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Astex, the fragment-based drug discovery and development company, today announced that the United States Food and Drug Administration (FDA) has approved its Investigational New Drug (IND) application for the clinical development of its proprietary cell cycle inhibitor, AT7519, for the treatment of cancer. AT7519 was discovered and developed internally using Astex's fragment-based drug discovery platform, Pyramid™, and progressed from first synthesis to regulatory approval in just 14 months. The Company is in the process of initiating a multi-centre Phase I trial of AT7519 in patients with refractory solid tumours in the US and in the UK.

The IND approval closely follows that of Astex's Clinical Trial Authorisation (CTA) application for AT7519 by the UK Medicines and Healthcare Products Regulatory Agency (MHRA). The Phase I study will be conducted at the Arizona Cancer Center under the direction of Dr Daniel Von Hoff and Dr Daruka Mahadevan and at the Northern Institute for Cancer Research at the University of Newcastle upon Tyne under the direction of Professor Hilary Calvert, who is the International Co-ordinating Principle Investigator.

"We are very pleased to have been given the go-ahead by the regulatory authorities both in the US and in the UK to advance AT7519 into clinical development and to be working with some of the world's leading cancer experts on our Phase I study. We are now putting the final preparations in place to begin the clinical trial of AT7519 in the coming weeks," said Dr Harren Jhoti, Chief Scientific Officer of Astex.

Editor's notes:

AT7519

AT7519 is Astex's most progressed drug candidate and is anticipated to enter Phase I clinical trials mid 2005. AT7519 is a potent cell cycle inhibitor that targets key Cyclin Dependent Kinases (CDKs) resulting in tumour shrinkage

CDKs are regulatory proteins of the eukaryotic cell cycle. They act, after association with a number of different cyclins throughout the progression of the cell cycle, as central mediators of cell division. Inhibition of CDKs could allow disruption of the cell cycle, evoking an anti-proliferative effect that may be useful as an intervention in the treatment of cancer and other diseases characterized by the rapid proliferation of cells

About Astex

Astex is a biotechnology company producing novel small molecule therapeutics. Using its pioneering fragment-based drug discovery approach, Astex has rapidly established a broad pipeline of next generation, molecularly targeted oncology drugs, the first of which is about to enter clinical trials.

Astex's leading position in fragment-based drug discovery derives from its integrated discovery engine, Pyramid™. High throughput X-ray crystallography is used to identify drug fragments bound to target proteins and to transform the fragments, using efficient medicinal chemistry, into potent, selective lead compounds. Pyramid™ has been successfully applied across a wide variety of therapeutic targets, including those regarded as 'intractable' by the pharmaceutical industry, resulting in lead compounds for the potential treatment of cancer, inflammation and Alzheimer's disease.

Astex's unprecedented productivity in lead discovery has been endorsed by drug discovery alliances with major pharmaceutical companies including AstraZeneca, Sanofi-Aventis, Boehringer Ingelheim, Astellas Pharma, Mitsubishi Pharma and Schering AG. Astex was established in 1999 and is well financed by leading, blue chip US and European investors (Abingworth, Advent International, Alta Partners, Apax, GIMV, HypoVereinsbank, Oxford Bioscience Partners, Schering AG and the University of

Cambridge).

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