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Cambridge, UK, May 23 2005.

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Astex, the fragment-based drug discovery and development company, today announced that the UK Medicines and Healthcare Products Regulatory Agency (MHRA) has approved its Clinical Trial Authorisation (CTA) application for the clinical development of its proprietary cell cycle inhibitor, AT7519, for the treatment of cancer. The Company now plans to initiate a multi-centre Phase I trial of AT7519 in patients with refractory solid tumours.

Astex also announced that it has selected two further drug candidates, AT9283 and AT9311 from its internal oncology pipeline. Both novel drugs recently entered formal preclinical development in advance of anticipated IND and CTA filings within 9 months. All three of Astex's drug candidates were discovered using the company's proprietary fragment-based drug discovery platform, Pyramid™.

"We are very pleased to advance AT7519 into clinical development in such a rapid timeframe having gone from first synthesis of this compound to CTA approval in just 14 months - less than half the industry average. This approval is an important milestone for Astex as a clinical stage biotechnology company taking the first compound from its own pipeline of novel cancer drugs into the clinic. Together with our two other drug candidates, AT9283 and AT9311, it also exemplifies the potential of our fragment-based drug discovery platform to rapidly generate high value assets," said Dr. Harren Jhoti, Chief Scientific Officer of Astex.

Tim Haines, Chief Executive, remarked, "This announcement marks a major achievement for the company and establishes Astex as one of a limited number of biotechnology companies that have built a validated 'platform to products' capability. Our ability to rapidly and consistently generate multiple drug candidates ensures a sustainable pipeline of novel drug products for the treatment of cancer and other diseases and underscores the significant investment opportunity that Astex represents."

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 resulting in tumour shrinkage in a range of tumour xenograft models.

Cyclin-dependent kinases (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.

AT9283

AT9283 is an inhibitor of mitosis (cell division) that is currently in formal preclinical development. AT9283 is the second most progressed drug candidate in the Astex portfolio with an IND/CTA filing planned for late 2005. AT9283 is a potent inhibitor of the Aurora kinases and has been shown to arrest tumour growth in a range of tumour models. Aurora kinases play a key role in mitotic checkpoint control in cell division. Both Aurora A and B are over-expressed in many human tumours and are believed to be excellent targets for anti-cancer therapy.

AT9311

AT9311 is a cell cycle inhibitor with a differentiated biological profile to AT7519. AT9311 inhibits selected Cyclin Dependent Kinases and has been shown to arrest tumour growth in xenograft models. An IND/CTA filing is planned for early 2006.

Each of Astex's drug candidates has been designed to target either a single protein or a group of key proteins implicated in the pathology of a specific cancer and thereby defining a distinct 'molecular signature'. These drug molecules are expected to exhibit differentiated clinical profiles and so improve the success rates of developing novel treatments for cancer.

The company is currently involved in discussions with pharmaceutical and biotechnology companies regarding both pre-clinical and clinical-stage out-licensing. Astex seeks to retain significant commercialization rights to the compounds it has developed in addition to upfront cash, research and development funding, success-based milestones payments and royalties on products sold.

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 Inc. (formerly Fujisawa), 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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Source: Astex Pharmaceuticals, Inc.