



## **BiTE<sup>®</sup> (Bispecific T Cell Engager) Fact Sheet**

### **What is BiTE<sup>®</sup>?**

Bispecific T cell engagers (BiTE<sup>®</sup>) are a type of immunotherapy developed to fight cancer by helping the body's immune system to detect and target malignant cells.<sup>1</sup> They represent an innovative immunotherapy approach that can help the body's immune system fight cancer cells.<sup>1,2</sup>

### **The Immune System & Cancer**

T cells are special white blood cells that play a central role in the body's immune system.<sup>3</sup> T cells are one of the body's main defenses and are designed to help the immune system combat foreign invaders, such as viruses, helping to prevent and fight illness.<sup>3</sup> They also have the ability to inject toxins into cancer cells, triggering cell death.<sup>3</sup>

Though T cells have the ability to fight cancer cells, the challenge is getting them to recognise these invaders.<sup>4</sup> Cancer cells may evade the immune system by using a variety of mechanisms, making them hard to detect.<sup>4</sup> Cancer cells develop inside the body and are able to trick the immune system into thinking they are normal healthy cells, helping tumours evade attack and destruction from the immune system.<sup>4</sup>

### **The Role of BiTE Antibodies**

BiTE antibodies help T cells engage and target cancer cells.<sup>1,2</sup> The goal is to overcome the cancer cells' ability to hide from the body's immune system.<sup>2</sup> The modified antibodies work by bridging two targets at the same time (one target is a receptor on T cells, and the other is on a target cell).<sup>1</sup> BiTE antibodies are then thought to bring T cells in close proximity to cancer cells, allowing T cells to recognise and fight the cancer cells.<sup>1,2</sup> Once the T cells use the bridge created by the BiTE antibodies, they are close enough to fight the cancer cells.<sup>1</sup>

Amgen is continuing to investigate the ability of BiTE antibodies to help T cells recognise and continue to fight cancer cells.

#### **Fast Facts**

- *Cancer cells develop inside the body and are able to trick the immune system into thinking they are normal healthy cells, helping tumours evade attack and destruction from the immune system.<sup>4</sup>*
- *BiTE antibodies were developed to help endogenous T cells engage and target cancer cells.<sup>1,2</sup>*
- *BiTE antibodies may be engineered to target a range of different tumours.<sup>2</sup>*

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## Additional Information

For further information, visit [www.amgen.com](http://www.amgen.com).

## Forward-Looking Statements

This fact sheet contains forward-looking statements that are based on the current expectations and beliefs of Amgen Inc. and its subsidiaries (Amgen or us) and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission (SEC) reports filed by Amgen Inc., including Amgen Inc.'s most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and Form 8-K. Please refer to Amgen Inc.'s most recent Forms 10-K, 10-Q and 8-K for additional information on the uncertainties and risk factors related to our business. Unless otherwise noted, Amgen is providing this information as of Nov. 20, 2015, and expressly disclaims any duty to update information contained in this news release.

No forward-looking statement can be guaranteed and actual results may differ materially from those we project. Discovery or identification of new product candidates or development of new indications for existing products cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate or development of a new indication for an existing product will be successful and become a commercial product. Further, preclinical results do not guarantee safe and effective performance of product candidates in humans. The complexity of the human body cannot be perfectly, or sometimes, even adequately modeled by computer or cell culture systems or animal models. The length of time that it takes for us and our partners to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and we expect similar variability in the future. We develop product candidates internally and through licensing collaborations, partnerships and joint ventures. Product candidates that are derived from relationships may be subject to disputes between the parties or may prove to be not as effective or as safe as we may have believed at the time of entering into such relationship. Also, we or others could identify safety, side effects or manufacturing problems with our products after they are on the market. Our business may be impacted by government investigations, litigation and product liability claims. If we fail to meet the compliance obligations in the corporate integrity agreement between us and the U.S. government, we could become subject to significant sanctions. We depend on third parties for a significant portion of our manufacturing capacity for the supply of certain of our current and future products and limits on supply may constrain sales of certain of our current products and product candidate development.

In addition, sales of our products (including products of our wholly-owned subsidiaries) are affected by the reimbursement policies imposed by third-party payers, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and healthcare cost containment as well as U.S. legislation affecting pharmaceutical pricing and reimbursement. Government and others' regulations and reimbursement policies may affect the development, usage and pricing of our products. In addition, we compete with other companies with respect to some of our marketed products as well as for the discovery and development of new products. We believe that some of our newer products, product candidates or new indications for existing products, may face competition when and as they are approved and marketed. Our products may compete against products that have lower prices, established reimbursement, superior performance, are easier to administer, or that are otherwise competitive with our products. In addition, while Amgen and its partners routinely obtain patents for their products and technology, the protection of our products offered by patents and patent applications may be challenged, invalidated or circumvented by our or our partners' competitors and there can be no guarantee of our or our partners' ability to obtain or maintain patent protection for our products or product candidates. We cannot guarantee that we will be able to produce commercially successful products or maintain the commercial success of our existing products. Our stock price may be affected by actual or perceived market opportunity, competitive position, and success or failure of our products or product candidates. Further, the discovery of significant problems with a product similar to one of our products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on our business and results of operations. Our efforts to integrate the operations of companies we have acquired may not be successful. We may experience difficulties, delays or unexpected costs and not achieve anticipated benefits and savings from our ongoing restructuring plan. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or their ability to pay a dividend or repurchase our common stock.

The scientific information discussed in this factsheet related to our product candidates is limited to the European Union. Such product candidates are not approved by the European Medicines Agency, and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates.



## References

1. Amgen Oncology. "BiTE® Immunotherapy: Bispecific T Cell Engager Antibodies: Designed to Bridge T Cells and Cancer Cells." Available at: [www.amgenoncology.com/#!/our-science/BiTE-immunotherapy/](http://www.amgenoncology.com/#!/our-science/BiTE-immunotherapy/). Accessed on October 02, 2015.
2. Baeuerle PA, Kufer P, Bargou R. Bispecific T Cell Engaging Antibodies for Cancer Therapy. *Cancer Res* 2009;69:4941-4944
3. National Cancer Institute "Biological Therapies for Cancer", June 12, 2013. <http://www.cancer.gov/cancertopics/factsheet/Therapy/biological>. Accessed October 02, 2015.
4. Rabinovich GA, Gabrilovich D, Sotomayor EM. Immunosuppressive strategies that are mediated by tumor cells. *Annu Rev Immunol.* 2007; 25: 267-296.

