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FDA Approves ERBITUX(R) (cetuximab) as First-Line Treatment in KRAS Mutation-Negative (Wild-Type) Epidermal Growth Factor Receptor (EGFR)-Expressing Metastatic Colorectal Cancer in Combination with FOLFIRI (Irinotecan, 5-Fluorouracil, Leucovorin)

- *First and only FDA-approved, biomarker-directed therapy for a specific subset of newly diagnosed EGFR-expressing metastatic colorectal cancer (mCRC) patients, targeting those with KRAS mutation-negative (wild-type) tumors*
- *ERBITUX plus FOLFIRI is the first biologic treatment regimen approved in nearly a decade for newly diagnosed mCRC*

NEW YORK & INDIANAPOLIS--(BUSINESS WIRE)-- [Eli Lilly and Company](#) (NYSE: LLY) and [Bristol-Myers Squibb Company](#) (NYSE: BMY) today announced that ERBITUX[®] (cetuximab) in combination with the chemotherapy regimen FOLFIRI (irinotecan, 5-fluorouracil, leucovorin) has been granted full approval by the U.S. Food and Drug Administration (FDA) for the first-line treatment of patients with *KRAS* mutation-negative (commonly known as *KRAS* wild-type), epidermal growth factor receptor (EGFR)-expressing metastatic colorectal cancer (mCRC) as determined by FDA-approved tests for this use. ERBITUX is not indicated for the treatment of *KRAS* mutation-positive colorectal cancer. Concurrently, the FDA also approved the first *KRAS* companion diagnostic test, the *therascreen*[®] *KRAS* diagnostic kit developed by QIAGEN.

"Cancer is a heterogeneous disease and we have learned that not all patients with mCRC should be viewed as the same," said [Brian Daniels](#), senior vice president, Global Development and Medical Affairs, Bristol-Myers Squibb. "Today's approval demonstrates our ability to bring diverse cancer therapies to market that address the needs of patients with *KRAS* mutation-negative (wild-type) mCRC."

The new indication is based on data from the CRYSTAL (Cetuximab combined with iRinotecan in first-line therapY for metaSTatic colorectAL cancer) trial, a Phase 3 open-label, randomized, multicenter study conducted outside the U.S. that used European Union (EU)-approved cetuximab as the clinical trial material. ERBITUX provides approximately 22 percent higher exposure relative to the EU-approved cetuximab; these pharmacokinetic data, together with the results of this trial and other clinical trial data, establish the efficacy of ERBITUX at the recommended dose in combination with FOLFIRI for first-line *KRAS* mutation-negative (wild-type) EGFR-expressing mCRC.

With today's approval, ERBITUX is now the first and only FDA-approved therapy for a specific subset of mCRC patients, targeting those with *KRAS* mutation-negative (wild-type) tumors. This is based on the positive CRYSTAL study with progression-free survival (PFS) as the primary endpoint in the all randomized patient population treated with EU-approved cetuximab plus FOLFIRI (the CRYSTAL regimen) versus FOLFIRI alone.

The Full Prescribing Information for ERBITUX includes a Boxed WARNING regarding infusion reactions. Serious infusion reactions occurred with the administration of ERBITUX in approximately 3 percent of patients in clinical trials, with fatal outcome reported in less than 1 in 1000. Healthcare providers should immediately interrupt and permanently discontinue ERBITUX infusion for serious infusion reactions.

Please see Important Safety Information including Boxed WARNINGS on pages 6-10.

Among the all randomized patient population, a statistically significant improvement in PFS was observed for the EU-approved cetuximab plus FOLFIRI arm compared with the FOLFIRI-alone arm (median PFS 8.9 vs. 8.1 months, HR 0.85 [95% CI, 0.74-0.99], p-value=0.0358). Additionally, the median overall survival (OS) in each arm was 19.6 months (95% CI, 18-21) and 18.5 months (95% CI, 17-20), respectively (HR= 0.88; 95% CI, 0.78-1.0), which was not significantly different. The objective response rate (ORR) in each arm was 46% (95% CI, 42-50) and 38% (95% CI, 34-42), respectively.

In the post-hoc analysis of the *KRAS* subgroups, the median PFS of the *KRAS* mutation-negative (wild-type) patients treated with EU-approved cetuximab plus FOLFIRI (n=320) or FOLFIRI alone (n=356) was 9.5 months (95% CI, 8.9-11.1) and 8.1 months (95% CI, 7.4-9.2), respectively (HR= 0.70; 95% CI, 0.57-0.86). The median OS in each arm was 23.5 months (95% CI, 21-26) and 19.5 months (95% CI, 17-21), respectively (HR= 0.80; 95% CI, 0.67-0.94). The ORR in each arm was 57% (95% CI, 51-62) and 39% (95% CI, 34-44), respectively.

There is no evidence of effectiveness in the subgroup of patients with *KRAS* mutation-positive tumors. The median PFS of the *KRAS* mutation-positive patients treated with EU-approved cetuximab (n=216) or FOLFIRI alone (n=187) was 7.5 months (95%

CI, 6.7-8.7) versus 8.2 months (95% CI, 7.4-9.2), respectively (HR= 1.13; 95% CI, 0.88-1.46). The median OS in each arm was 16.0 months (95% CI, 15-18) versus 16.7 months (95% CI, 15-19), respectively (HR=1.04; 95% CI, 0.84-1.29). The ORR in each arm was 31% (95% CI, 25-38) and 35% (95% CI, 28-43), respectively.

"Both response rates and overall survival in *KRAS* wild-type patients treated with the CRYSTAL regimen are important when considering the treatment options for patients with first-line mCRC," said Eric Van Cutsem, MD, PhD, professor of medicine and digestive oncology, University Hospital Gasthuisberg, Leuven, Belgium, and lead investigator of the pivotal trial.

Selected adverse events of any grade from the CRYSTAL trial occurring in at least 10 percent of patients receiving EU-approved cetuximab in combination with FOLFIRI versus FOLFIRI alone were: acne-like rash (86% vs. 13%, respectively), diarrhea (66% vs. 60%), neutropenia (49% vs. 42%), rash (44% vs. 4%), stomatitis (31% vs. 19%), anorexia (30% vs. 23%), pyrexia (26% vs. 14%), dermatitis acneiform (26% vs. < 1%), dry skin (22% vs. 4%), acne (14% vs. 0), paronychia (20% vs. < 1%), palmar-plantar erythrodysesthesia syndrome (19% vs. 4%), skin fissures (19% vs. 1%), conjunctivitis (18% vs. 3%), dyspepsia (16% vs. 9%), weight decreased (15% vs. 9%), pruritis (14% vs. 3%), and infusion-related reaction (14% vs. < 1%). U.S.-licensed ERBITUX provides approximately 22 percent higher exposure relative to the EU-approved cetuximab. The data provided above are consistent in incidence and severity of adverse reactions with those seen for ERBITUX in this indication. The tolerability of the recommended dose is supported by safety data from additional studies of ERBITUX.

"The totality of the data from CRYSTAL, along with data from other ERBITUX trials, provide compelling and consistent evidence of the benefit of ERBITUX in the treatment of *KRAS* mutation negative (wild-type) EGFR-expressing mCRC," said Richard Gaynor, MD, vice president, Product Development and Medical Affairs, Oncology, Eli Lilly and Company.

KRAS: The Biomarker in mCRC to Help Identify Appropriate Patients for ERBITUX Therapy

Data from the landmark CRYSTAL study, along with other cetuximab studies, demonstrate the importance of testing for *KRAS* status at diagnosis of mCRC to identify appropriate patients for ERBITUX therapy.

Both the National Comprehensive Cancer Network® (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®, Category 2A)* and the American Society of Clinical Oncology (ASCO) recommend *KRAS* gene testing in colorectal cancer patients at diagnosis of metastatic disease.

"Research results have consistently demonstrated that *KRAS* is an important biomarker in mCRC, underscoring the need for all patients with this disease to undergo testing for *KRAS* status at initial diagnosis," said John Mendelsohn, MD, The University of Texas MD Anderson Cancer Center. "The field of biomarker-driven cancer therapy has come a long way since my colleagues and I began our research on EGF receptor inhibition with this monoclonal antibody in 1980. It is gratifying to see such progress being made, and I am honored to have been involved in the success of ERBITUX."

NCCN Guidelines recommend ERBITUX (cetuximab) for first-line as a treatment option in combination with FOLFIRI for patients with advanced or metastatic *KRAS* wild-type mCRC (Category 2A).*

Since its first approval in 2004, approximately 139,814 patients have received ERBITUX therapy in the U.S. alone.

About CRYSTAL

The approval is based on a Phase 3 randomized, open-label multicenter study of patients with mCRC, which was sponsored by Merck KGaA, Darmstadt, Germany. Patients were randomized (1:1) to receive either EU-approved cetuximab with FOLFIRI (the CRYSTAL regimen) or FOLFIRI alone as first-line treatment (n=1,217). The primary endpoint was PFS in all randomized patients. Secondary endpoints were overall survival and response rate. CRYSTAL was conducted outside the U.S. using EU-approved cetuximab as the clinical trial material. ERBITUX provides approximately 22 percent higher exposure relative to the EU-approved cetuximab; these pharmacokinetic data, together with the results of this trial and other clinical trial data, establish the efficacy of ERBITUX at the recommended dose in combination with FOLFIRI for first-line *KRAS* mutation-negative (wild-type) EGFR-expressing mCRC.

Study treatment continued until disease progression or unacceptable toxicity occurred. Eighty-five percent of patients required no dose reduction (minimum cetuximab dose level greater than or equal to 225 mg/m²) and received the full treatment regimen.

About Metastatic Colorectal Cancer (mCRC)

In 2012, 143,460 new cases of colorectal cancer (CRC) are estimated to occur, and an estimated 51,690 deaths from CRC are expected to occur, accounting for 9 percent of all projected cancer deaths. Colorectal cancer is a cancer that develops in the colon or the rectum, which are both parts of the gastrointestinal system. Metastatic colorectal cancer (mCRC) occurs when the disease has spread to at least one distant organ and tissues, such as the liver, lungs, lining of the abdomen or ovaries. One out

of five CRC patients is diagnosed with metastatic disease. The five-year survival rate for patients with mCRC is 12 percent.

"For colorectal cancer patients who are diagnosed at the late stage, it is devastating," said Andrew Spiegel, chief executive officer, Colon Cancer Alliance. "Knowing their *KRAS* status at the time of diagnosis provides patients, physicians, and their families with a new understanding in how to best manage their care."

[About ERBITUX® \(cetuximab\)](#)

ERBITUX (cetuximab) is a monoclonal antibody (IgG1 Mab) designed to inhibit the function of a molecular structure expressed on the surface of normal and tumor cells called the epidermal growth factor receptor (EGFR, HER1, c-ErbB-1). *In vitro* assays and *in vivo* animal studies have shown that binding of cetuximab to the EGFR blocks phosphorylation and activation of receptor-associated kinases, resulting in inhibition of cell growth induction of apoptosis (cell death), and decreased matrix metalloproteinase and vascular endothelial growth factor production. Signal transduction through the EGFR results in activation of *KRAS* wild-type protein. However, in cells with activating *KRAS* somatic mutations, the mutant *KRAS* protein is continuously active and appears independent of EGFR regulation. *In vitro*, cetuximab can mediate antibody-dependent cellular cytotoxicity (ADCC) against certain human tumor types. *In vitro* assays and *in vivo* animal studies have shown that cetuximab inhibits the growth and survival of tumor cells that express the EGFR. No anti-tumor effects of cetuximab were observed in human tumor xenografts lacking EGFR expression.

INDICATIONS

Head and Neck Cancer

- ERBITUX® (cetuximab), in combination with radiation therapy, is indicated for the initial treatment of locally or regionally advanced squamous cell carcinoma of the head and neck
- ERBITUX is indicated in combination with platinum-based therapy with 5-FU for the first-line treatment of patients with recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck
- ERBITUX, as a single agent, is indicated for the treatment of patients with recurrent or metastatic squamous cell carcinoma of the head and neck for whom prior platinum-based therapy has failed

Colorectal Cancer

ERBITUX is indicated for the treatment of *KRAS* mutation-negative (wild-type) epidermal growth factor receptor (EGFR)-expressing metastatic colorectal cancer (mCRC) as determined by FDA-approved tests for this use

- in combination with FOLFIRI (irinotecan, 5-fluorouracil, leucovorin) for first-line treatment,
- in combination with irinotecan in patients who are refractory to irinotecan-based chemotherapy,
- as a single agent in patients who have failed oxaliplatin- and irinotecan-based chemotherapy or who are intolerant to irinotecan

Limitation of Use: ERBITUX is not indicated for treatment of *KRAS* mutation-positive colorectal cancer

IMPORTANT SAFETY INFORMATION INCLUDING BOXED WARNINGS

Infusion Reactions

- **Grade 3/4 infusion reactions occurred in approximately 3% of patients receiving ERBITUX® (cetuximab) in clinical trials, with fatal outcome reported in less than 1 in 1000**
 - **Serious infusion reactions, requiring medical intervention and immediate, permanent discontinuation of ERBITUX, included rapid onset of airway obstruction (bronchospasm, stridor, hoarseness), hypotension, shock, loss of consciousness, myocardial infarction, and/or cardiac arrest**
 - **Immediately interrupt and permanently discontinue ERBITUX infusions for serious infusion reactions**
- **Approximately 90% of the severe infusion reactions were associated with the first infusion of ERBITUX despite premedication with antihistamines**
 - **Caution must be exercised with every ERBITUX infusion, as there were patients who experienced their first severe infusion reaction during later infusions**
 - **Monitor patients for 1 hour following ERBITUX infusions in a setting with resuscitation equipment and other agents necessary to treat anaphylaxis (eg, epinephrine, corticosteroids, intravenous**

antihistamines, bronchodilators, and oxygen). Longer observation periods may be required in patients who require treatment for infusion reactions

Cardiopulmonary Arrest

- **Cardiopulmonary arrest and/or sudden death occurred in 4 (2%) of 208 patients with squamous cell carcinoma of the head and neck treated with radiation therapy and ERBITUX, as compared to none of 212 patients treated with radiation therapy alone. In 3 patients with prior history of coronary artery disease, death occurred 27, 32, and 43 days after the last dose of ERBITUX. One patient with no prior history of coronary artery disease died one day after the last dose of ERBITUX. Fatal cardiac disorders and/or sudden death occurred in 7 (3%) of the 219 patients with squamous cell carcinoma of the head and neck treated with platinum-based therapy with 5-fluorouracil (FU) and European Union (EU)-approved cetuximab as compared to 4 (2%) of the 215 patients treated with chemotherapy alone. Five of these 7 patients in the chemotherapy plus cetuximab arm received concomitant cisplatin and 2 patients received concomitant carboplatin. All 4 patients in the chemotherapy-alone arm received cisplatin**
 - **Carefully consider the use of ERBITUX in combination with radiation therapy or platinum-based therapy with 5-FU in head and neck cancer patients with a history of coronary artery disease, congestive heart failure or arrhythmias in light of these risks**
 - **Closely monitor serum electrolytes including serum magnesium, potassium, and calcium during and after ERBITUX therapy**

Pulmonary Toxicity

- Interstitial lung disease (ILD), which was fatal in one case, occurred in 4 of 1570 (< 0.5%) patients receiving ERBITUX in Studies 1, 3, and 6, as well as other studies, in colorectal cancer and head and neck cancer. Interrupt ERBITUX for acute onset or worsening of pulmonary symptoms. Permanently discontinue ERBITUX for confirmed ILD

Dermatologic Toxicities

- In clinical studies of ERBITUX, dermatologic toxicities, including acneiform rash, skin drying and fissuring, paronychia inflammation, infectious sequelae (eg, *S. aureus* sepsis, abscess formation, cellulitis, blepharitis, conjunctivitis, keratitis/ulcerative keratitis with decreased visual acuity, cheilitis), and hypertrichosis, occurred in patients receiving ERBITUX therapy. Acneiform rash occurred in 76-88% of 1373 patients receiving ERBITUX in Studies 1, 3, 5, and 6. Severe acneiform rash occurred in 1-17% of patients
 - Acneiform rash usually developed within the first 2 weeks of therapy and resolved in a majority of the patients after cessation of treatment, although in nearly half, the event continued beyond 28 days
 - Monitor patients receiving ERBITUX for dermatologic toxicities and infectious sequelae
 - Sun exposure may exacerbate these effects

ERBITUX Plus Radiation Therapy and Cisplatin

- The safety of ERBITUX in combination with radiation therapy and cisplatin has not been established
 - Death and serious cardiotoxicity were observed in a single-arm trial with ERBITUX, radiation therapy, and cisplatin (100 mg/m²) in patients with locally advanced squamous cell carcinoma of the head and neck
 - Two of 21 patients died, one as a result of pneumonia and one of an unknown cause
 - Four patients discontinued treatment due to adverse events. Two of these discontinuations were due to cardiac events

Electrolyte Depletion

- Hypomagnesemia occurred in 55% of 365 patients receiving ERBITUX in Study 5 and two other clinical trials in colorectal cancer and head and neck cancer, respectively and was severe (NCI CTC grades 3 & 4) in 6-17%. In Study 2 the addition of EU-approved cetuximab to cisplatin and 5-FU resulted in an increased incidence of hypomagnesemia (14% vs. 6%) and of Grade 3—4 hypomagnesemia (7% vs. 2%) compared to cisplatin and 5-FU alone. In contrast, the incidence of hypomagnesemia was similar for those who received cetuximab, carboplatin, and 5-FU compared to carboplatin and 5-FU (4% vs. 4%). No patient experienced Grade 3—4 hypomagnesemia in either arm in the carboplatin subgroup. The onset of hypomagnesemia and accompanying electrolyte abnormalities occurred days to months after initiation of ERBITUX therapy
 - Monitor patients periodically for hypomagnesemia, hypocalcemia and hypokalemia, during, and for at least 8 weeks following the completion of ERBITUX therapy

- Replete electrolytes as necessary

Late Radiation Toxicities

- The overall incidence of late radiation toxicities (any grade) was higher with ERBITUX in combination with radiation therapy compared with radiation therapy alone. The following sites were affected: salivary glands (65%/56%), larynx (52%/36%), subcutaneous tissue (49%/45%), mucous membranes (48%/39%), esophagus (44%/35%), and skin (42%/33%) in the ERBITUX and radiation versus radiation alone arms, respectively
 - The incidence of grade 3 or 4 late radiation toxicities were similar between the radiation therapy alone and the ERBITUX plus radiation therapy arms

Pregnancy and Nursing

- In women of childbearing potential, appropriate contraceptive measures must be used during treatment with ERBITUX and for 6 months following the last dose of ERBITUX. ERBITUX may be transmitted from the mother to the developing fetus, and has the potential to cause fetal harm when administered to pregnant women. ERBITUX should only be used during pregnancy if the potential benefit justifies the potential risk to the fetus
- It is not known whether ERBITUX is secreted in human milk. IgG antibodies, such as ERBITUX, can be excreted in human milk. Because of the potential for serious adverse reactions in nursing infants from ERBITUX, a decision should be made whether to discontinue nursing or to discontinue ERBITUX, taking into account the importance of ERBITUX to the mother. If nursing is interrupted, based on the mean half-life of cetuximab, nursing should not be resumed earlier than 60 days following the last dose of ERBITUX

Adverse Events

- The most **serious adverse reactions** associated with ERBITUX across all studies were infusion reactions, cardiopulmonary arrest, dermatologic toxicity and radiation dermatitis, sepsis, renal failure, interstitial lung disease, and pulmonary embolus
- The most common adverse reactions associated with ERBITUX (incidence $\geq 25\%$) are cutaneous adverse reactions (including rash, pruritus, and nail changes), headache, diarrhea, and infection
- The most frequent adverse events seen in patients with carcinomas of the head and neck receiving ERBITUX in combination with radiation therapy (n=208) versus radiation alone (n=212) (incidence $\geq 50\%$) were acneiform rash (87%/10%), radiation dermatitis (86%/90%), weight loss (84%/72%), and asthenia (56%/49%). The most common grade 3/4 adverse events for ERBITUX in combination with radiation therapy ($\geq 10\%$) versus radiation alone included: radiation dermatitis (23%/18%), acneiform rash (17%/1%), and weight loss (11%/7%)
- The most frequent adverse events for EU-approved cetuximab in combination with platinum-based therapy with 5-FU (CT) (n=219) versus CT alone (n=215) (incidence $\geq 40\%$) were acneiform rash (70%/2%), nausea (54%/47%), and infection (44%/27%). The most common grade 3/4 adverse events for cetuximab in combination with CT ($\geq 10\%$) versus CT alone included: infection (11%/8%). Since U.S.-licensed ERBITUX provides approximately 22% higher exposure relative to the EU-approved cetuximab, the data provided above may underestimate the incidence and severity of adverse reactions anticipated with ERBITUX for this indication. However, the tolerability of the recommended dose is supported by safety data from additional studies of ERBITUX
- The most frequent events seen in patients with *KRAS* mutation-negative (wild-type) metastatic colorectal cancer treated with EU-approved cetuximab + FOLFIRI (n=317) versus FOLFIRI alone (n=350) (incidence $\geq 50\%$) were acne-like rash (86% vs 13%) and diarrhea (66% vs 60%). The most common grade 3/4 adverse events ($\geq 10\%$) included: neutropenia (31% vs 24%), acne-like rash (18% vs < 1%), and diarrhea (16% vs 10%). Since U.S.-licensed ERBITUX provides approximately 22% higher exposure relative to the EU-approved cetuximab, the data provided above may underestimate the incidence and severity of adverse reactions anticipated with ERBITUX for this indication. However, the tolerability of the recommended dose is supported by safety data from additional studies of ERBITUX
- The most frequent events seen in patients with *KRAS* mutation-negative (wild-type) metastatic colorectal cancer treated with ERBITUX + best supportive care (BSC) (n=118) versus BSC alone (n=124) (incidence $\geq 50\%$) were rash/desquamation (95% vs 21%), fatigue (91% vs 79%), nausea (64% vs 50%), dry skin (57% vs 15%), pain-other (59% vs 37%), and constipation (53% vs 38%). The most common grade 3/4 adverse events ($\geq 10\%$) included: fatigue (31% vs 29%), pain-other (18% vs 10%), rash/desquamation (16% vs 1%), dyspnea (16% vs 13%), other-gastrointestinal (12% vs 5%), and infection without neutropenia (11% vs 5%)
- The most frequent adverse events seen in patients with metastatic colorectal cancer (n=354) treated with ERBITUX plus irinotecan in clinical trials (incidence $\geq 50\%$) were acneiform rash (88%), asthenia/malaise (73%), diarrhea (72%), and nausea (55%). The most common grade 3/4 adverse events ($\geq 10\%$) included: diarrhea (22%), leukopenia (17%), asthenia/malaise (16%), and acneiform rash (14%)

Please see Important Safety Information and [U.S. Full Prescribing Information](#) including **Boxed WARNINGS**.

About ERBITUX Patient Programs

Bristol-Myers Squibb and Eli Lilly and Company are committed to supporting patient access to ERBITUX and have put in place a number of programs to help patients and providers. Destination Access™, which is a Reimbursement Support Program, helps 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, The ERBITUX PATIENT SUPPORT PROGRAM has been developed to provide patients and healthcare providers with information and helpful resources on dermatological reactions associated with ERBITUX and guidance on how to manage them. For additional information, visit www.erbitux.com.

About Eli Lilly and Company

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers — through medicines and information — for some of the world's most urgent medical needs. Additional information about Lilly is available at www.lilly.com.

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. Among other risks, there can be no guarantee that additional indications will be approved, or if approved, that they will be commercially successful. Forward-looking statements in this press release should be evaluated together with the many uncertainties that affect Bristol-Myers Squibb's and Lilly's businesses, particularly those identified in the cautionary statement and risk factors discussion in Bristol-Myers Squibb's and Lilly's Annual Reports on Form 10-K for the year ended December 31, 2011, in their Quarterly Reports on Form 10-Q and their Current Reports on Form 8-K. Neither Bristol-Myers Squibb nor Lilly undertakes any obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

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