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Two Clinical Studies Evaluating Benefits of ABRAXANE® Combinations in Patients with Unresectable Melanoma Presented at ASCO

Studies report one-year survival rates of nearly 60%

BOUDRY, Switzerland, Jun 06, 2011 (BUSINESS WIRE) --

Celgene International Sàrl (Nasdaq:CELG) today announced that results from two investigator initiated studies including ABRAXANE (paclitaxel albumin-bound particles for injectable suspension), and bevacizumab in unresectable melanoma were presented at the 2011 American Society of Clinical Oncology Annual Meeting in Chicago, IL.

In the first study, patients were given either ABRAXANE (100 mg/m^2) on days 1, 8 and 15 carboplatin (AUC 6 IV) on day 1 and bevacizumab (10 mg/kg IV) on days 1 and 15, each of a 28 day cycle (n=51); or temozolomide (200 mg/m^2) on days 1-5 and bevacizumab (10 mg/kg IV) on days 1 and 15 of a 28 day cycle (n=42). The two arms were run independently. Starting doses were reduced following an addendum to the study: ABRAXANE was lowered to 80 mg/m^2 and carboplatin to AUC 5. For both arms, 6-month progression-free survival rate was the primary endpoint.

After a median 4-cycles of therapy (range 1-27+), the 6-month progression free survival (PFS) rate for patients in the ABRAXANE arm was 54.9% (95% CI; 42.8%-70.4%) and the one-year PFS rate was 27.5% (95% CI: 17.6%-42.9%). Median PFS for patients in the ABRAXANE arm was estimated to be 6.6 months and the median overall survival (OS) was estimated to be 13.9 months. The 12-month survival rate was 58.1% (95% CI: 45.9%-73.6%). The confirmed response rate was 33.3%.

In the temozolomide arm, patients received a median 4-cycles of therapy (range 1-30+). The 6-month PFS rate was 32% (95% CI; 20.5-50.1%). Median PFS for patients in the temozolomide arm was estimated at 3.8 months and the median OS was 12.3 months.

The most common grade 3 or higher adverse events in the ABRAXANE arm (following addendum) were neutropenia (43%), leukopenia (26%), thrombocytopenia (17%) and anemia (17%). In the temozolomide arm, the most common grade 3 or higher adverse events were vomiting (12%), fatigue (10%), leukopenia (10%) and neutropenia (10%).

In the second, single-arm study, patients received ABRAXANE (150 mg/m^2) on days 1, 8 and 15, and bevacizumab (10mg/m^2) on days 1 and 15 of a 28-day cycle (n=50).

The PFS rate at 4 months, which was the primary endpoint of the study, was 73%. The median PFS for patients in the study was 7.63 months (95% CI: 5.56 to 9.93 months). The median overall survival was 16.8 months (95% CI: 11.3 to 20.7 months). The 12-month survival rate was 62% and the 2-year survival rate was 30%. The response rate was 36.0%.

In the study, the most common grade 3 or higher adverse events related to study drug were neutropenia (20%), neuropathy (14%), mucositis (8%) and fatigue (6%).

These results are from investigational studies. ABRAXANE is not approved as a treatment for melanoma. CA033, a phase III, pivotal study of ABRAXANE versus DTIC for the initial treatment of over 500 patients with metastatic malignant melanoma is currently underway.

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

ABRAXANE® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) is indicatedfor 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/mm^3 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 Melanoma

Melanoma is a malignant tumor of melanocytes. Melanocytes are cells that produce the dark pigment, melanin, which is responsible for the color of skin. They predominantly occur in skin, but are also found in other parts of the body, including the bowel and the eye (see uveal melanoma). Melanoma can occur in any part of the body that contains melanocytes.

Melanoma is less common than other skin cancers. However, it is much more dangerous and causes the majority (75%) of deaths related to skin cancer. Worldwide, doctors diagnose about 160,000 new cases of melanoma yearly. The diagnosis is more frequent in women than in men and is particularly common among Caucasians living in sunny climates, with high rates of incidence in Australia, New Zealand, North America, and northern Europe. According to a WHO report about 48,000 melanoma related deaths occur worldwide per year.

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