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Astex Pharma cancer drug receives US marketing approval

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Astex Pharmaceuticals, a pharmaceutical company dedicated to the discovery and development of novel small molecule therapeutics for oncology and diseases of the central nervous system, announced that its long-standing pharmaceutical collaborator, Novartis, has received US Food and Drug Administration (FDA) marketing approval for Kisqali (ribociclib, formerly known as LEE011) plus an aromatase inhibitor as a first-line treatment in post-menopausal women with hormone receptor positive, human epidermal growth factor receptor-2 negative (HR+/HER2-) advanced (metastatic) breast cancer.

Astex is eligible to receive a milestone payment in respect of this FDA marketing approval and on approval of additional regulatory filings in Europe and Japan, as well as royalty payments on annual sales of Kisqali, under the drug discovery alliance entered into between Astex and Novartis in 2005. The partnership was struck to discover cell cycle inhibitors which represented a novel class of compounds that target the mechanisms of cell division in order to prevent or interfere with cancer growth.

Under the collaboration, Astex scientists, based at the company's research laboratories in Cambridge UK, were responsible for solving the crystal structure of the key cancer target protein CDK4. This was an important scientific breakthrough that no other group had previously been able to achieve, leading to a peer-reviewed publication in PNAS. Working with the Novartis team at the Novartis Institutes for BioMedical Research (NIBR), Cambridge, Mass., USA, Astex then applied its structure-based drug discovery technology, part of its Pyramid platform, in the collaboration that led to the discovery of LEE011, (now known as Kisqali) which was then taken forward by Novartis into clinical trials. In total, a team of some 25 Astex scientists

were involved in this research program.

Kisqali (ribociclib) is a selective cyclin-dependent kinase inhibitor, a class of drug that helps slow the progression of cancer by inhibiting two proteins (CDK4 & CDK6) which, when over-activated, can enable cancer cells to grow and divide quickly.

Novartis received the approval under the FDA Breakthrough Therapy Designation and Priority Review programs, based on data from a first-line Phase III trial that met its primary endpoint at interim analysis, due to its superior efficacy compared to letrozole alone. The combination of Kisqali plus letrozole reduced the risk of disease progression or death by 44% over letrozole alone. There was a sustained separation of the progression free survival curves evident as early as 8 weeks and more than 53% of patients with measurable disease who took Kisqali plus letrozole saw their tumor size shrink by at least 30%. The combination also showed significant clinical benefit in all patient subgroups regardless of disease burden or tumour location.

Harren Jhoti, President and CEO of Astex, UK, said, "We're committed to the fight against cancer and so we are absolutely delighted that Novartis has received this first approval of a cancer drug arising from our productive collaboration. This milestone further validates the power of our Pyramid platform and the excellence of our science. It's a moment to celebrate when such ground-breaking scientific work results in a new treatment option for women with advanced breast cancer."