Astex Granted Orphan Drug Status for AT9283 in AML in USA and Europe

Cambridge, UK, 23rd November 2009

Astex Therapeutics announced today that it has been granted orphan-drug designation by the U.S. Food and Drug Administration for AT9283, its combinatorial oncogenic kinase inhibitor, for the treatment of patients with Acute Myeloid Leukaemia (AML). The Company also confirmed that AT9283 was recently granted an Orphan Medicinal Product Designation by the European Commission for the same indication following a positive opinion from the European Medicines Agency (EMEA) Committee for Orphan Medicinal Products in October. Orphan drug legislation in Europe and the United States provides specific incentives for sponsors to develop products for rare diseases such as AML.

Astex is currently completing the enrollment of patients in a Phase I/IIa trial of AT9283 in patients with leukemia at two clinical sites in the USA. The potential value of AT9283 in AML is supported by the observation that approximately one third of the relapsed or refractory AML patients treated in this study have shown a reduction in bone marrow blasts and evidence of hematological improvement. This group of patients had either failed or were unsuitable for multiple lines of standard therapy. Astex has also completed a Phase I study of AT9283 in patients with refractory solid tumours, and is conducting a further Phase I study in patients with refractory solid tumours in partnership with the Clinical Trials Group of the National Cancer Institute of Canada. Further clinical studies are also currently underway and being planned with Cancer Research UK to investigate the use of AT9283 as a treatment for children and adolescents with solid tumours and leukemias and with the National Cancer Institute of Canada as a treatment for patients with multiple myeloma.

If AT9283 is approved for the treatment of patients with AML in the U.S. or in Europe, orphan drug designation could provide Astex with potential market exclusivity for ten years in Europe and seven years in the U.S. Orphan drug designation also allows for Astex to seek scientific advice and guidance from the EMEA in optimizing the clinical development of AT9283. In addition, a drug candidate designated by the FDA and EMEA as an orphan-drug product may qualify for subsidies on regulatory fees and tax incentives and may be eligible for research grant funding to assist in further clinical development.

Harren Jhoti, Chief Executive Officer of Astex Therapeutics, said, “The orphan drug designations for AT9283 underscore the high unmet medical need faced by patients with AML where only a minority of patients are currently cured of their disease. We are hopeful that we can build on the early evidence of clinical efficacy with AT9283 and translate this into new treatment opportunities for patients with AML.”

About Astex Therapeutics

Astex is a UK-based biotechnology company that discovers and develops novel small molecule therapeutics. Using its pioneering fragment-based drug discovery platform Pyramid™, Astex has built a pipeline of five molecularly targeted oncology drugs, of which three are currently being tested in clinical trials and two are in pre-clinical development.

In addition to its proprietary research programmes, Astex’s productivity in lead discovery has been endorsed through numerous partnerships with major pharmaceutical companies, including AstraZeneca, Bayer-Schering, Boehringer Ingelheim, GlaxoSmithKline, Novartis and Johnson & Johnson.

For further information on Astex please visit the Company’s website at www.astex-therapeutics.com

About Orphan Drug Designation

Orphan drug legislation is intended to encourage pharmaceutical companies to develop drugs for diseases that have a small market. Under the legislation in the European Union and the Unites States of America, companies that develop an designated orphan drug for a disorder affecting fewer than 200,000 people in the U.S. and no more than five in 10,000 persons in the European Union may sell it without competition for a specified number of years (7 in the US and 10 in Europe) and may receive additional benefits from government and the regulatory authorities in the form of tax incentives, regulatory fee subsidies and specific assistance with clinical trial design and protocol development.

The US Orphan Drug Act (ODA) of January 1983 is administered by the US FDA while in the European Union orphan drug legislation is administered by the Committee on Orphan Medicinal Products of the European Medicines Agency (EMEA). In an

effort to reduce the burden on manufacturers applying for orphan drug status, the FDA and EMEA agreed in late 2007 to utilize a common application process for both agencies, although the two agencies continue to maintain separate approval processes.