



Amgen To Acquire Otezla® For \$13.4 Billion In Cash, Or Approximately \$11.2 Billion Net Of Anticipated Future Cash Tax Benefits

August 26, 2019

Innovative Therapy Will Strengthen Amgen's Inflammation Portfolio for Patients Around the World Acquisition Expected to Accelerate Growth and Enhance Value for Amgen Shareholders Amgen to Host Call With Investors at 5 a.m. PT (8 a.m. ET)

THOUSAND OAKS, Calif., Aug. 26, 2019 /PRNewswire/ -- Amgen (NASDAQ: AMGN) announced today that it has entered into an agreement with Celgene Corporation (NASDAQ: CELG) in connection with its previously announced merger with Bristol-Myers Squibb Company (NYSE: BMY) to acquire worldwide rights to Otezla® (apremilast), the only oral, non-biologic treatment for psoriasis and psoriatic arthritis, and certain related assets and liabilities, for \$13.4 billion in cash, or approximately \$11.2 billion, net of the present value of \$2.2 billion in anticipated future cash tax benefits. Amgen believes that the acquisition of Otezla offers many benefits including:

- **A strong strategic fit with Amgen's long-standing expertise in psoriasis and inflammation**
- **A differentiated, oral therapy complementary to Amgen's existing inflammation franchise of innovative biologics and biosimilar products**
- **At least low double-digit Otezla sales growth, on average, over the next five years**
- **Acceleration of Amgen's near- and long-term revenue growth**
- **Immediate non-GAAP EPS accretion**
- **Intellectual Property exclusivity through at least 2028 in the U.S.**
- **Worldwide rights which fit well with Amgen's international presence and global expansion objectives**
- **Support of increased R&D investment in 2020 to advance Amgen's innovative pipeline of first-in-class molecules**
- **No interruption in deployment of Amgen's capital allocation priorities**

"The acquisition of Otezla offers a unique opportunity for Amgen to provide patients an innovative oral therapy for psoriasis and psoriatic arthritis that fits squarely within our portfolio and complements our Enbrel® and AMGEVITA® brands," said Robert A. Bradway, chairman and chief executive officer at Amgen. "We will take advantage of our 20 years of experience in inflammatory disease to realize the full global potential of Otezla as an affordable option for patients with these serious, chronic inflammatory conditions."

Otezla is the leading treatment in the post-topical, pre-biologic segment in its approved indications. Otezla is currently approved for three indications in the U.S.—the treatment of patients with moderate-to-severe plaque psoriasis who are candidates for phototherapy or systemic therapy; adult patients with active psoriatic arthritis; and adult patients with oral ulcers associated with Behçet's Disease. Otezla is approved in more than 50 markets outside the U.S., including the European Union and Japan, and has patent exclusivity through at least 2028 in the U.S.

Sales of Otezla in 2018 were \$1.6 billion driven by strong volume growth. Amgen has stated previously that it will focus on medicines that can deliver sustained, long-term volume driven growth and the Company believes there is a significant opportunity to grow Otezla through global expansion and new indications, with expectations for Otezla to realize at least low double-digit sales growth, on average, over the next five years.

Strategic Benefits of the Transaction

This transaction will advance Amgen's strategy in several ways:

- **Bringing Innovative Medicines to Patients** -- The number of patients suffering from chronic inflammatory diseases is growing worldwide. Amgen is already a leader in this very large therapeutic category with Enbrel® (etanercept), a biologic medicine marketed by Amgen in the U.S. and Canada to treat several chronic inflammatory diseases, including moderate-to-severe rheumatoid arthritis, moderate-to-severe plaque psoriasis, and psoriatic arthritis (PsA). ENBREL and Otezla are complementary. ENBREL is most frequently prescribed to treat moderate-to-severe rheumatoid arthritis, while Otezla is positioned as a therapy of first-choice in patients with moderate-to-severe psoriasis who are not satisfied with topical therapies given its differentiated mechanism of action and established efficacy and safety profile. In PsA, Otezla is positioned for use in patients early in their disease and/or with moderate joint involvement. Additionally, studies are currently underway exploring potential new indications for Otezla, including mild-to-moderate psoriasis.
- **Expanding Geographic Reach** -- Otezla is approved in 54 countries, including major markets such as France, Germany and Japan. Amgen is well positioned to continue driving Otezla international sales growth.
- **Investing for Long-Term Growth with Uninterrupted Capital Allocation Plans** -- The transaction is expected to contribute to Amgen's near- and long-term revenue growth rate and will be immediately accretive from close to non-GAAP earnings per share growth, with acceleration thereafter. Amgen will finance the transaction with current balance sheet cash and expects to retain its investment grade credit rating. Additionally, Amgen's capital allocation priorities will remain unchanged as we invest to grow our business through internal investment and business development, maintain an optimal capital structure to minimize our Weighted Average Cost of Capital and continue to provide capital returns to shareholders through a growing dividend and continued share repurchases.

The closing of the acquisition is contingent on Bristol-Myers Squibb entering into a consent decree with the Federal Trade Commission in connection

with the pending Celgene merger, the closing of the pending merger with Celgene and the satisfaction of other customary closing conditions. The transaction is expected to close by the end of 2019.

"Otezla represents an exciting opportunity to strengthen Amgen's presence in inflammation and continue Amgen's geographic expansion," said Bradway. "We are excited about the opportunity that Otezla represents for Amgen, for our shareholders, and for patients worldwide, and we look forward to welcoming those staff members who support Otezla to the Amgen family."

Dyal Co. LLC is acting as the lead financial advisor to Amgen. Goldman Sachs & Co. is serving as a financial advisor and Sullivan & Cromwell LLP is serving as legal advisor to Amgen.

Amgen To Webcast Investor Call on Otezla Acquisition

Amgen will host a webcast investor call on Monday, Aug. 26 at 5 a.m. PT (8 a.m. ET). Participating in the call from Amgen will be Robert A. Bradway, chairman and chief executive officer, and other members of Amgen's senior management team.

Live audio of the investor meeting will be broadcast over the internet simultaneously and will be available to members of the news media, investors and the general public.

The webcast, as with other selected presentations regarding developments in Amgen's business given at certain investor and medical conferences, can be accessed on Amgen's website, www.amgen.com, under Investors. Information regarding presentation times, webcast availability and webcast links are noted on Amgen's Investor Relations Events Calendar. The webcast will be archived and available for replay for at least 90 days after the event.

Non-GAAP Financial Measures

In this press release we reference non-GAAP EPS. We use non-GAAP EPS in connection with our own budgeting and financial planning internally to evaluate the performance of our business. Non-GAAP EPS is derived by excluding certain amounts, expenses or income, from EPS determined in accordance with GAAP. The determination of the amounts that are excluded from non-GAAP EPS is a matter of management judgment and depend upon, among other factors, the nature of the underlying expense or income amounts recognized in a given period. Historically, management has excluded the following items from non-GAAP EPS, and such items may also be excluded in future periods and could be significant: expenses related to acquisition of businesses, including amortization and/or impairment of acquired intangible assets, including in-process research and development, inventory step-ups, adjustments to contingent consideration, integration costs, severance and retention costs and transaction costs; charges associated with restructuring or cost saving initiatives, including but not limited to asset impairments, accelerated depreciation, severance costs and lease abandonment charges; legal settlements or awards; non-routine settlements with tax authorities; and the impact of the adoption of the U.S. corporate tax reform. Non-GAAP financial measures are in addition to, not a substitute for, or superior to, measures of financial performance prepared in accordance with GAAP.

About Amgen

Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer since 1980, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

For more information, visit www.amgen.com and follow us on www.twitter.com/amgen.

About OTEZLA® (apremilast)

OTEZLA® (apremilast) 30 mg tablets is an oral small-molecule inhibitor of phosphodiesterase 4 (PDE4) specific for cyclic adenosine monophosphate (cAMP). PDE4 inhibition results in increased intracellular cAMP levels, which is thought to indirectly modulate the production of inflammatory mediators. The specific mechanism(s) by which OTEZLA exerts its therapeutic action in patients is not well defined.

U.S. PRESCRIBING INFORMATION

INDICATIONS

Otezla® (apremilast) is indicated for the treatment of patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

Otezla is indicated for the treatment of adult patients with active psoriatic arthritis.

Otezla is indicated for the treatment of adult patients with oral ulcers associated with Behçet's Disease.

IMPORTANT SAFETY INFORMATION

Contraindications

Otezla® (apremilast) is contraindicated in patients with a known hypersensitivity to apremilast or to any of the excipients in the formulation.

Warnings and Precautions

Diarrhea, Nausea and Vomiting: Cases of severe diarrhea, nausea, and vomiting were associated with the use of Otezla. Most events occurred within the first few weeks of treatment. In some cases patients were hospitalized. Patients 65 years of age or older and patients taking medications that can lead to volume depletion or hypotension may be at a higher risk of complications from severe diarrhea, nausea, or vomiting. Monitor patients who are more susceptible to complications of diarrhea or vomiting; advise patients to contact their healthcare provider. Consider Otezla dose reduction or suspension if patients develop severe diarrhea, nausea, or vomiting.

Depression: Carefully weigh the risks and benefits of treatment with Otezla for patients with a history of depression and/or suicidal thoughts/behavior, or in patients who develop such symptoms while on Otezla. Patients, caregivers, and families should be advised of the need to be alert for the emergence or worsening of depression, suicidal thoughts or other mood changes, and they should contact their healthcare provider if such changes occur.

Psoriasis: Treatment with Otezla is associated with an increase in depression. During clinical trials, 1.3% (12/920) of patients reported depression compared to 0.4% (2/506) on placebo. Depression was reported as serious in 0.1% (1/1308) of patients exposed to Otezla, compared to none in placebo-treated patients (0/506). Suicidal behavior was observed in 0.1% (1/1308) of patients on Otezla, compared to 0.2% (1/506) on placebo. One patient treated with Otezla attempted suicide; one patient on placebo committed suicide.

Psoriatic Arthritis: Treatment with Otezla is associated with an increase in depression. During clinical trials, 1.0% (10/998) reported depression or depressed mood compared to 0.8% (4/495) treated with placebo. Suicidal ideation and behavior was observed in 0.2% (3/1441) of patients on Otezla, compared to none in placebo-treated patients. Depression was reported as serious in 0.2% (3/1441) of patients exposed to Otezla, compared to none in placebo-treated patients (0/495). Two patients who received placebo committed suicide compared to none on Otezla.

Behçet's Disease: Treatment with Otezla is associated with an increase in depression. During the clinical trial, 1% (1/104) reported depression or depressed mood compared to 1% (1/103) treated with placebo. No instances of suicidal ideation or behavior were reported in patients treated with Otezla or treated with placebo.

Weight Decrease: Monitor body weight regularly; evaluate unexplained or clinically significant weight loss, and consider discontinuation of Otezla.

Psoriasis: Body weight loss of 5-10% occurred in 12% (96/784) of patients treated with Otezla and in 5% (19/382) of patients treated with placebo. Body weight loss of \geq 10% occurred in 2% (16/784) of patients treated with Otezla compared to 1% (3/382) of patients treated with placebo.

Psoriatic Arthritis: Body weight loss of 5-10% was reported in 10% (49/497) of patients taking Otezla and in 3.3% (16/495) of patients taking placebo.

Behçet's Disease: Body weight loss of $>$ 5% was reported in 4.9% (5/103) of patients taking Otezla and in 3.9% (4/102) of patients taking placebo.

Drug Interactions: Apremilast exposure was decreased when Otezla was co-administered with rifampin, a strong CYP450 enzyme inducer; loss of Otezla efficacy may occur. Concomitant use of Otezla with CYP450 enzyme inducers (e.g., rifampin, phenobarbital, carbamazepine, phenytoin) is not recommended.

Adverse Reactions

Psoriasis: Adverse reactions reported in \geq 5% of patients were (Otezla%, placebo%): diarrhea (17, 6), nausea (17, 7), upper respiratory tract infection (9, 6), tension headache (8, 4), and headache (6, 4).

Psoriatic Arthritis: Adverse reactions reported in at least 2% of patients taking Otezla, that occurred at a frequency at least 1% higher than that observed in patients taking placebo, for up to 16 weeks (after the initial 5-day titration), were (Otezla%, placebo%): diarrhea (7.7, 1.6); nausea (8.9, 3.1); headache (5.9, 2.2); upper respiratory tract infection (3.9, 1.8); vomiting (3.2, 0.4); nasopharyngitis (2.6, 1.6); upper abdominal pain (2.0, 0.2).

Behçet's Disease: Adverse reactions reported in at least \geq 5% of patients taking Otezla, that occurred at a frequency at least 1% higher than that observed in patients taking placebo, for up to 12 weeks were (Otezla%, placebo%): diarrhea (41.3, 20.4); nausea (19.2, 10.7); headache (14.4, 10.7); upper respiratory tract infection (11.5, 4.9); upper abdominal pain (8.7, 1.9), vomiting (8.7, 1.9); back pain (7.7, 5.8); viral upper respiratory tract infection (6.7, 4.9); arthralgia (5.8, 2.9).

Use in Specific Populations

Pregnancy: Otezla has not been studied in pregnant women. Advise pregnant women of the potential risk of fetal loss. Consider pregnancy planning and prevention for females of reproductive potential. There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Otezla during pregnancy. Information about the registry can be obtained by calling 1-877-311-8972 or visiting <https://mothertobaby.org/ongoing-study/otezla/>.

Lactation: There are no data on the presence of apremilast or its metabolites in human milk, the effects of apremilast on the breastfed infant, or the effects of the drug on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Otezla and any potential adverse effects on the breastfed child from Otezla or from the underlying maternal condition.

Renal Impairment: Otezla dosage should be reduced in patients with severe renal impairment (creatinine clearance less than 30 mL/min); for details, see Dosage and Administration, Section 2, in the Full Prescribing Information.

Please [click here](#) for Full Prescribing Information.

Otezla[®] is a registered trademark of Celgene Corporation.

Please see [Full Prescribing Information](#) for ENBREL.

Amgen Forward-Looking Statements

This news release contains forward-looking statements that are based on the current expectations and beliefs of Amgen. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including any statements on the outcome, benefits and synergies of the transaction described in this press release, including anticipated Otezla sales growth and the timing of non-GAAP EPS accretion, as well as 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 reports filed by Amgen, including our most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and current reports on Form 8-K. Unless otherwise noted, Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information,

future events or otherwise.

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 to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and we expect similar variability in the future. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints we have selected. 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, including our devices, after they are on the market.

Our results may be affected by our ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments involving current and future products, sales growth of recently launched products, competition from other products including biosimilars, difficulties or delays in manufacturing our products and global economic conditions. In addition, sales of our products are affected by pricing pressure, political and public scrutiny and 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. Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. Our business may be impacted by government investigations, litigation and product liability claims. In addition, our business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. Further, while we routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors, or we may fail to prevail in present and future intellectual property litigation. We perform a substantial amount of our commercial manufacturing activities at a few key facilities, including in Puerto Rico, and also depend on third parties for a portion of our manufacturing activities, and limits on supply may constrain sales of certain of our current products and product candidate development. In addition, we compete with other companies with respect to many of our marketed products as well as for the discovery and development of new products. Further, some raw materials, medical devices and component parts for our products are supplied by sole third-party suppliers. Certain of our distributors, customers and payers have substantial purchasing leverage in their dealings with us. 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 acquire other companies or products and to integrate the operations of companies we have acquired may not be successful. A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of our systems and our data. Our stock price is volatile and may be affected by a number of events. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or our ability to pay a dividend or repurchase our common stock. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

CONTACT: Amgen, Thousand Oaks
Trish Hawkins, 805-447-5631 (media)
Jessica Akopyan, 805-447-0974 (media)
Arvind Sood, 805-447-1060 (investors)



[View original content to download multimedia: http://www.prnewswire.com/news-releases/amgen-to-acquire-otezla-for-13-4-billion-in-cash-or-approximately-11-2-billion-net-of-anticipated-future-cash-tax-benefits-300906718.html](http://www.prnewswire.com/news-releases/amgen-to-acquire-otezla-for-13-4-billion-in-cash-or-approximately-11-2-billion-net-of-anticipated-future-cash-tax-benefits-300906718.html)

SOURCE Amgen