June 4, 2011

Final Phase III Data from Study CA031 of ABRAXANE® in Combination with Carboplatin in Patients with Non-Small Cell Lung Cancer Presented at ASCO

Achieved primary endpoint with significantly improved overall response rate for patients receiving ABRAXANE combination

Strong trends in favor of ABRAXANE combination in elderly patients and squamous cell histology

Patients 70 years and older receiving ABRAXANE combination achieved overall survival of 19.9 months versus 10.4 months in comparator arm

Expect to file ABRAXANE sNDA with FDA as first-line therapy for patients with NSCLC by year-end

BOUDRY, Switzerland, Jun 04, 2011 (BUSINESS WIRE) --

Celgene International Sàrl (Nasdaq:CELG) today announced that final results from a phase III study of ABRAXANE (paclitaxel albumin-bound particles for injectable suspension) in combination with carboplatin in patients with advanced non-small cell lung cancer (NSCLC) were presented at the 2011 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, Illinois.

In the study, patients were randomized to receive either ABRAXANE (100 mg/m²) every week without premedication plus carboplatin (AUC=6) every 3 weeks (n=521) or paclitaxel (200 mg/m²) every 3 weeks with premedication (n=531) plus carboplatin (AUC=6) as first-line therapy.

As reported at ASCO 2010, the primary endpoint of overall response rate was 33% of patients in the ABRAXANE arm, compared to 25% in the paclitaxel arm (p=0.005). Histology subset analysis demonstrated an overall response rate of 41% vs. 24% (p<0.001) in patients with squamous histology (n=450) treated with Abraxane/carboplatin vs cremophor-based paclitaxel/carboplatin, however no difference in overall response rate was seen in the non-squamous patients (26% vs. 25%, n=602).

For the intent-to-treat (ITT) population, the median progression-free survival (PFS) for patients in the ABRAXANE arm was 6.3 months, compared to 5.8 months in the paclitaxel arm (p=0.214, HR 0.902) Additionally, the median overall survival (OS) for patients in the ABRAXANE arm was 12.1 months, compared to 11.2 months in the paclitaxel arm (p=0.271, HR 0.922). In the ITT population, improvement was seen in PFS and OS endpoints favouring ABRAXANE, although this did not reach statistical significance.

In patients 70 years and older, those receiving ABRAXANE (n=74) achieved a median overall survival of 19.9 months, compared to 10.4 months for patients receiving cremaphor-based paclitaxel (n=82) (HR 0.583). This observation supports further investigation in the treatment of elderly NSCLC patients.

Patients with squamous cell disease receiving ABRAXANE (n=229) achieved a median overall survival of 10.7 months, compared to 9.5 months for patients receiving cremaphor-based paclitaxel (n=221) (HR 0.890).

The most common grade 3 or higher adverse events in the ABRAXANE arm and paclitaxel arm, respectively, were neutropenia (42% vs. 48%, p=0.081), anemia (28% vs. 7%, p<0.001), thrombocytopenia (18% vs. 7%, p<0.001), leukopenia (14% vs. 13%, p=0.787), fatigue (7% vs. 9%, p=0.423) and sensory neuropathy (3% vs. 12% p<0.001).

ABRAXANE demonstrated lower rates of grade 3-4 neuropathy, despite 30% higher mean total paclitaxel being delivered (1514 vs. 1169 mg/m²).

Based on these clinical results, and the agreement reached in the Special Protocol Assessment, Celgene is planning the submission of a sNDA for Abraxane for the first-line treatment of patients with advanced NSCLC. Celgene continues
discussions with international regulatory authorities around these data.

These data are reported from an investigational study. ABRAXANE is not approved as a treatment for first-line advanced NSCLC.

About ABRAXANE®

ABRAXANE is a solvent-free chemotherapy treatment option for metastatic breast cancer which was developed using Celgene's proprietary nab® technology platform. This protein-bound chemotherapy agent combines paclitaxel with albumin, a naturally-occurring human protein. ABRAXANE is currently in various stages of investigation for the treatment of the following cancers: expanded applications for metastatic breast, non-small cell lung, malignant melanoma, pancreatic and gastric.

The U.S. Food and Drug Administration approved ABRAXANE for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) in January 2005 for the treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within six months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated. For the full prescribing information for ABRAXANE please visit http://www.abraxane.com.

ABRAXANE® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) is indicated for the treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated.

Important Safety Information

WARNING

ABRAXANE for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) should be administered under the supervision of a physician experienced in the use of cancer chemotherapeutic agents. Appropriate management of complications is possible only when adequate diagnostic and treatment facilities are readily available.

ABRAXANE therapy should not be administered to patients with metastatic breast cancer who have baseline neutrophil counts of less than <1,500 cells/mm$^3$. In order to monitor the occurrence of bone marrow suppression, primarily neutropenia, which may be severe and result in infection, it is recommended that frequent peripheral blood cell counts be performed on all patients receiving ABRAXANE.

Note: An albumin form of paclitaxel may substantially affect a drug's functional properties relative to those of drug in solution. DO NOT SUBSTITUTE FOR OR WITH OTHER PACLITAXEL FORMULATIONS.

ADDITIONAL WARNINGS

- The use of ABRAXANE has not been studied in patients with renal dysfunction. In the randomized controlled trial, patients were excluded for baseline serum bilirubin >1.5 mg/dL or baseline serum creatinine >2 mg/dL

Pregnancy-Teratogenic Effects: Pregnancy Category D

- ABRAXANE can cause fetal harm when administered to a pregnant woman

- If this drug is used during pregnancy, or if the patient becomes pregnant while receiving this drug, the patient should be apprised of the potential hazard to the fetus

- Women of childbearing potential should be advised to avoid becoming pregnant while receiving treatment with ABRAXANE

Use in Males:

- Men should be advised to not father a child while receiving treatment with ABRAXANE Albumin (human):

- ABRAXANE contains albumin (human), a derivative of human blood

PRECAUTIONS

Drug Interactions:
- No drug interaction studies have been conducted with ABRAXANE

- Caution should be exercised when administering ABRAXANE concomitantly with medicines known to inhibit or induce either CYP2C8 or CYP3A4 Hematology:

- ABRAXANE therapy should not be administered to patients with baseline neutrophil counts of less than 1,500 cells/mm$^3$

- It is recommended that frequent peripheral blood cell counts be performed on all patients receiving ABRAXANE

- Patients should not be retreated with subsequent cycles of ABRAXANE until neutrophils recover to a level >1,500 cells/mm$^3$ and platelets recover to >100,000 cells/mm$^3$

- In the case of severe neutropenia (<500 cells/mm3 for 7 days or more), during a course of ABRAXANE therapy, a dose reduction for subsequent courses of therapy is recommended

Nervous System:

- Sensory neuropathy occurs frequently with ABRAXANE

- The occurrence of grade 1 or 2 sensory neuropathy does not generally require dose modification

- If grade 3 sensory neuropathy develops, treatment should be withheld until resolution to grade 1 or 2 followed by a dose reduction for all subsequent courses of ABRAXANE

Hepatic Impairment:

- Because the exposure and toxicity of paclitaxel can be increased with hepatic impairment, administration of ABRAXANE in patients with hepatic impairment should be performed with caution

- The starting dose should be reduced for patients with moderate and severe hepatic impairment

Injection Site Reaction:

- Injection site reactions occur infrequently with ABRAXANE and were mild in the randomized clinical trial

- Given the possibility of extravasation, it is advisable to closely monitor the infusion site for possible infiltration during drug administration

Nursing Mothers:

- It is not known whether paclitaxel is excreted in human milk

- Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants, it is recommended that nursing be discontinued when receiving ABRAXANE therapy

Ability to Drive and Use Machines:

- Adverse events such as fatigue, lethargy, and malaise may affect the ability to drive and use machines

ADVERSE EVENTS

- Severe cardiovascular events possibly related to single-agent ABRAXANE occurred in approximately 3% of patients in the randomized trial

- These events included chest pain, cardiac arrest, supraventricular tachycardia, edema, thrombosis, pulmonary thromboembolism, pulmonary emboli, and hypertension

- Cases of cerebrovascular attacks (strokes) and transient ischemic attacks have been reported rarely
During postmarketing surveillance, rare reports of congestive heart failure and left ventricular dysfunction were observed, primarily among individuals with underlying cardiac history or prior exposure to cardiotoxic drugs.

In the randomized metastatic breast cancer study, the most important adverse events included alopecia (90%), neutropenia (all cases 80%; severe 9%), sensory neuropathy (any symptoms 71%; severe 10%), asthenia (any 47%; severe 8%), myalgia/arthralgia (any 44%; severe 8%), anemia (all 33%; severe 1%), nausea (any 30%; severe 3%), diarrhea (any 27%; severe <1%) infections (24%), vomiting (any 18%; severe 4%), and mucositis (any 7%; severe <1%).

Other adverse reactions have included ocular/visual disturbances (any 13%; severe 1%), renal dysfunction (any 11%; severe 1%), fluid retention (any 10%; severe 0%), hepatic dysfunction (elevations in bilirubin 7%, alkaline phosphatase 36%, AST [SGOT] 39%), hypersensitivity reactions (any 4%; severe 0%), cardiovascular reactions (severe 3%), thrombocytopenia (any 2%; severe <1%), and injection site reactions (<1%). In clinical trials and during postmarketing surveillance, dehydration was common and pyrexia was very common. Rare occurrences of severe hypersensitivity reactions have also been reported during postmarketing surveillance.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS.

About Non-small cell lung cancer

Non-small cell lung carcinoma (NSCLC) is any type of epithelial lung cancer other than small-cell lung carcinoma (SCLC). As a class, NSCLCs are relatively insensitive to chemotherapy, compared to small-cell carcinoma. When possible, they are primarily treated by surgical resection with curative intent, although chemotherapy is increasingly being used both pre-operatively (so-called "neoadjuvant chemotherapy") and post-operatively ("adjuvant chemotherapy").

About Celgene International Sàrl

Celgene International Sàrl, located in Boudry, in the Canton of Neuchâtel, Switzerland, is a wholly owned subsidiary and international headquarters of Celgene Corporation. Celgene Corporation, headquartered in Summit, New Jersey, is an integrated global pharmaceutical company engaged primarily in the discovery, development and commercialization of innovative therapies for the treatment of cancer and inflammatory diseases through gene and protein regulation. For more information, please visit the Company's website at www.celgene.com.

This release contains certain forward-looking statements which involve known and unknown risks, delays, uncertainties and other factors not under the Company's control. The Company's actual results, performance, or achievements could be materially different from those projected by these forward-looking statements. The factors that could cause actual results, performance, or achievements to differ from the forward-looking statements are discussed in the Company's filings with the Securities and Exchange Commission, such as the Company's Form 10-K, 10-Q and 8-K reports. Given these risks and uncertainties, you are cautioned not to place undue reliance on the forward-looking statements.

SOURCE: Celgene International Sàrl

Celgene International Sàrl
Kevin Loth, +41 32 729 86 21
Director of External Relations