Amgen Completes Acquisition Of Otezla® (apremilast)

November 21, 2019

Differentiated Therapy Strengthens Amgen's Long-Standing Expertise in Inflammation

THOUSAND OAKS, Calif., Nov. 21, 2019 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced the successful completion of its acquisition of worldwide rights to Otezla® (apremilast), the only oral, non-biologic treatment for moderate-to-severe plaque psoriasis and psoriatic arthritis. Otezla was acquired from Celgene Corporation (NASDAQ:CELG) in connection with its previously announced merger with Bristol-Myers Squibb Company (NYSE:BMY), which was completed on Nov. 20.

Otezla is an important treatment in the post-topical, pre-biologic segment in its approved indications in the U.S., including 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.

"As the prevalence of chronic inflammatory diseases increases worldwide, Otezla represents a unique opportunity to further Amgen's mission of bringing innovative medicines to patients, while building on our long-standing expertise in inflammation," said Robert A. Bradway, chairman and chief executive officer at Amgen. "We look forward to working with the dedicated professionals joining us from Celgene to help realize the global potential of Otezla as an important option for patients."

The closing of the Otezla acquisition offers Amgen many potential benefits including:

- A strong strategic fit with Amgen's long-standing expertise in moderate-to-severe plaque psoriasis and active psoriatic arthritis.
- A differentiated, oral therapy complementary to Amgen's existing inflammation franchise of innovative biologics and biosimilar products.
- At least low double-digit percentage Otezla sales growth, on average, anticipated over the next five years.
- Expected acceleration of Amgen's near- and long-term revenue growth.
- Worldwide rights which fit well with Amgen's international presence and global expansion objectives.

"This move also provides Amgen with an important strategic product offering new opportunities for growth and serving patients," Bradway said.

Terms of the Acquisition and 2019 Guidance
Otezla, along with certain related assets and liabilities, was acquired 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.

With the closing of the Otezla acquisition, the Company is updating its overall 2019 guidance. For the full year 2019, the Company now expects total revenues in the range of $23.1 billion to $23.3 billion. Previously, the Company expected total revenues in the range of $22.8 billion to $23.0 billion. On a GAAP basis, the Company now expects earnings per share (EPS) in the range of $12.50 to $12.75. Previously, the Company expected GAAP EPS in the range of $12.50 to $12.80. The updated GAAP guidance reflects charges between close and the end of the year related to the intangibles and inventory acquired. On a non-GAAP basis, the Company now expects EPS in the range of $14.50 to $14.70. Previously, the Company expected non-GAAP EPS in the range of $14.20 to $14.45.

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. 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.

U.S. 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 ≥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 ≥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 ≥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 Otezla® Full Prescribing Information.

Otezla® is a registered trademark.

Non-GAAP Financial Measures
In this news release, management has presented earnings per share guidance for 2019, in accordance with U.S. Generally Accepted Accounting Principles (GAAP) and on a non-GAAP basis. This non-GAAP financial measure is computed by excluding certain items related to acquisitions, restructuring and certain other items from the related GAAP financial measures. A reconciliation for this non-GAAP financial measure to the most directly comparable GAAP financial measure is included in the news release.

The Company believes that its presentation of non-GAAP financial measures provides useful supplementary information to and facilitates additional

analysis by investors. The Company uses certain non-GAAP financial measures to enhance an investor's overall understanding of the financial performance and prospects for the future of the Company's ongoing business activities by facilitating comparisons of results of ongoing business operations among current, past and future periods.

The Company uses the non-GAAP financial measures set forth in the news release in connection with its own budgeting and financial planning internally to evaluate the performance of the business, including to allocate resources and to evaluate results relative to incentive compensation targets. The 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.

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 collaboration with any other company, 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. The acquisition of Otezla may result in unanticipated costs, delays or other operational or financial problems related to integrating the Otezla business with our company, which may divert our management's attention from other business issues and opportunities and restrict the full realization of the anticipated benefits of the transaction within the expected timeframe or at all. Further, failures or difficulties in integrating or retaining new personnel or in integrating the operations of the Otezla business, products or assets we acquire (including related technology, commercial operations, compliance programs, manufacturing, distribution and general business operations and procedures, and failures or difficulties relating to any transition services agreements, supply agreements, toll manufacturing agreements, and intellectual property licensing and transfer agreements) may affect our ability to realize the benefits of the transaction and grow our business, and may result in us incurring asset impairment or restructuring charges. These and/or other challenges may arise in connection with our acquisition of Otezla or other acquisition activities, which could have a material adverse effect on our business, results of operations and stock price.

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 collaborate with or acquire other companies or products, and to integrate the operations of companies or in support of products 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.

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Reconciliation of GAAP EPS Guidance to Non-GAAP EPS Guidance for the Year Ending December 31, 2019 (Unaudited)

GAAP diluted EPS guidance	$ 12.50	-	$ 12.75
Known adjustment to arrive at non-GAAP*:			
Acquisition-related expenses (a)	1.84	-	1.89
Cost savings initiatives		0.05	
Tax adjustments		0.06	
Non-GAAP diluted EPS guidance	$ 14.50	-	$ 14.70

***** The known adjustments are presented net of their related tax impact, which amount to approximately $0.41 per share.

(a) The adjustments relate primarily to non-cash amortization of intangible assets acquired in business combinations. Our GAAP diluted EPS guidance does not include the effect of GAAP adjustments triggered by events that may occur subsequent to this press release such as acquisitions, collaborations, asset impairments, litigation and changes in the fair value of our contingent consideration.

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