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## Cabrellis Pharmaceuticals Initiates Phase II Study of Calsed™ in Small Cell Lung Cancer; Additional Clinical Data Presented at ASCO Annual Meeting

**SAN DIEGO, CA – June 5, 2006** – Cabrellis Pharmaceuticals Corporation today announced the initiation of a phase II clinical trial of its totally synthetic, next-generation anthracycline, Calsed™ (amrubicin), in small cell lung cancer (SCLC). This phase II study is an open-label, randomized trial designed to assess the safety and efficacy of Calsed™ in reference to topotecan in the second-line treatment of patients with SCLC who previously responded to platinum-based chemotherapy. Cabrellis will conduct the study at multiple clinical centers in the United States through the US Oncology network and at the Sidney Kimmel Cancer Center of Johns Hopkins University.

Cabrellis also announced that the results of two clinical studies of Calsed in relapsed or refractory SCLC, conducted in Japan, were presented as posters at the American Society of Clinical Oncology (ASCO) 42<sup>nd</sup> Annual Meeting in Atlanta, Georgia. Investigators who conducted the studies presented data on the use of amrubicin in patients with relapsed or refractory SCLC. These two longitudinal studies of Calsed™ demonstrated notably high response rates in patients with relapsed or refractory SCLC, suggesting the drug's promise in second-line therapy in addition to its current first-line use in Japan.

“We are delighted to initiate the clinical investigation of Calsed™ in the US, and we are energized by the new data presented at ASCO,” said Thomas M. Estok, president and CEO of Cabrellis. “Proof of concept for Calsed™ in relapsed and refractory SCLC has been established through three independent clinical studies conducted in Japan. We hope to confirm this striking activity in our US trial and we look forward to bringing this new potential option to lung cancer patients.”

"The effectiveness of chemotherapy for patients with small cell lung cancer has been on a plateau for over a decade," said Mark R. Green, M.D., clinical professor of medicine at the Medical University of South Carolina. "Among patients with extensive disease at presentation and for relapsed patients, the outlook is poor. The activity of amrubicin demonstrated by Japanese investigators is extremely encouraging. It is terrific that this agent is now being evaluated for US patients."

### **Abstract #7060**

Results from a longitudinal study of amrubicin in SCLC patients previously treated with at least one platinum-based chemotherapy were presented. In total, 60 patients consisting of 44 sensitive patients and 16 refractory patients were enrolled. Patients received amrubicin (40mg/m<sup>2</sup>/day) on days 1-3 every 3

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weeks for 4 to 6 courses. The median number of treatment cycles was 4. The overall response rates were 52% (95% CI: 37%-68%) in the sensitive cases, and 50% (95% CI: 25%-75%) in the refractory cases. The progression-free survival, overall survival and 1-year survival in the sensitive and refractory cases were 4.0 and 3.2 months, 11.7 and 10.9 months and 48.2 and 37.8%, respectively.

Grade 3/4 hematological toxicities per patient were neutropenia (83%), thrombocytopenia (20%), and anemia (33%). Febrile neutropenia was observed in 3 patients. Grade 3/4 non-hematological toxicities per patient were pneumonia (3%), anorexia (15%), low Na levels (8.3%), pneumonitis (1.7%) and cerebral hemorrhage (1.7%). No treatment-related death was observed.

#### **Abstract #7061**

Results from a longitudinal study (June 2003 – January 2005) of amrubicin in 34 patients with refractory or relapsed SCLC were presented. Patients received amrubicin (45mg/m<sup>2</sup>/day) on days 1-3 every 3 weeks for 4 to 6 courses. Four courses or more were administered in 59% (20/34) of the patients, and dose reduction was required in 52% (15/29) of patients who received 2 courses or more. Four complete responses and 14 partial responses were observed, yielding a response rate of 53% (95% CI: 35.1%-70.2%). The median survival was 8.8 months and the 1-year survival rate was 26%.

Grade 3/4 leukopenia, neutropenia, and thrombocytopenia were observed in 76%, 97% and 38% of patients, respectively. Febrile neutropenia occurred in 12 patients (35%) and one patient died from treatment related pneumonia.

#### **About Calsed™**

Calsed™ (amrubicin hydrochloride) is a third generation, totally synthetic anticancer drug. In pre-clinical studies, amrubicin demonstrated a higher level of anti-tumor activity than conventional anthracycline drugs without exhibiting any indication of the cumulative cardiac toxicity common to this class of compounds. In clinical trials conducted in Japan, Calsed™ has been proven to be effective in patients with small cell lung cancer as well as non-small cell lung cancer. Dainippon Sumitomo launched Calsed™ in Japan in December 2002 and the drug has been administered to over 6000 patients without any reports of cumulative cardiotoxicity to date. Dainippon Sumitomo is conducting additional Calsed™ clinical trials in Japan in lung cancer and Non-Hodgkin's Lymphoma. Calsed™ is marketed in Japan as an injectable freeze-dried preparation, indicated for use in both non-small cell and small cell lung cancers. Cabrellis has the exclusive rights to develop and commercialize Calsed™ in North America and Europe, licensed from Dainippon Sumitomo Pharma of Osaka, Japan. Calsed™ is currently in Phase II clinical testing in the United States.

#### **About Cabrellis Pharmaceuticals**

Cabrellis is a specialty pharmaceutical company committed to the development of therapies for the treatment of cancer. The Company's lead product, Calsed™ (amrubicin), a third generation anthracycline and the world's first totally synthetic anthracycline drug, is currently in Phase II clinical testing in the United States. Further information regarding Cabrellis is available at [www.cabrellis.com](http://www.cabrellis.com).

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