INVVESTIGATING TKI258

DOVITINIB

In HER2- and HR+ Breast Cancer

A multicenter, randomized, double-blind, placebo-controlled, phase II trial evaluating the safety and efficacy of dovitinib (TKI258) combined with fulvestrant in postmenopausal patients with HER2- and HR+ breast cancer that have evidence of disease progression on or after prior endocrine therapy.

Primary Endpoint
• Progression-free survival (PFS)

Secondary Endpoints
• Overall response rate (ORR)
• Duration of response (DOR)
• Overall survival (OS)
• Safety
• Time to worsening of ECOG performance status and other scales
• Assessment of pharmacokinetic concentrations of dovitinib (TKI258) and fulvestrant for repeated dose

For more information about study design or enrollment:
• For countries outside of the US, please contact your local Novartis Medical Representative
• Visit www.clinicaltrials.gov (NCT01528345)

*Protocol No. CTK258A2210; section 4.1

Dovitinib (TKI258) is an investigational compound. Efficacy and safety have not been established. There is no guarantee that dovitinib will become commercially available.

www.annonc.oxfordjournals.org
www.esmo.org
www.jsmo.or.jp