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FDA Approves Portrazza™ (necitumumab) for Specific Type of Lung Cancer

Portrazza, in combination with gemcitabine and cisplatin, is the first biologic approved for first-line treatment of people with metastatic squamous non-small cell lung cancer

INDIANAPOLIS, Nov. 24, 2015 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that the U.S. Food and Drug Administration (FDA) has approved Portrazza™ (necitumumab injection for intravenous use, 800 mg/50 mL), in combination with gemcitabine and cisplatin, as the first biologic for the first-line treatment of people with metastatic squamous non-small cell lung cancer (NSCLC). Portrazza is not indicated for treatment of nonsquamous NSCLC.

Metastatic squamous NSCLC is a difficult-to-treat form of lung cancer with few treatment options.[1],[2],[3],[4] The five-year survival rate for patients with metastatic disease is less than five percent.[5]

"We have seen advances in lung cancer in the last 20 years, but not for the initial treatment of patients battling metastatic squamous non-small cell lung cancer. This is a complex disease and there is an urgent need for effective, first-line treatments," said Richard Gaynor, M.D., senior vice president, product development and medical affairs for Lilly Oncology. "The approval of Portrazza is an important step forward that reaffirms Lilly's commitment to discovering new treatments that respond to the needs of individual patients."

Portrazza has been granted Orphan Drug Designation by the FDA. Orphan drug status is given in the U.S. by the FDA's Office of Orphan Products Development (OOPD) to medicines that demonstrate promise for the diagnosis and/or treatment of rare diseases or conditions.

The Portrazza approval is based on the results of SQUIRE, an open-label, randomized, multi-center Phase III trial that compared first-line treatment with Portrazza in combination with gemcitabine and cisplatin to treatment with gemcitabine and cisplatin alone in patients with metastatic squamous NSCLC. The main outcome measure, or primary endpoint, was overall survival. Portrazza is not indicated for treatment of nonsquamous NSCLC. The labeling for Portrazza contains Boxed Warnings regarding cardiopulmonary arrest and hypomagnesemia. See the full Important Safety Information, including Boxed Warnings, at the end of this press release and the Prescribing Information.

"Lung cancer is an extremely complicated disease that requires a variety of therapy options so doctors can choose an appropriate treatment for each patient's unique circumstances," said Bonnie J. Addario, founder and chair of the Bonnie J. Addario Lung Cancer Foundation, and a lung cancer survivor. "Today's approval represents progress for patients diagnosed with metastatic squamous non-small cell lung cancer, as each new therapy advances cancer care and gives patients hope for improved outcomes."

Lilly is committed to offering assistance programs for eligible patients receiving Portrazza, including a co-pay program that allows qualified patients to pay no more than $25 per dose. Patients, physicians, pharmacists or other healthcare professionals with questions about Portrazza should contact The Lilly Answers Center at 1-800-LillyRx (1-800-545-5979) or visit www.lilly.com.

About Portrazza (necitumumab)

Portrazza (necitumumab), in combination with gemcitabine and cisplatin, is approved for the first-line treatment of people with metastatic squamous non-small cell lung cancer (NSCLC). Portrazza is not indicated for treatment of nonsquamous NSCLC. Portrazza is a recombinant human IgG1 monoclonal antibody that is designed to block the ligand binding site of the human epidermal growth factor receptor 1 (EGFR). Activation of EGFR has been correlated with malignant progression, induction of angiogenesis and inhibition of apoptosis, or cell death. As demonstrated in preclinical studies, EGFR plays a role in the formation (tumorigenesis) and spread (metastasis) of tumors.[6]

About the SQUIRE Trial

SQUIRE was an open-label, randomized, multi-center Phase III trial that compared first-line treatment with Portrazza in combination with gemcitabine and cisplatin to treatment with gemcitabine and cisplatin alone in patients with metastatic squamous NSCLC. Patients on both arms of the study were allowed to receive a maximum of six cycles of chemotherapy.

Patients on the Portrazza arm demonstrating at least stable disease continued to receive additional cycles of Portrazza until disease progression or unacceptable toxicity. The trial enrolled 1,093 people with stage IV squamous NSCLC, of which 91 percent had a baseline performance status (PS) 0-1, and nine percent had PS 2. Of patients enrolled, 91 percent had metastatic disease at two or more sites. The SQUIRE study was conducted across 184 investigative sites in 26 countries.[7]

SQUIRE was the first and only randomized Phase III study conducted specifically in patients with metastatic squamous NSCLC to demonstrate a statistically significant improvement in overall survival over gemcitabine and cisplatin alone, specifically in the first-line setting. Portrazza combination therapy showed a statistically significant improvement in overall survival, the main outcome measure (HR 0.84; 95% CI: 0.74-0.96; p=0.01), with a median overall survival of 11.5 months (95% CI: 10.4-12.6) for the Portrazza arm, as compared to 9.9 months (95% CI: 8.9-11.1) for those treated with gemcitabine and cisplatin alone. This translated to a 16 percent reduction in risk of death. The percentage of deaths at the time of analysis was 77 percent (418 patients) on the Portrazza arm and 81 percent (442 patients) on the control arm. The significant survival improvement observed in SQUIRE was supported by a statistically significant improvement in progression-free survival (HR 0.85; 95% CI: 0.74-0.98; p=0.02), with a median progression-free survival (PFS) of 5.7 months (95% CI: 5.6-6.0) on the Portrazza arm, as compared to 5.5 months (95% CI: 4.8-5.6) for those treated with gemcitabine and cisplatin alone. The percentage of events at the time of analysis was 79 percent (431 patients) on the Portrazza arm and 76 percent (417 patients) on the control arm. Overall response rate (ORR) was also assessed and there was no difference between arms, with an ORR of 31 percent (95% CI: 27-35) for the Portrazza plus gemcitabine and cisplatin arm and an ORR of 29 percent (95% CI: 25-33) for the gemcitabine and cisplatin arm (p=0.40).

Cardiopulmonary arrest or sudden death occurred in 15 (3%) of 538 patients treated with Portrazza plus gemcitabine and cisplatin as compared to three (0.6%) of 541 patients treated with gemcitabine and cisplatin alone in SQUIRE. Twelve of the 15 patients died within 30 days of the last dose of Portrazza and had comorbid conditions including history of coronary artery disease (n=3), hypomagnesemia (n=4), chronic obstructive pulmonary disease (n=7), and hypertension (n=5). Eleven of the 12 patients had an unwitnessed death. Patients with significant coronary artery disease, myocardial infarction within six months, uncontrolled hypertension, and uncontrolled congestive heart failure were not enrolled in SQUIRE. The incremental risk of cardiopulmonary arrest or sudden death in patients with a history of coronary artery disease, congestive heart failure, or arrhythmias as compared to those without these comorbid conditions is not known. Hypomagnesemia occurred in 83 percent of patients receiving Portrazza in combination with gemcitabine and cisplatin, as compared to 70 percent of patients treated with gemcitabine and cisplatin alone. Hypomagnesemia was severe (grade 3 or 4) in 20 percent of patients on the Portrazza plus gemcitabine and cisplatin arm, compared to seven percent of patients on the gemcitabine and cisplatin alone arm. Because of these risks, the Portrazza Prescribing Information contains instructions about monitoring for electrolyte imbalances and treating as necessary. Portrazza labeling contains additional Warnings and Precautions for venous and arterial thromboembolic events (some fatal), dermatologic toxicities, infusion-related reactions, increased toxicity and increased mortality in patients with nonsquamous NSCLC, and embryofetal toxicity. See the full Important Safety Information, including Boxed Warnings, at the end of this press release and the Prescribing Information.

The most common adverse reactions (all grades) observed in Portrazza-treated patients at a rate of ≥ 15 percent and ≥ 2 percent higher than gemcitabine and cisplatin alone were rash (44% vs 6%), vomiting (29% vs 25%), diarrhea (16% vs 11%), and dermatitis acneiform (15% vs 0.6%). The most common severe (grade 3 or higher) adverse events that occurred at a ≥ 2 percent higher rate in Portrazza-treated patients compared to patients treated with gemcitabine and cisplatin alone were venous thromboembolic events (5%; including pulmonary embolism), rash (4%), and vomiting (3%). See the full Important Safety Information, including Boxed Warnings, at the end of this press release and the Prescribing Information.

About Squamous Non-Small Cell Lung Cancer (NSCLC)

NSCLC is the most common type of lung cancer, and accounts for about 85 percent of all lung cancer cases.[8] Squamous NSCLC, which represents about 30 percent of all lung cancer cases, is a devastating, difficult-to-treat form of the disease.[1],[2],[3],[8] Patients face an imposing disease and symptom burden with very poor prognosis; the five-year survival rate for patients with metastatic disease is less than five percent.[5] Until now, little progress has been made over the last two decades, particularly in the first-line setting, leaving a significant unmet medical need.[4]

Lilly PatientOne

The Lilly PatientOne program addresses financial and coverage issues for qualified uninsured, underinsured, and insured patients who are prescribed a Lilly Oncology product. Lilly PatientOne provides reimbursement assistance for eligible patients who are prescribed a Lilly Oncology product, such as information about coding and billing, prior authorization, benefits investigation, and denied claim appeals, as well as operating a patient assistance program. Lilly also offers a co-pay program that allows qualified Portrazza patients to pay no more than $25 per dose. To learn more, visit www.LillyPatientOne.com or call 1-866-4PatOne (1-866-472-8663).

INDICATION

Portrazza™ is indicated, in combination with gemcitabine and cisplatin, for first-line treatment of patients with metastatic squamous non-small cell lung cancer. Portrazza is not indicated for treatment of nonsquamous non-small cell lung cancer.

IMPORTANT SAFETY INFORMATION FOR PORTRAZZA

WARNING: CARDIOPULMONARY ARREST and HYPOMAGNESEMIA

- **Cardiopulmonary arrest and/or sudden death occurred in 3% of patients treated with Portrazza in combination with gemcitabine and cisplatin. Closely monitor serum electrolytes, including serum magnesium, potassium, and calcium, with aggressive replacement when warranted during and after Portrazza administration.**
- **Hypomagnesemia occurred in 83% of patients receiving Portrazza in combination with gemcitabine and cisplatin, and was severe in 20% of patients. Monitor patients for hypomagnesemia, hypocalcemia, and hypokalemia prior to each dose of Portrazza during treatment and for at least 8 weeks following completion of Portrazza. Withhold Portrazza for grade 3 or 4 electrolyte abnormalities. Replete electrolytes as medically appropriate.**

Warnings and Precautions

Cardiopulmonary Arrest

- Cardiopulmonary arrest or sudden death occurred in 15 (3%) of 538 patients treated with Portrazza plus gemcitabine and cisplatin as compared to 3 (0.6%) of 541 patients treated with gemcitabine and cisplatin alone in study 1. Twelve of the 15 patients died within 30 days of the last dose of Portrazza and had comorbid conditions including history of coronary artery disease (n=3), hypomagnesemia (n=4), chronic obstructive pulmonary disease (n=7), and hypertension (n=5). Eleven of the 12 patients had an unwitnessed death. Patients with significant coronary artery disease, myocardial infarction within 6 months, uncontrolled hypertension, and uncontrolled congestive heart failure were not enrolled in study 1. The incremental risk of cardiopulmonary arrest or sudden death in patients with a history of coronary artery disease, congestive heart failure, or arrhythmias as compared to those without these comorbid conditions is not known. Closely monitor serum electrolytes, including serum magnesium, potassium, and calcium prior to each infusion of Portrazza during treatment and after Portrazza administration for at least 8 weeks after the last dose. Withhold Portrazza for grade 3 or 4 electrolyte abnormalities; subsequent cycles of Portrazza may be administered in these patients once electrolyte abnormalities have improved to grade $\leq$ 2. Replete electrolytes as medically appropriate.

Hypomagnesemia

- Hypomagnesemia occurred in 83% of 461/538 patients with available laboratory results treated with Portrazza as compared to 70% of 457/541 patients with available laboratory results treated with gemcitabine and cisplatin alone in study 1. Hypomagnesemia was severe (grade 3 or 4) in 20% of the patients treated with Portrazza compared to 7% of the patients treated with gemcitabine and cisplatin alone. The median time to development of hypomagnesemia and accompanying electrolyte abnormalities was 6 weeks (25th percentile 4 weeks; 75th percentile 9 weeks) after initiation of Portrazza. Monitor patients for hypomagnesemia, hypocalcemia, and hypokalemia prior to each infusion of Portrazza during treatment, and for at least 8 weeks following the completion of Portrazza. Withhold Portrazza for grade 3 or 4 electrolyte abnormalities; subsequent cycles of Portrazza may be administered in these patients once hypomagnesemia and related electrolyte abnormalities have improved to grade $\leq$ 2. Replete electrolytes as medically appropriate.

Venous and Arterial Thromboembolic Events (VTE and ATE)

- VTE and ATE, some fatal, were observed with Portrazza in combination with gemcitabine and cisplatin. In study 1, the incidence of VTE was 9% in patients receiving Portrazza plus gemcitabine and cisplatin versus 5% in patients receiving gemcitabine and cisplatin alone, and the incidence of grade 3 or higher VTEs was 5% versus 3%, respectively. The incidence of fatal VTEs was similar between arms (0.2% vs 0.2%). The most common VTEs were pulmonary embolism (5%) and deep-vein thrombosis (2%).
- The incidence of ATEs of any grade was 5% versus 4%, and the incidence of grade 3 or higher ATE was 4% versus 2% in the Portrazza-containing and gemcitabine and cisplatin arms, respectively, in study 1. The most common ATEs were cerebral stroke and ischemia (2%) and myocardial infarction (1%). In an exploratory analysis of study 1, the relative risk of VTE or ATE was approximately 3-fold higher in patients with a reported history of VTE or ATE than in patients with no reported history of VTE or ATE. Discontinue Portrazza for patients with serious or life-threatening VTE or ATE.

Dermatologic Toxicities

- Dermatologic toxicities, including rash, dermatitis acneiform, acne, dry skin, pruritus, generalized rash, skin fissures, maculo-papular rash, and erythema, occurred in 79% of patients receiving Portrazza in study 1. Skin toxicity was severe in 8% of patients. Skin toxicity usually developed within the first 2 weeks of therapy and resolved within 17 weeks after onset. For grade 3 skin reactions, modify the dose of Portrazza. Limit sun exposure. Discontinue Portrazza for severe

(grade 4) skin reactions or grade 3 skin induration/fibrosis.

Infusion-Related Reactions (IRRs)

- In study 1, 1.5% of Portrazza-treated patients experienced IRRs of any severity with 0.4% grade 3 IRRs. No patients received premedication for IRR for the first dose of Portrazza in study 1. Most IRRs occurred after the first or second administration of Portrazza. Monitor patients during and following Portrazza infusion for signs and symptoms of IRR. Discontinue Portrazza for serious or life-threatening IRR.

Nonsquamous NSCLC—Increased Toxicity and Increased Mortality

- Portrazza is not indicated for the treatment of patients with nonsquamous NSCLC. In a study of Portrazza plus pemetrexed and cisplatin (PC) versus PC alone (study 2), patients treated with Portrazza and PC experienced more serious (51% vs 41%) and fatal toxicities (16% vs 10%) and cardiopulmonary arrest/sudden death within 30 days of the last study drug (3.3% vs 1.3%) compared to patients who received PC alone.

Embryofetal Toxicity

- Based on animal data and its mechanism of action, Portrazza can cause fetal harm when administered to a pregnant woman. Disruption or depletion of epidermal growth factor receptor (EGFR) in animal models results in impairment of embryofetal development, including effects on placental, lung, cardiac, skin, and neural development. The absence of EGFR signaling has resulted in embryolethality as well as postnatal death in animals. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with Portrazza and for 3 months following the final dose.

Most Common Adverse Reactions

- Adverse reactions (all grades; grade 3/4) that occurred at an incidence rate of $\geq$ 5% (all grades) or a $\geq$ 2% (grade 3/4) difference between patients receiving Portrazza plus gemcitabine and cisplatin versus gemcitabine and cisplatin alone in study 1 were rash (44% vs 6%; 4% vs 0.2%), dermatitis acneiform (15% vs 0.6%; 1% vs 0%), acne (9% vs 0.6%; 0.4% vs 0%), pruritus (7% vs 0.9%; 0.2% vs 0.2%), dry skin (7% vs 1%; 0% vs 0%), skin fissures (5% vs 0%; 0.4% vs 0%), vomiting (29% vs 25%; 3% vs 0.9%), diarrhea (16% vs 11%; 2% vs 1%), stomatitis (11% vs 6%; 1% vs 0.6%), weight decreased (13% vs 6%; 0.7% vs 0.6%), hemoptysis (10% vs 5%; 1% vs 0.9%), pulmonary embolism (5% vs 2%; 4% vs 2%), headache (11% vs 6%; 0% vs 0.4%), VTE (9% vs 5%; 5% vs 3%), paronychia (7% vs 0.2%; 0.4% vs 0%), and conjunctivitis (7% vs 2%; 0.4% vs 0%).
- The most common adverse reactions (all grades) observed in Portrazza-treated patients at a rate of $\geq$ 15% and $\geq$ 2% higher than gemcitabine and cisplatin alone were rash (44% vs 6%), vomiting (29% vs 25%), diarrhea (16% vs 11%), and dermatitis acneiform (15% vs 0.6%).
- The most common severe (grade 3 or higher) adverse events that occurred at a $\geq$ 2% higher rate in Portrazza-treated patients compared to patients treated with gemcitabine and cisplatin alone were VTE (5%; including pulmonary embolism), rash (4%), and vomiting (3%).
- Clinically relevant adverse reactions (all grades) reported in $\geq$ 1% and < 5% of patients treated with Portrazza were dysphagia (3%), oropharyngeal pain (1%), muscle spasms (2%), phlebitis (2%), and hypersensitivity/IRRs (1.5%).
- In study 1, 12% of the patients in the Portrazza arm discontinued study treatment due to an adverse reaction. The most common Portrazza-related toxicity leading to Portrazza discontinuation was skin rash (1%).
- Electrolyte abnormalities (all grades; grade 3 or 4) according to laboratory assessment at an incidence rate of > 10% and a > 2% difference between arms in patients receiving Portrazza plus gemcitabine and cisplatin versus gemcitabine and cisplatin alone in study 1 included hypomagnesemia (83% vs 70%; 20% vs 7%), hypokalemia (28% vs 18%; 5% vs 3%), hypocalcemia (45% vs 30%; 6% vs 2%), albumin corrected hypocalcemia (36% vs 23%; 4% vs 2%), and hypophosphatemia (31% vs 23%; 8% vs 6%).
- The median time to onset of hypomagnesemia was 6 weeks (25th percentile 4 weeks; 75th percentile 9 weeks). Hypomagnesemia was reported as resolved in 43% of the patients who received Portrazza. In study 1, 32% of the patients in the Portrazza arm and 16% of the patients who received gemcitabine and cisplatin alone received magnesium replacement.

Use in Specific Populations

- **Pregnancy:** Based on animal data and its mechanism of action, Portrazza can cause fetal harm when administered to a pregnant woman. Disruption or depletion of EGFR in animal models results in impairment of embryofetal development, including effects on placental, lung, cardiac, skin, and neural development. The absence of EGFR signaling has resulted in embryolethality as well as postnatal death in animals. No animal reproduction studies have been conducted with necitumumab. There are no available data for Portrazza exposure in pregnant women. Advise pregnant women of the potential risk to a fetus and the risk to postnatal development.
- **Lactation:** There is no information regarding the presence of necitumumab in human milk, the effects on the breastfed

infant, or the effects on milk production. Because of the potential for serious adverse reactions in breastfed infants from Portrazza, advise a nursing woman not to breastfeed during treatment with Portrazza and for 3 months following the final dose.

- **Females of Reproductive Potential:** Based on its mechanism of action, Portrazza can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with Portrazza and for 3 months following the final dose.
- **Geriatric Use:** Of the 545 patients in the Portrazza plus gemcitabine and cisplatin arm in Study 1, 213 (39%) were 65 years and over, while 108 (20%) were 70 years and over. In an exploratory subgroup analysis of study 1, the hazard ratio for overall survival in patients 70 years or older was 1.03 (95% CI: 0.75, 1.42). Of the adverse reactions that occurred at an incidence rate of ≥ 5% (all grades) or a ≥ 2% (grade 3/4) difference between patients receiving Portrazza plus gemcitabine and cisplatin versus gemcitabine and cisplatin alone, there was a higher incidence (≥ 3%) of venous thromboembolic events including pulmonary embolism in patients age 70 and over compared to those who were younger than age 70.

Please click to access full Prescribing Information for Portrazza, including Boxed Warnings for cardiopulmonary arrest and hypomagnesemia at http://pi.lilly.com/us/portrazza-uspi.pdf.

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About Lilly Oncology

For more than fifty years, Lilly has been dedicated to delivering life-changing medicines and support to people living with cancer and those who care for them. Lilly is determined to build on this heritage and continue making life better for all those affected by cancer around the world. To learn more about Lilly's commitment to people with cancer, please visit www.LillyOncology.com.

About Eli Lilly and Company

Lilly is a global healthcare leader that unites caring with discovery to make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at www.lilly.com and newsroom.lilly.com/social-channels. **(P-LLY)**

Lilly Forward-Looking Statement

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about the potential of Portrazza (necitumumab) as a treatment of metastatic squamous non-small cell lung cancer (NSCLC) and reflects Lilly's current beliefs. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. There can be no guarantee that future study results and patient experience will be consistent with the study findings to date. There can also be no guarantee that Portrazza will receive regulatory approval for any future indications or that it will prove to be commercially successful. For further discussion of these and other risks and uncertainties that could cause actual results to differ from Lilly's expectations, please see the company's latest Forms 10-K and 10-Q filed with the U.S. Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements.

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