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FDA Approves YERVOY™ (ipilimumab) for the Treatment of Patients with Newly Diagnosed or Previously-Treated Unresectable or Metastatic Melanoma, the Deadliest Form of Skin Cancer

- First and Only Approved Therapy for Unresectable or Metastatic Melanoma to Demonstrate a Significant Improvement in Overall Survival
- First FDA-Approved Therapy for Unresectable or Metastatic Melanoma in More than a Decade
- First Approved Cancer Immunotherapy for Melanoma to Target CTLA-4 and First FDA-Approved Compound in the Company's Robust Immuno-Oncology Pipeline
- Risk Evaluation and Mitigation Strategy Developed with FDA to Support the Safe and Appropriate Use of YERVOY and Help Inform Patients and Providers About Important Safety Risks

PRINCETON, N.J.-(BUSINESS WIRE)--[Bristol-Myers Squibb Company](#) (NYSE: BMY) today announced that the U.S. Food and Drug Administration (FDA) approved YERVOY™ (ipilimumab) 3 mg/kg for the treatment of patients with unresectable (inoperable) or metastatic melanoma. YERVOY is the first and only therapy for unresectable or metastatic melanoma to demonstrate a significant improvement in overall survival based on results from a pivotal randomized, double-blind Phase 3 study. Median overall survival was 10 months (95% CI: 8.0-13.8) for YERVOY, 6 months (95% CI: 5.5-8.7) for gp100 and 10 months (95% CI: 8.5-11.5) for YERVOY + gp100, with p-values of 0.0026 (not adjusted for multiple comparisons) for YERVOY and 0.0004 for YERVOY + gp100 vs. gp100, respectively. As published in the *New England Journal of Medicine*, the Kaplan-Meier estimated survival rate at 1 year was 46% (95% CI: 37.0, 54.1) in the YERVOY arm vs. 25% (95% CI: 18.1, 32.9) in the gp100 arm. The estimated survival rate at 2 years was 24% (95% CI: 16.0, 31.5) in the YERVOY arm vs. 14%² (95% CI: 8.0, 20.0) in the gp100 arm. YERVOY, which is a recombinant, human monoclonal antibody, is the first FDA-approved cancer immunotherapy that blocks the cytotoxic T-lymphocyte antigen-4 (CTLA-4).

The full Prescribing Information for YERVOY includes a boxed warning for immune-mediated adverse reactions. YERVOY can result in severe and fatal immune-mediated adverse reactions due to T-cell activation and proliferation. These immune-mediated reactions may involve any organ system; however, the most common severe immune-mediated adverse reactions are enterocolitis, hepatitis, dermatitis (including toxic epidermal necrolysis), neuropathy, and endocrinopathy. The majority of these immune-mediated reactions initially manifested during treatment; however, a minority occurred weeks to months after discontinuation of YERVOY (ipilimumab). Permanently discontinue YERVOY and initiate systemic high-dose corticosteroid therapy for severe immune-mediated reactions. Patients should be assessed for signs and symptoms of enterocolitis, dermatitis, neuropathy and endocrinopathy and clinical chemistries should be evaluated, including liver function tests and thyroid function tests, at baseline and before each dose. Please see complete Important Safety Information including Boxed WARNING regarding immune-mediated adverse reactions on pages 6-9.

"Metastatic melanoma is one of the most aggressive forms of cancer and despite the rising incidence, no new treatments have been approved in more than a decade," said Lamberto Andreotti, chief executive officer, Bristol-Myers Squibb. "Today's approval of YERVOY is an example of Bristol-Myers Squibb living its mission of developing and delivering innovative medicines that address the unmet needs of patients with serious diseases. It also represents a significant step forward in our commitment to deliver and execute against our differentiated and focused BioPharma strategy."

"For the first time, oncologists have a treatment option for patients with unresectable or metastatic melanoma that has been proven in a randomized Phase 3 clinical trial to significantly extend the lives of patients," said Steven J. O'Day, M.D., Chief of Research and Director of the Melanoma Program at The Angeles Clinic and Research Institute, California, and an investigator of the pivotal trial. "In fact, the Kaplan-Meier curve from this study suggests a prolonged survival benefit for some patients." Median overall survival was 10 months (95% CI: 8.0-13.8) for YERVOY (ipilimumab), 6 months (95% CI: 5.5-8.7) for gp100 and 10 months (95% CI: 8.5-11.5) for YERVOY + gp100, with p-values of 0.0026 (not adjusted for multiple comparisons) for YERVOY and 0.0004 for YERVOY + gp100 vs gp100, respectively.

"The FDA approval of YERVOY is the culmination of more than 14 years of research and development by our dedicated development teams and clinical trial investigators," said Elliott Sigal, M.D., Ph.D., executive vice president, chief scientific officer, and president, Research & Development, Bristol-Myers Squibb. "YERVOY is the first FDA-approved compound from our robust immuno-oncology pipeline, which comprises a variety of other compounds with the potential to harness the patient's immune system to fight cancer." The mechanism of action of ipilimumab's effect in patients with melanoma is indirect, possibly through T-cell mediated anti-tumor immune responses.

Bristol-Myers Squibb has agreed with the FDA to conduct a post-marketing study comparing the safety and efficacy of the 3 mg/kg dose vs. an investigational 10 mg/kg dose in patients with unresectable or metastatic melanoma.

The company expects to begin shipping YERVOY within weeks of today's FDA approval.

Overall Survival and Safety Profile of YERVOY in Patients with Unresectable or Metastatic Melanoma

YERVOY is the first and only therapy to demonstrate a statistically significant overall survival benefit in patients with unresectable or metastatic melanoma. The approval is based on a Phase 3, randomized (3:1:1), double-blind study that included 676 patients with unresectable or metastatic melanoma who were previously treated with one or more of the following: aldesleukin, dacarbazine, temozolomide, fotemustine, or carboplatin.

As published in the *New England Journal of Medicine*, the Kaplan-Meier estimated survival rate at 1 year was 46% (95% CI: 37.0, 54.1) in the YERVOY arm vs. 25% (95% CI: 18.1, 32.9) in the gp100 arm. The estimated survival rate at 2 years was 24% (95% CI: 16.0, 31.5) in the YERVOY arm vs. 14%² (95% CI: 8.0, 20.0) in the gp100 arm. Patients treated with YERVOY had a 34% reduction in the risk of death over the gp100 control arm (HR = 0.66 [95% CI: 0.51-0.87], P=0.0026). Patients treated with YERVOY (ipilimumab) plus gp100 had a 32% reduction in the risk of death over the gp100 control arm (HR = 0.68 [95% CI: 0.55-0.85], P=0.0004). Median overall survival was 10 (95% CI: 8.0-13.8), 10 (95% CI: 8.5-11.5) and 6 (95% CI: 5.5-8.7) months for the YERVOY alone, YERVOY + gp100 arm and gp100 alone arms, respectively.

The best overall response rate (BORR) as assessed by the investigator was 10.9% (95% CI: 6.3, 17.4) in patients treated with YERVOY (ipilimumab) (n=15 of 137), 5.7% (95% CI: 3.7, 8.4) in the YERVOY + gp100 arm (n=23 of 403) and 1.5% (95% CI: 0.2, 5.2) in the gp100 arm (n=2 of 136). BORR is defined as the total number of patients with the best response of a complete response (CR) or a partial response (PR) divided by the total number of patients treated. The median duration of response was 11.5 months in the YERVOY + gp100 arm and has not been reached in the YERVOY or gp100 arm at the time of the analysis because more than half of patients who had a confirmed CR or PR remained free of any relapse.

In patients who received 3 mg/kg YERVOY alone (n=131), severe to fatal immune-mediated adverse reactions were reported and included enterocolitis (7%), endocrinopathy (4%, all of which had hypopituitarism), dermatitis (2%), hepatitis (1%), neuropathy (1%), nephritis (1%), and eosinophilia (1%). In patients who received 3 mg/kg of YERVOY + gp100 (n=380) severe to fatal immune-mediated adverse reactions were reported and included enterocolitis (7%), hepatotoxicity (2%), dermatitis (3%), endocrinopathy (1%), hypopituitarism, 1% adrenal insufficiency), pneumonitis (<1%), meningitis (<1%), pericarditis (<1%). The most common adverse reactions were fatigue (41%), diarrhea (32%), pruritus (31%), rash (29%) and colitis (8%) for the YERVOY alone arm, diarrhea (37%), fatigue (34%), rash (25%), pruritus (21%), and colitis (5%) for the YERVOY + gp100 arm, and fatigue (31%), diarrhea (20%), pruritus (11%), rash (8%), and colitis (2%) for gp100 arm. YERVOY therapy was discontinued for adverse reactions in 10% of patients. Please see complete Important Safety Information including Boxed WARNING regarding immune-mediated adverse reactions on pages 6-9.

Results from this study were previously published in the *New England Journal of Medicine* and presented during a plenary session at the 46th Annual Meeting of the American Society of Clinical Oncology.

YERVOY: Risk Evaluation and Mitigation Strategy

Amgen Exhibit 1008
Amgen v. BMS

"Bristol-Myers Squibb is committed to the safe and appropriate use of our medicines," said Annalisa Jenkins, senior vice president global medical, Bristol-Myers Squibb. "As part of the U.S. approval of YERVOY, we have collaborated with the FDA on the development of a Risk Evaluation and Mitigation Strategy to help inform patients and providers about important safety risks associated with YERVOY."

The YERVOY Risk Evaluation and Mitigation Strategy (REMS) consists of a Communication Plan to inform potential prescribers and supportive healthcare providers about serious adverse reactions associated with YERVOY. To support this communication plan, Bristol-Myers Squibb has put in place a system that will enable the company to deliver these educational materials to the appropriate healthcare professional at the time of product order.

More information and downloadable safety education materials will be available at www.YERVOY.com.

YERVOY Was Studied in a Pivotal Phase 3 Clinical Trial of Patients with Unresectable or Metastatic Melanoma

The approval is based on a Phase 3, double-blind study that randomized 676 patients with unresectable or metastatic melanoma who were previously treated with one or more of the following: aldesleukin, dacarbazine, temozolomide, fotemustine, or carboplatin. Patients were randomized in a 3:1:1 ratio to receive either YERVOY (ipilimumab) (3mg/kg) in combination with the investigational peptide vaccine gp100 (n=403), YERVOY alone (3mg/kg; n=137), or gp100 alone (n=136).

The primary endpoint of the pivotal Phase 3 study was overall survival in the YERVOY plus gp100 arm vs. the gp100 arm. Secondary efficacy endpoints included overall survival in the YERVOY plus gp100 arm vs. the YERVOY arm, overall survival in the YERVOY arm vs. the gp100 arm, BORR at week 24 and duration of response.

Patients received YERVOY (3mg/kg) as an intravenous infusion administered over 90 minutes every 3 weeks for four doses. Assessment of tumor response to YERVOY was conducted at weeks 12 and 24, and every 3 months thereafter. Patients with evidence of objective tumor response at 12 or 24 weeks had assessment for confirmation of durability of response at 16 or 28 weeks, respectively. Between 57% and 64% of patients treated in each study arm received all four planned doses.

YERVOY was studied in patients with a typically poor prognosis, including those with brain metastases, elevated LDH, and visceral disease (M1c). In the study, 71% had M1c stage, 12% had a history of previously-treated brain metastasis, 98% had ECOG performance status of 0 and 1, 23% had received aldesleukin and 38% had elevated LDH level. Additionally, 29% of patients were 65 years or older with a median age of 57 years. The median duration of follow-up was 8.9 months. Please see complete Important Safety Information including Boxed WARNING regarding immune-mediated adverse reactions on pages 6-9.

YERVOY: Mechanism of Action

Cytotoxic T-lymphocyte antigen-4 (CTLA-4) is a negative regulator of T-cell activation. Ipilimumab binds to CTLA-4 and blocks the interaction of CTLA-4 with its ligands, CD80/CD86. Blockade of CTLA-4 has been shown to augment T-cell activation and proliferation. The mechanism of action of ipilimumab's effect in patients with melanoma is indirect, possibly through T-cell mediated anti-tumor immune responses.

About the YERVOY Filing

YERVOY (ipilimumab) was granted orphan drug status in 2004, which is a designation given to drugs that treat rare diseases. In 2006, YERVOY received a fast track designation. The FDA's fast track process is designed to facilitate the development, and expedite the review, of drugs to treat serious diseases and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier. In August of 2010, YERVOY received a priority review designation, which is given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists.

Metastatic Melanoma is the Deadliest Form of Skin Cancer

Melanoma is a form of skin cancer characterized by the uncontrolled growth of pigment-producing cells (melanocytes) located in the skin. Metastatic melanoma is the deadliest form of the disease, and occurs when cancer spreads beyond the surface of the skin to other organs, such as the lymph nodes, lungs, brain or other areas of the body. Some cancer cells can actively evade surveillance by the immune system, allowing tumors to survive. Melanoma is mostly curable when treated in its early stages. However, in its late stages, the average survival rate is just 6 months with a 1-year mortality rate of 75%, making it one of the most aggressive forms of cancer. These rates are based on a meta-analysis of 42 Phase 2 trials of more than 2,100 previously-treated and treatment-naïve patients with Stage IV metastatic melanoma conducted by multiple cooperative groups from 1975-2005.

"Metastatic melanoma is a devastating disease and treating it has been a significant challenge," said Tim Turnham, executive director of the Melanoma Research Foundation. "The incidence of melanoma has been increasing for at least 30 years. The median age at diagnosis for melanoma is 57 and the median age at death is 67."

About Bristol-Myers Squibb's Patient Access Programs

Bristol-Myers Squibb is committed to supporting patient access to YERVOY and has put in place a number of programs to help patients and providers. Destination Access™, which is the Bristol-Myers Squibb Reimbursement Support Program, is a comprehensive service that supports patient access by providing benefits investigation support, prior authorization assistance, appeals assistance and patient assistance. More information about our patient assistance program can be obtained by calling 1-800-861-0048.

In addition to Destination Access, Bristol-Myers Squibb has developed the YERVOY Co-Pay Program to help eligible, commercially insured patients who have been prescribed YERVOY for unresectable or metastatic melanoma with their co-pay or co-insurance costs for this drug. Additional information about this program will be available at www.YERVOY.com.

Important Safety Information

WARNING: IMMUNE-MEDIATED ADVERSE REACTIONS

YERVOY can result in severe and fatal immune-mediated adverse reactions due to T-cell activation and proliferation. These immune-mediated reactions may involve any organ system; however, the most common severe immune-mediated adverse reactions are enterocolitis, hepatitis, dermatitis (including toxic epidermal necrolysis), neuropathy, and endocrinopathy. The majority of these immune-mediated reactions initially manifested during treatment; however, a minority occurred weeks to months after discontinuation of YERVOY.

Assess patients for signs and symptoms of enterocolitis, dermatitis, neuropathy and endocrinopathy and evaluate clinical chemistries including liver function tests (LFTs) and thyroid function tests at baseline and before each dose.

Permanently discontinue YERVOY and initiate systemic high-dose corticosteroid therapy for severe immune-mediated reactions.

Recommended Dose Modifications

Withhold dose for moderate immune-mediated adverse reactions until return to baseline, improvement to mild severity, or complete resolution, and patient is receiving <7.5 mg prednisone or equivalent per day.

Permanently discontinue YERVOY for any of the following:

- Persistent moderate adverse reactions or inability to reduce corticosteroid dose to 7.5 mg prednisone or equivalent per day.
- Failure to complete full treatment course within 16 weeks from administration of first dose.
- Severe or life-threatening adverse reactions.

Immune-mediated Enterocolitis:

- In the pivotal Phase 3 study in YERVOY-treated patients, severe, life-threatening or fatal (diarrhea of ≥7 stools above baseline, fever, ileus, peritoneal signs; Grade 3-5) immune-mediated enterocolitis occurred in 34 (7%) and moderate (diarrhea with up to 6 stools above baseline, abdominal pain, mucus or blood in stool; Grade 2) enterocolitis occurred in 28 (5%) patients.
- Across all YERVOY-treated patients (n=511), 5 (1%) developed intestinal perforation, 4 (0.8%) died as a result of complications, and 26 (5%) were hospitalized for severe enterocolitis.
- Monitor patients for signs and symptoms of enterocolitis (such as diarrhea, abdominal pain, mucus or blood in stool, with or without fever) and of bowel perforation (such as peritoneal signs and ileus).
 - In symptomatic patients, rule out infectious etiologies and consider endoscopic evaluation for persistent or severe symptoms.

Immune-mediated Hepatitis:

- In the pivotal Phase 3 study in YERVOY-treated patients, severe, life-threatening, or fatal hepatotoxicity (AST or ALT elevations >5X the upper limit of normal (ULN) or total bilirubin elevations >3X the ULN; Grade 3–5) occurred in 8 (2%), with fatal hepatic failure in 0.2% and hospitalization in 0.4%.
- 13 (2.5%) additional YERVOY-treated patients experienced moderate hepatotoxicity manifested by LFT abnormalities (AST or ALT elevations >2.5X but ≤5X the ULN or total bilirubin elevation >1.5X but ≤3X the ULN; Grade 2).
- Monitor LFTs (hepatic transaminase and bilirubin levels) and assess patients for signs and symptoms of hepatotoxicity before each dose of YERVOY.
 - In patients with hepatotoxicity, rule out infectious or malignant causes and increase frequency of LFT monitoring until resolution.

Immune-mediated Dermatitis:

- In the pivotal Phase 3 study in YERVOY-treated patients, severe, life-threatening or fatal immune-mediated dermatitis (e.g., Stevens-Johnson syndrome, toxic epidermal necrolysis, or rash complicated by full thickness dermal ulceration, or necrotic, bullous, or hemorrhagic manifestations; Grade 3–5) occurred in 13 (2.5%) patients.
 - 1 (0.2%) patient died as a result of toxic epidermal necrolysis.
 - 1 additional patient required hospitalization for severe dermatitis.
- There were 63 (12%) YERVOY-treated patients with moderate (Grade 2) dermatitis.
- Monitor patients for signs and symptoms of dermatitis such as rash and pruritus. Unless an alternate etiology has been identified, signs or symptoms of dermatitis should be considered immune-mediated.

Immune-mediated Neuropathies:

- In the pivotal Phase 3 study in YERVOY-treated patients, 1 case of fatal Guillain-Barré syndrome and 1 case of severe (Grade 3) peripheral motor neuropathy were reported.
- Across the clinical development program of YERVOY, myasthenia gravis and additional cases of Guillain-Barré syndrome have been reported.
- Monitor for symptoms of motor or sensory neuropathy such as unilateral or bilateral weakness, sensory alterations, or paresthesia.

Immune-Mediated Endocrinopathies:

- In the pivotal Phase 3 study in YERVOY-treated patients, severe to life-threatening immune-mediated endocrinopathies (requiring hospitalization, urgent medical intervention, or interfering with activities of daily living; Grade 3–4) occurred in 9 (1.8%).
 - All 9 patients had hypopituitarism and some had additional concomitant endocrinopathies such as adrenal insufficiency, hypogonadism, and hypothyroidism.
 - 6 of the 9 patients were hospitalized for severe endocrinopathies.
- Moderate endocrinopathy (requiring hormone replacement or medical intervention; Grade 2) occurred in 12 (2.3%) YERVOY-treated patients and consisted of hypothyroidism, adrenal insufficiency, hypopituitarism, and 1 case each of hyperthyroidism and Cushing's syndrome.
- Median time to onset of moderate to severe immune-mediated endocrinopathy was 11 weeks and ranged up to 19.3 weeks after the initiation of YERVOY.
- Monitor patients for clinical signs and symptoms of hypophysitis, adrenal insufficiency (including adrenal crisis), and hyper- or hypothyroidism.
 - Patients may present with fatigue, headache, mental status changes, abdominal pain, unusual bowel habits, and hypotension, or nonspecific symptoms which may resemble other causes such as brain metastasis or underlying disease.
 - Unless an alternate etiology has been identified, signs or symptoms of endocrinopathies should be considered immune-mediated.
 - Monitor thyroid function tests and clinical chemistries at the start of treatment, before each dose, and as clinically indicated based on symptoms.
 - In a limited number of patients, hypophysitis was diagnosed by imaging studies through enlargement of the pituitary gland.

Other Immune-mediated Adverse Reactions, Including Ocular Manifestations:

- In the pivotal Phase 3 study in YERVOY-treated patients, clinically significant immune-mediated adverse reactions seen in <1% were: nephritis, pneumonitis, meningitis, pericarditis, uveitis, iritis, and hemolytic anemia.
- Across the clinical development program for YERVOY, immune-mediated adverse reactions also reported with <1% incidence were: myocarditis, angioedema, temporal arteritis, vasculitis, polymyalgia rheumatica, conjunctivitis, blepharitis, episcleritis, scleritis, leukocytoclastic vasculitis, erythema multiforme, psoriasis, pancreatitis, arthritis, and autoimmune thyroiditis.

Pregnancy & Nursing:

- YERVOY is classified as pregnancy category C. There are no adequate and well-controlled studies of YERVOY in pregnant women. Use YERVOY during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- Human IgG1 is known to cross the placental barrier and YERVOY is an IgG1; therefore, YERVOY has the potential to be transmitted from the mother to the developing fetus.
- It is not known whether YERVOY is secreted in human milk. Because many drugs are secreted in human milk and because of the potential for serious adverse reactions in nursing infants from YERVOY, a decision should be made whether to discontinue nursing or to discontinue YERVOY.

Common Adverse Reactions:

- The most common adverse reactions (≥5%) in patients who received YERVOY at 3 mg/kg were fatigue (41%), diarrhea (32%), pruritus (31%), rash (29%), and colitis (8%).

Please see full Prescribing Information, including **Boxed Warnings regarding Immune-related side effects at www.YERVOY.com or www.bms.com.**

Immuno-Oncology at Bristol-Myers Squibb

Immuno-oncology, which focuses on the scientific potential of harnessing the unique properties of the immune system to fight cancer, is a key area of focus at Bristol-Myers Squibb. A variety of compounds and immunotherapeutic approaches are being explored for patients with different types of cancer. The substantial potential of the immune system's intrinsic ability to fight cancer is fundamental to the immuno-oncology research at Bristol-Myers Squibb and its ongoing commitment to shaping and advancing cancer care. The mechanism of action of ipilimumab's effect in patients with melanoma is indirect, possibly through T-cell mediated anti-tumor immune responses.

About Bristol-Myers Squibb

Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information about Bristol-Myers Squibb, visit www.bms.com, or follow us on Twitter at <http://twitter.com/bmsnews>.

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995 regarding product development. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes and results to differ materially from current expectations. No forward-looking statement can be guaranteed. Among other risks, there can be no guarantee that ipilimumab will become a commercially successful product. Forward-looking statements in this press release should be evaluated together with the many uncertainties that affect Bristol-Myers Squibb's business, particularly those identified in the cautionary factors discussion in Bristol-Myers Squibb's Annual Report on Form 10-K for the year ended December 31, 2010, in our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K. Bristol-Myers Squibb undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

Photos/Multimedia Gallery Available: <http://www.businesswire.com/cgi-bin/mmg.cgi?eid=6660960&lang=en>

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