NEW CLINICAL TRIAL OPEN FOR INCLUSION

PROTOCOL TITLE

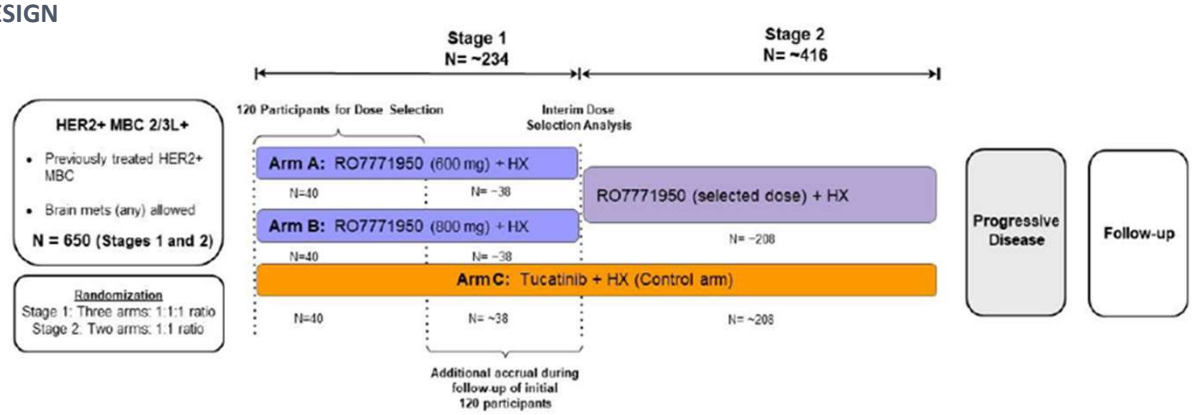
A two-part, seamless, multicenter, randomized, open-label, adaptive Phase II/III study of the blood-brain barrier penetrant RO7771950 versus Tucatinib, both in combination with Trastuzumab and Capecitabine, in patients with pretreated unresectable locally advanced or metastatic HER2-positive breast cancer, with or without central nervous system metastases

ALIAS	CTO NUMBER	SPONSOR
BREnna	CTO25068ROC	Roche

KEY ELIGIBILITY CRITERIA

- Voorbehandeling met minstens 1 lijn anti-HER2 therapie voor gevorderde ziekte of progressie binnen 12 maanden na (neo)adjuvant anti-HER2 ADC
- Voorbehandeling met anti-HER2 ADC (T-DXd of T-DM1) in (neo)adjuvante of gemetastaseerde setting
- Meetbare of evalueerbare ziekte (RECIST v1.1 en/of RANO-BM)
- Behandelde en klinisch stabiele onbehandelde hersen- en leptomeningeale metastasen toegestaan (indien onbehandeld letsel >2cm goedkeuring medical monitor vereist)
- Centrale bevestiging van HER2+ (gearchiveerd of vers weefsel)

DESIGN



2/3L+ = second line, third line, or beyond; HER2 = human epidermal growth factor 2; HX = trastuzumab plus capecitabine; MBC = metastatic breast cancer; mets = metastases.

Note: Stage 1 consists of participants recruited to contribute to the RO7771950 dose selection decision. Stage 2 consists of participants recruited after the RO7771950 dose selection decision, however both Stage 1 and Stage 2 participants contribute to the endpoint assessment to demonstrate the overall objective of superiority.

PRINCIPAL INVESTIGATOR

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