Media Release

For immediate release

Senz Oncology initiates VAL-1000 clinical trial in patients with acute leukaemias

MELBOURNE, AUSTRALIA: November 07, 2012 — Senz Oncology Pty Ltd ("Senz") announced today that the first patient has commenced treatment in a Phase I/II clinical evaluation of VAL-1000 in patients with acute leukaemias (protocol SO-2012-1).

The single-arm, open-label clinical trial will be conducted under the guidance of Principal Investigator, Dr Andrew Wei, Head of Leukaemia Services at The Alfred Hospital, Melbourne, Australia.

"We are very pleased to have Dr Wei as Principal Investigator for the VAL-1000 Phase I/II clinical trial," said Dr Ian Nisbet, Executive Director, Senz Oncology. "Dr Wei's input into the preclinical studies provided new scientific insights and the clinical rationale for VAL-1000 in acute leukaemias".

The primary objective of the trial is to evaluate the safety and tolerability of VAL-1000 in adult patients with acute leukaemias that are unsuitable for treatment with standard chemotherapy treatments.

The trial will also evaluate secondary objectives including assessing patient related efficacy outcomes, measuring VAL-1000 pharmacokinetics and defining a dose level for testing in subsequent Phase II clinical trials.

Approximately 900 patients are diagnosed with Acute Myeloid Leukaemia (AML) in Australia annually. The majority will relapse, especially those over the age of 60 and with poor risk cytogenetic and molecular characteristics. Patients falling into these categories have very limited treatment options once standard approaches have been exhausted.

According to Dr Anthony Filippis, Executive Director, Senz Oncology, "The trial will be the first time that VAL-1000 has been tested clinically for the treatment of acute leukaemias; if ultimately shown to be safe and efficacious it could provide a completely new treatment option for patients."

About Senz Oncology

Senz Oncology Pty Ltd (www.senzoncology.com) is a private drug development company leveraging the Australian regulatory framework and taxation environment to conduct time and cost effective development of new cancer therapies.

About VAL-1000

VAL-1000 is a synthetic derivative of a natural alkaloid. It has a history of safe use in humans but has not been tested previously in acute leukaemias. It is an orally bioavailable, small molecule drug that is active in vitro against both primary human leukaemia cells and leukaemia cell lines. VAL-1000 induces cell death of leukaemic cells by a mechanism of action that is distinct from other chemotherapeutic drugs.

About the SO-2012-1 clinical trial

SO-2012-1 is an open-label, Phase I/II clinical trial to evaluate VAL-1000 in acute leukaemias. It is being conducted at a single site, The Alfred Hospital, under the Clinical Trials Notification (CTN) scheme. Dr Andrew Wei is the Principal Investigator.

The primary objective of the trial is to evaluate the safety and tolerability of VAL-1000 in adult patients with acute leukaemias that are unsuitable for treatment with standard chemotherapy treatments. Eligible patients include patients with acute myeloid leukaemia (AML), acute lymphocytic leukaemia (ALL) or high risk myodysplastic syndrome (MDS) who are unsuitable for treatment with standard chemotherapeutic regimens, such as patients who are elderly (>70 years), poor risk (adverse risk karyotype) or who have failed up to three lines of intensive chemotherapy.

The trial will also evaluate secondary objectives including assessing patient related efficacy outcomes, measuring VAL-1000 pharmacokinetics and defining a dose level for testing in subsequent Phase II clinical trials.

The study design includes a dose escalation component (four dose levels of three to six patients) to identify a maximum tolerated dose (MTD), followed by an expansion of the MTD patient cohort. Patients will be able to receive up to 48 weeks of treatment with VAL-1000. Up to 30 evaluable patients will be enrolled in the trial.

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