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Astex celebrates as breast cancer drug gets European marketing approval

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Astex Pharmaceuticals ("Astex"), a pharmaceutical company dedicated to the discovery and development of novel small molecule therapeutics for oncology and diseases of the central nervous system, announced today that its long-standing pharmaceutical collaborator, Novartis, has received marketing approval in Europe for Kisqali® (ribociclib) 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-) locally advanced or metastatic breast cancer.

Astex is eligible to receive a milestone payment in respect of the European marketing approval, as well as royalty payments on annual sales of Kisqali, under the drug discovery alliance entered into between Astex and Novartis in 2005.

Approval by the European Commission follows a positive opinion granted in June by the Committee for Medicinal Products for Human Use (CHMP). The positive CHMP opinion was based on superior efficacy and demonstrated safety of Kisqali plus letrozole versus letrozole alone in the pivotal Phase III MONALEESA-2 clinical trial of first-line ribociclib plus letrozole in hormone receptor-positive HER2-negative advanced breast cancer which showed that Kisqali plus letrozole reduced the risk of progression or death by over 44% over letrozole alone at interim analysis. In a subsequent analysis of the trial data, after nearly one year of additional follow-up, Kisqali plus letrozole demonstrated median progression-free survival (PFS) of 25.3 months and 16.0 months for letrozole alone. The European approval allows for oncologists to prescribe Kisqali with letrozole, anastrozole or with exemestane and to use their discretion to select the treatment choice they believe is best for each individual patient.

Harren Jhoti, President and CEO of Astex, UK, said, "We are delighted that Novartis has received European approval of Kisqali arising from our productive collaboration with the opportunity to bring a new treatment option to many more women in Europe with advanced breast cancer."

Astex received a milestone payment following the FDA approval of Kisqali in March 2017 and has received a first royalty payment from Novartis based on sales of Kisqali in the US, and is eligible to receive a milestone payment on approval of an additional regulatory filing in Japan.

Source:

http://astx.com/astex-pharmaceuticals-celebrates-as-cancer-drug-receives-marketing-approval-in-europe/