Phase II results for CDP791 in non-small cell lung cancer support further clinical development

Results provide evidence of CDP791's biological activity. Positive trends were observed on several efficacy endpoints. Data are encouraging in supporting further clinical development of CDP791 in first line non-small cell lung cancer. UCB is evaluating partnership options.

Brussels (Belgium) - March 31, 2008 – 7 AM (CET) - UCB today announces first results of its phase II exploratory study of CDP791, a specific VEGFR-2/KDR inhibitor, in combination with carboplatin and paclitaxel chemotherapy in first line non-small cell lung cancer (NSCLC). Positive improvements were observed on several efficacy endpoints including tumour response rate and time to tumour progression. The data support further late stage clinical development of the drug in first line NSCLC. UCB will now work on the consequent clinical development plans and is evaluating partnership options.

The primary efficacy variable was tumour response rate as assessed by independent review. A 17.7% improvement in the tumour response rate was observed between the higher dose 20mg/kg CDP791 plus chemotherapy treatment arm (37.7%) and the chemotherapy alone treatment arm (20.0%).

The risk of tumour progression was reduced by 32% for patients receiving 20mg/kg CDP791 plus chemotherapy compared to chemotherapy alone. Patients who received 20mg/kg CDP791 plus chemotherapy had a median time to progression of 30.1 weeks compared to 27.3 weeks for patients receiving chemotherapy alone. While progression-free survival did not show a treatment effect in this exploratory Phase II trial, preliminary analysis of overall survival is sufficiently encouraging to support further development of the molecule.

About the trial design

This multi-centre trial was conducted in two parts and enrolled patients with locally advanced and metastatic (Stage IIIb or Stage IV) non-squamous NSCLC. In part one the tolerability of 10mg/kg and 20mg/kg CDP791 plus standard carboplatin and paclitaxel chemotherapy was assessed in two cohorts of patients. Both doses were well tolerated. In part two, 156 patients were randomized to one of three treatment arms; 20mg/kg CD791 plus chemotherapy, 10mg/kg CDP791 plus chemotherapy or chemotherapy alone for 6 cycles. Thereafter, eligible patients crossed over to CDP791 treatment alone. An independent Data Monitoring Committee reviewed an interim safety dataset and emerging safety data.

About CDP791

CDP791 is a PEGylated, humanised di-Fab fragment specifically inhibiting VEGFR-2 activation by its ligands VEGF-A, VEGF-C, VEGF-D. As CDP791 does not contain an Fc part, its activity is entirely due to its potent blocking ability. CDP791 binds specifically to VEGFR-2 and blocks all signaling through this receptor. This is a different mechanism of action from any of the marketed VEGF inhibitors and is a novel point of attack on the VEGF pathway. VEGFR-2 is a key component of the angiogenesis pathway involved in formation of new blood vessels supporting tumor growth.
CDP791 has been shown to potently inhibit binding of VEGF to VEGFR-2 in vitro, and has been shown to inhibit angiogenesis in pharmacological models.

About Non-Small Cell Lung Cancer (NSCLC)

According to the World Health Organization, there are more than 1.2 million cases worldwide of lung and bronchial cancer each year, causing approximately 1.1 million deaths annually. NSCLC is the most common form of the disease and accounts for roughly 80-85 percent of all lung cancer.

Further information

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About UCB

UCB (Brussels, Belgium) (www.ucb-group.com) is a global leader in the biopharmaceutical industry dedicated to the research, development and commercialization of innovative pharmaceutical and biotechnology products in the fields of central nervous system disorders, allergy/respiratory diseases, immune and inflammatory disorders and oncology. UCB focuses on securing a leading position in severe disease categories. Employing around 12 000 people in over 40 countries, UCB achieved revenue of 3.6 billion euro in 2007. UCB S.A. is listed on Euronext Brussels.

UCB Forward-Looking Statement

This news release contains forward-looking statements that involve risks and uncertainties, including statements with respect to the development and commercialization of CDP791. Among the factors that could cause actual results to differ materially from those indicated by such forward-looking statements are: the results of research, development and clinical trials; the timing and success of submission, acceptance, and approval of regulatory filings; the time and resources UCB devotes to the development and commercialization of CDP791 and the scope of UCB's patents and the patents of others.