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ONO PHARMACEUTICAL CO., LTD.

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Code No.:4528 at the 1st section of Tokyo / Osaka Stock Exchange
INQUIRIES: Kinya Morimoto, Executive Officer, Director, Corporate Communications

Announcement of the results from a Phase 2 study of "ONO-5163/KAI-4169": a calcium sensing receptor agonist

KAI Pharmaceuticals, Inc. (KAI) announced results from a Phase 2 study of "ONO-5163/KAI-4169", a calcium sensing receptor agonist being studied in end-stage renal disease patients on hemodialysis (Randomized, double-blind, placebo-controlled, dose-escalation study), at the annual meeting of the American Society of Nephrology (ASN) held on 12, November 2011 (local time) in Philadelphia, Pennsylvania, USA.
"ONO-5163/KAI-4169" is a novel long-acting intravenous (IV) peptide agonist of the calcium sensing receptor that is administered during hemodialysis. KAI is currently developing KAI-4169 for the treatment of secondary hyperparathyroidism (SHPT) in patients with ESRD.
Ono Pharmaceutical Co., Ltd. (Ono) is currently preparing for Phase I clinical studies in Japan based on the license agreement with KAI concluded in September 2011.

* In Japan, Ono is granted the rights to exclusively develop and commercialize KAI-4169, which is currently being developed in the United States by KAI.

KAI issued a press-release on the reporting the clinical study results to be presented at ASN as follows.

- ONO-5163/KAI-4169 5 mg (active drug 13 subjects, placebo 13 subjects) and 10 mg (active drug 21 subjects, placebo 21 subjects) were administered three times weekly by IV bolus during hemodialysis for up to four weeks.

- ONO-5163/KAI-4169 reduced parathyroid hormone (PTH) by 33% and 49% from baseline in the 5 mg and 10 mg dose groups, respectively. Both groups showed a significant reduction in PTH compared to the placebo group ($p < 0.05$). In the 10 mg dose group, 76% of subjects achieved ≥30% reduction in PTH, and 67% of subjects achieved a PTH ≤300 pg/mL at the end of the ONO-5163/KAI-4169 treatment period.

- ONO-5163/KAI-4169 was well-tolerated. The incidence of gastrointestinal adverse events such as nausea and vomiting in the ONO-5163/KAI-4169 treatment groups was similar to the placebo group and no patients discontinued therapy due to an adverse event. No subjects developed symptomatic hypocalcemia; the mean percentage change in serum calcium was -6% and -13% in the KAI-4169 5 mg and 10 mg dose groups at the end of the treatment period, respectively.

Geoffrey A. Block, M.D., Director of Clinical Research, Denver Nephrology, and a principal investigator in the Phase 2 study, stated, “KAI-4169 represents a new innovative therapeutic approach for the treatment of CKD-MBD. There is a consensus among clinicians that abnormalities in PTH, phosphorus and calcium contribute significantly to the morbidity experienced by patients with end-stage renal disease. I am pleased this novel IV CaSR peptide agonist resulted in profound and sustained control of PTH with excellent tolerability.”

Steven James, President and CEO of KAI, commented, “We are pleased with the momentum and continued progress of KAI-4169, the Company’s lead product candidate. We plan to initiate our second Phase 2 study by the end of this year. We believe KAI-4169 may satisfy important unmet needs in CKD and have important differentiating therapeutic and economic advantages over current therapies.”

Further Phase 1 data being presented at ASN demonstrated that single IV doses of KAI-4169 were safe and well-tolerated and resulted in sustained reductions in PTH in both healthy male subjects and ESRD patients with SHPT.

This is a brief summary of the press release issued by KAI on 11 November 2011 (the U.S. time) and the poster presented at ASN by KAI. The contents and interpretation of the original KAI English version will take precedence.
Attached is the press release made by KAI pertaining to the study results for your information.

KAI Pharmaceuticals Announces Late Breaker Poster Presentation of KAI-4169 Phase 2 Clinical Results at the American Society of Nephrology's Kidney Week 2011

Phase 2 Findings Show KAI-4169 Met the Study's Primary Efficacy Endpoint in Reducing Parathyroid Hormone Levels and Was Well-Tolerated

South San Francisco, CA — **November 11, 2011** — KAI Pharmaceuticals, Inc., a privately held drug discovery and development company, today announced that results from the Company's Phase 2 study of KAI-4169 will be presented in a late breaker poster presentation at the ongoing annual meeting of the American Society of Nephrology (ASN) on Saturday, November 12, 2011.

KAI-4169 a novel long-acting intravenous (IV) peptide agonist of the calcium sensing receptor (CaSR), is being developed for the treatment of secondary hyperparathyroidism (SHPT) in patients with chronic kidney disease-mineral and bone disorder (CKD-MBD). In a randomized, double-blind, placebo-controlled, dose escalation, Phase 2 study, KAI-4169 was administered three times weekly by IV bolus during hemodialysis for up to 4 weeks.

The clinical results demonstrated that KAI-4169 was highly effective in the treatment of SHPT with 33% and 49% reductions from baseline in the 5 mg and 10 mg dose groups, respectively ($P < 0.05$ vs. placebo for both dose groups). In the 10 mg dose group, 76% of subjects achieved ≥30% reduction in PTH, and 67% of subjects achieved a PTH ≤300 pg/mL at the end of the treatment period.

KAI-4169 was very well-tolerated. The incidence of GI adverse events was similar in the KAI-4169 and placebo treatment groups and no patients discontinued therapy due to an adverse event. No subject developed symptomatic hypocalcemia; the mean percentage change in serum calcium was -6% and -13% in the KAI-4169 5 mg and 10 mg dose groups at the end of the treatment period, respectively.

The Phase 2 study results are being presented in a poster titled, "Results of a Phase 2

Study Evaluating the Safety and Efficacy of KAI-4169, A Novel Peptide for the Treatment of Chronic Kidney Disease-Mineral and Bone Disorder in Hemodialysis Subjects" (Poster # LBCT-PO3147, Late Breaking Clinical Trials Poster session, 10:00 a.m. – 12:00 p.m., November 12, 2011).

Geoffrey A. Block, M.D., Director of Clinical Research, Denver Nephrology, and a principal investigator in the Phase 2 study, stated, "KAI-4169 represents a new innovative therapeutic approach for the treatment of CKD-MBD. There is a consensus among clinicians that abnormalities in PTH, phosphorus and calcium contribute significantly to the morbidity experienced by patients with end-stage renal disease. I am pleased this novel IV CaSR peptide agonist resulted in profound and sustained control of PTH with excellent tolerability."

Steven James, President and CEO of KAI, commented, "We are pleased with the momentum and continued progress of KAI-4169, the Company's lead product candidate. In September, we signed a deal with Ono Pharmaceutical for the development and commercialization of KAI-4169 in Japan, and we plan to initiate our second Phase 2 study by the end of this year. We believe KAI-4169 may satisfy important unmet needs in CKD and have important differentiating therapeutic and economic advantages over current therapies."

Previous Phase 1 data being presented at ASN demonstrated that single IV doses of KAI-4169 were safe and well-tolerated and resulted in sustained reductions in PTH in both healthy male subjects and end-stage renal disease (ESRD) patients with SHPT.

About CKD-MBD

In the U.S., there are roughly 600,000 and eight million patients with Stage 5 and Stage 3/4 CKD, respectively. Bone disease often develops early in CKD and worsens as renal function declines and the disease progresses. Most ESRD patients on dialysis are affected by CKD-MBD, which can lead to significant morbidity and mortality, including bone pain and fractures, vascular calcification and cardiovascular events.

About ASN Kidney Week

ASN Kidney Week 2011, the largest nephrology meeting of its kind, provides a forum for 13,000 professionals to discuss the latest findings in renal research and engage in educational sessions related to advances in the care of patients with kidney and related disorders. ASN Kidney Week 2011 is taking place November 8 – November 13 at the

Pennsylvania Convention Center in Philadelphia, PA. Founded in 1966, and with more than 12,000 members, ASN leads the fight against kidney disease by educating health professionals, sharing new knowledge, advancing research, and advocating the highest quality care for patients.

About KAI Pharmaceuticals

KAI is a clinical-stage, biopharmaceutical company with a lead peptide product candidate, KAI-4169, in development for the treatment of SHPT in patients with CKD-MBD. Building on promising, early-stage clinical data, KAI has advanced KAI-4169 into Phase 2 clinical testing in ESRD patients on dialysis.

Further, KAI recently entered into a partnership with Ono Pharmaceutical Co., Ltd. wherein Ono Pharmaceutical will develop and commercialize KAI-4169 in Japan. In addition, KAI is conducting preclinical research on pre-hemodialysis applications of KAI-4169.

KAI's leadership team has a strong background and track record in successful product development and commercialization. The Company is backed by a leading syndicate of venture investors, having raised $63 million in Series A and B rounds. KAI is headquartered in South San Francisco, California, and can be found online at www.kaipharma.com.

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