIC  
APPROACHES  
REMAINS HIGH

Despite recent advancements in immuno-oncology, not enough patients benefit from current treatments. Therefore, additional immuno-oncology options are needed to address both hematologic and solid tumor malignancies.

Considerations for addressing the unmet need



Designed to be readily available to patients<sup>1</sup>



Ensure broad patient access<sup>1,2</sup>



Management of treatment and patient care costs<sup>1,3</sup>



Limit the impact of burden of care<sup>1</sup>

Amgen is committed to advancing the field of immuno-oncology



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## BiTE® TECHNOLOGY IS DESIGNED TO ENGAGE THE NATURAL POWER OF T CELLS

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.<sup>4,5</sup>

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 bind a tumor-associated antigen on tumor cells and CD3 on T cells.<sup>4,6</sup>

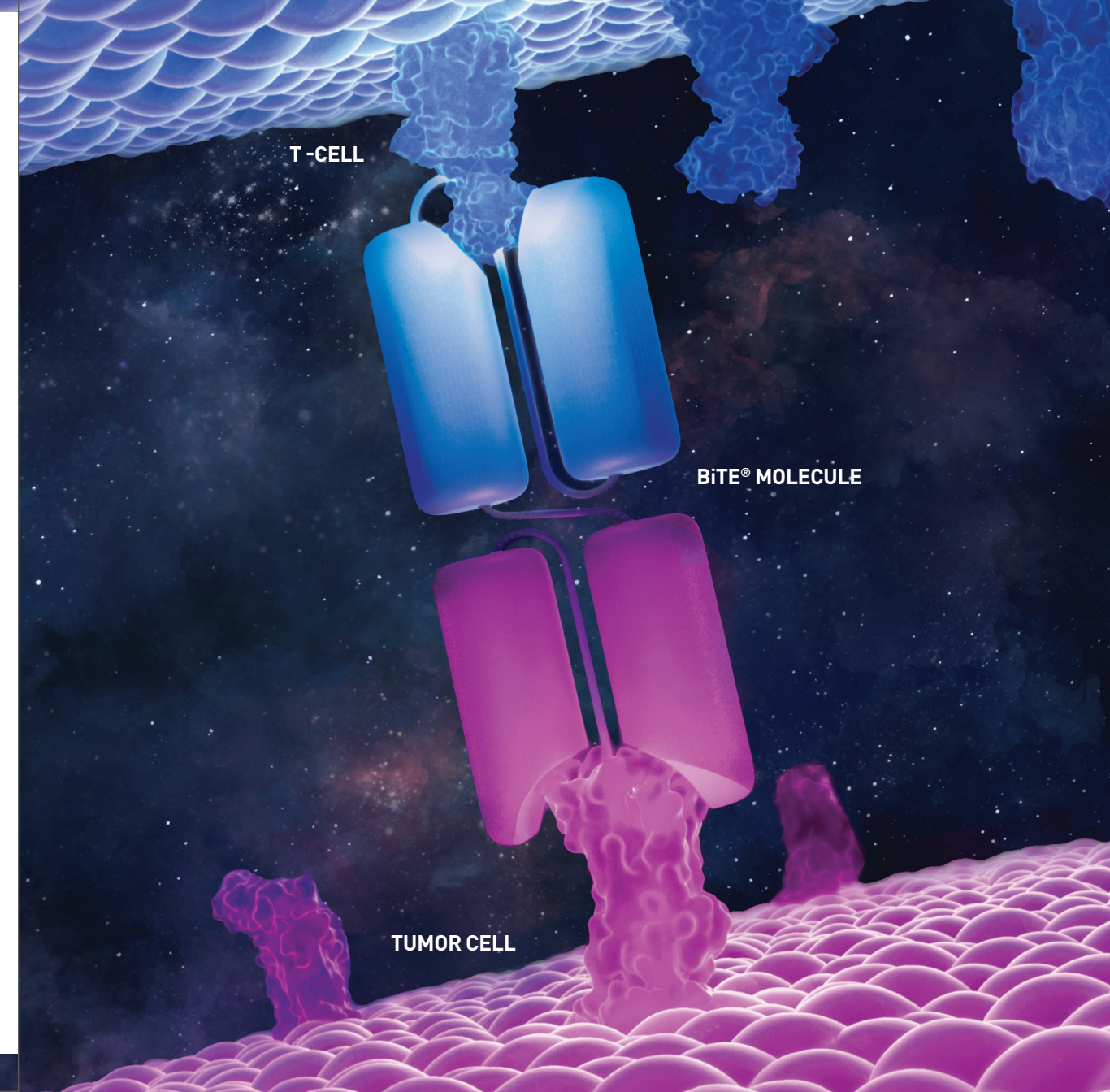
The BiTE® molecule is designed to activate the cytotoxic potential of T cells with the goal of eliminating cancer cells.<sup>7</sup>

- 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 granzymes that induce tumor cell apoptosis<sup>7</sup>

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

Once T cells are activated by a BiTE® molecule, the T cells may induce further T-cell proliferation and cytokine production.<sup>8</sup>

- Activation of a single T cell may potentially result in the serial lysis of multiple tumor cells<sup>7</sup>
- T-cell activation results in T-cell proliferation that may expand the memory T-cell population<sup>4,7</sup>





## BiTE® TECHNOLOGY ENABLES OFF-THE-SHELF THERAPIES

### The BiTE® immuno-oncology platform offers versatility to potentially target any tumor-associated antigen

The CD3-targeting domain is designed to bind to the T cell, while the tumor-targeted domain can be engineered to target tumor-associated antigens across both hematologic and solid tumor malignancies.<sup>4</sup>

This approach is being studied across a wide range of settings:<sup>4,6</sup>

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

### BiTE® molecules under clinical investigation include the following targets:<sup>4,9</sup>



### BiTE® molecules are designed to bring T-cell innovation to more patients

- Designed to engage T cells to target tumor-associated antigens<sup>4</sup>
- Being investigated across a broad range of hematologic and solid tumor malignancies<sup>4</sup>
- Designed to lead to off-the-shelf therapies without the need for ex vivo manipulation of patients' cells<sup>4,6</sup>
- Investigated for use as monotherapies and in combination with other treatments<sup>10</sup>

The BiTE® immuno-oncology platform aims to make innovative T-cell therapies available to more healthcare providers and their patients<sup>4,6</sup>



## THE BiTE® PLATFORM IS BEING INVESTIGATED ACROSS A DIVERSE SET OF TUMOR TYPES

The BiTE® immuno-oncology platform has been studied in thousands of patients, many of whom have been followed for up to 5 years.<sup>11</sup>

**Amgen is committed to developing innovative medicines that address important unmet medical needs**

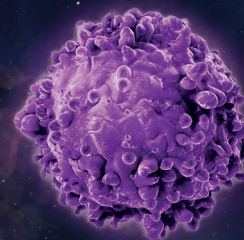
Amgen is a pioneer in immuno-oncology and developed the first approved BiTE® molecule. The BiTE® immuno-oncology platform continues to be investigated across multiple different hematologic and solid tumor malignancies.<sup>10</sup>

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:

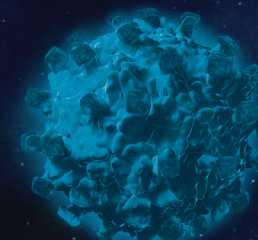
- Leveraging innovative trial designs<sup>12,13</sup>
- Investigating clinically relevant endpoints and outcomes such as MRD and long-term survival<sup>14,15</sup>
- Generating BiTE® molecules with varying levels of T-cell affinity while maintaining antitumor potency<sup>10</sup>

**BiTE® therapies are being investigated for use as monotherapies and in combination with other treatments<sup>10</sup>**

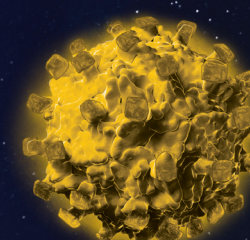
## Cancers being targeted by the BiTE® platform<sup>9,16</sup>



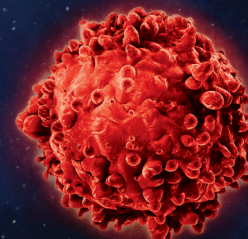
Multiple Myeloma



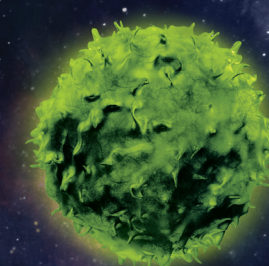
ALL



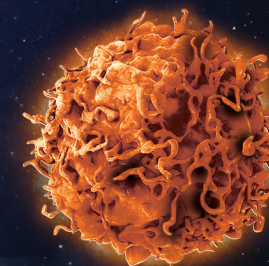
AML



SCLC



Prostate Cancer



Gastric or Gastroesophageal  
Junction Cancer

ALL, acute lymphoblastic leukemia; AML, acute myeloid leukemia;  
SCLC, small cell lung cancer.

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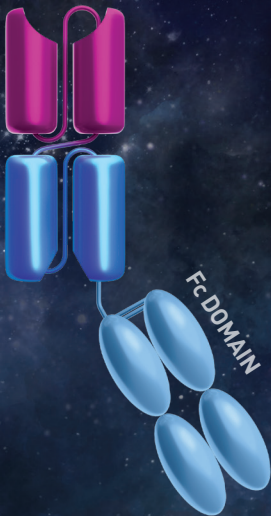
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AMGEN IS  
COMMITTED TO  
BRINGING T-CELL  
INNOVATION TO  
PATIENTS

Features of the BiTE® platform

Canonical BiTE® molecules are designed to be relatively small recombinant proteins that are cleared through the kidney, with a typical serum half-life of a few hours.<sup>10</sup> Currently, Amgen is investigating BiTE® molecules with additional features, including a HLE BiTE® molecule containing a



Fc domain.<sup>17</sup> Adding an Fc portion to the BiTE® molecule is designed to extend the amount of time before it is eliminated from the body.<sup>18</sup>

The growing BiTE® immuno-oncology pipeline<sup>9</sup>

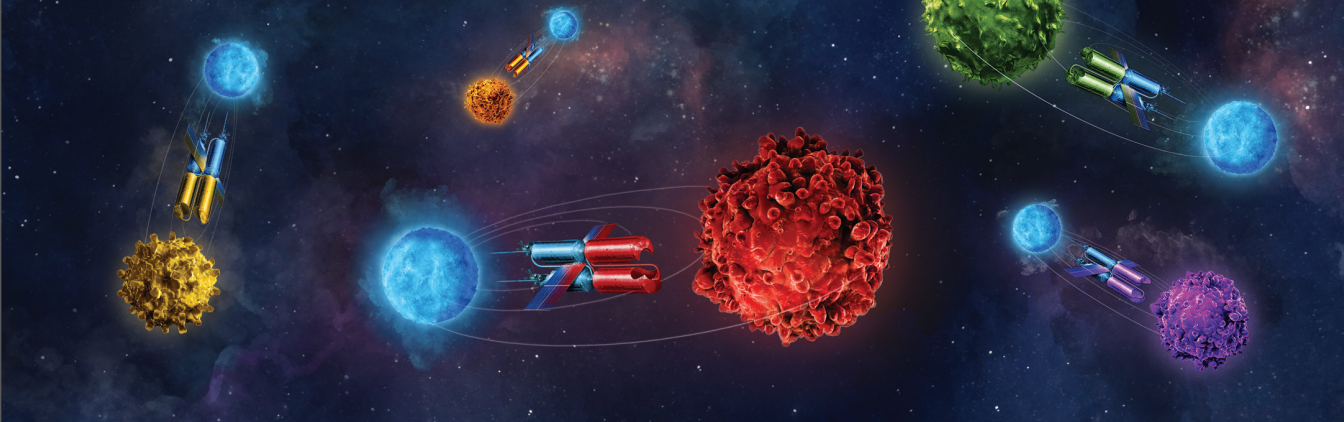
Investigational BiTE® molecule	Tumor-associated antigen target	Cancer type
Acapatomab (AMG 160)*	PSMA	Prostate cancer, NSCLC
AMG 340	PSMA	Prostate cancer
AMG 199*	MUC17	Gastric, gastroesophageal junction, colorectal, and pancreatic cancers
AMG 427*	FLT3	AML
Pavurutamab (AMG 701)*	BCMA	Multiple myeloma
Tarlatamab (AMG 757)*	DLL3	SCLC, neuroendocrine prostate cancer

**References:** **1.** Einsele H, et al. *Cancer*. 2020;126:3192-3201. **2.** Goebeler ME, et al. *Nat Rev Clin Oncol*. 2020;17:418-434. **3.** Delea TE, et al. *Pharmacoeconomics*. 2019;37:1177-1193. **4.** Baeuerle PA, et al. *Curr Opin Mol Ther*. 2009;11:22-30. **5.** Ferrone S, et al. *Surg Oncol Clin N Am*. 2007;16:755-774. **6.** Frankel SR, et al. *Curr Opin Chem Biol*. 2013;17:385-392. **7.** Nagorsen D, et al. *Exp Cell Res*. 2011;317:1255-1260. **8.** Baeuerle PA, et al. *Cancer Res*. 2009;69:4941-4944. **9.** Amgen Pipeline. <https://www.amgenpipeline.com/-/media/Themes/Amgen/amgenpipeline-com/amgenpipeline-com/PDF/amgen-pipeline-chart.pdf>. Accessed April 11, 2022. **10.** Yuraszeck T, et al. *Clin Pharmacol Ther*. 2017;101:634-645. **11.** Data on file, Amgen; 2019. **12.** Berry DA. *Clin Pharmacol Ther*. 2016;99:82-91. **13.** Amgen Science. <https://www.amgenscience.com/features/a-strategy-for-making-clinical-trials-more-successful/>. Accessed April 11, 2022. **14.** Gökbuget N, et al. *Blood*. 2018;131:1522-1531. **15.** Hoelzer D. *Haematologica*. 2015;100:855-858. **16.** ClinicalTrials.gov. <https://www.clinicaltrials.gov/ct2/show/NCT04117958>. Accessed April 11, 2022. **17.** Raum T, et al. US Patent 2017/0218077 A1. August 3, 2017. **18.** Weidle UH, et al. *Cancer Genomics Proteomics*. 2013;10:1-18.

The BiTE® platform has the potential to bring hope to patients, including those with rare and aggressive diseases

<sup>10</sup> \*HLE BiTE® Platform.  
Fc, fragment crystallizable; HLE, half-life extended; NSCLC, non-small cell lung cancer





## **BiTE: THE ENGAGER™**

### **The BiTE® universe is expanding**

The BiTE® immuno-oncology platform:

- Engages patients' own T cells to target tumor-associated antigens, with the goal of activating the cytotoxic potential of T cells to fight cancer<sup>4</sup>
- Has already been investigated in thousands of patients and continues to be investigated across various hematologic and solid tumor malignancies<sup>9,11</sup>
- Pioneered by Amgen, which continues to accelerate the investigation of BiTE® technology with the goal of enhancing patient experience and therapeutic potential<sup>8,10</sup>

**Learn more at [amgenoncology.com/bite-platform.html](https://amgenoncology.com/bite-platform.html)**

