Additionally, current post and has similar activity to doses >30 mg. Treatment with any investigational therapy Availability of blood sample for ctDNA must also setting.

Advanced, symptomatic, visceral spread Early New therapy options are therefore needed Measurable disease (RECIST v.1.1) or evaluable While phase I SERD combination data in the post CDK4/6i setting are J Clin Oncol (locally advanced) LA/mBC, the acelERA BC study Endocrine therapy (ET) modulates estrogen synthesis and/or estrogen receptor SABCS 2021; P5 Clinical benefit rate Eligible pts (Table 1) are randomized 1:1 to giredestrant + everolimus or, and achieves high ER occupancy Study therapy is given until disease progression or unacceptable toxicity. The first interim overall survival analysis will be performed at the time of the and the author of this poster. BC For premenopausal or perimenopausal women, Patient This study is currently open for enrollment. Giredestrant has demonstrated greater potency in vivo than fulvestrant (the only currently approved SERD), and achieves high ER occupancy in vivo at all dose levels studied.

Epidemiological clinical studies have demonstrated that giredestrant has promising clinical and pharmacodynamic activity, and is well tolerated in ER+ HER2- either as a single agent or in combination with other endocrine therapies. The primary results of the phase II, randomized clinical trial of giredestrant in pts with ER+HER2- locally advanced (LA) BC, the acelera BC study (NCIT04056458), showed a clinical response rate in pts with physician’s choice of ET, with a more pronounced effect in pts with ER+ mutated tumors. While in phase II, SERD combination data in the post CDK4/6i setting is encouraging, there are no randomized combination data.15 Combining giredestrant and exemestane may potentially improve outcomes after CDK4/6is and in pts with ER+ mutated tumors, evIRA BC is investigating this combination to address the unmet need in the post-CDK4/6i settings. Further studies of giredestrant will be presented at SABCS (please see references).16

This is a phase II, randomised, open-label, multicentre study evaluating the efficacy and safety of giredestrant + exemestane vs exemestane + everolimus in pts with ER+/HER2- metastatic breast cancer (with or without brain metastases) with WHO performance status ≤1. Patients will be randomised 2:1 to giredestrant + exemestane + everolimus or exemestane + everolimus. The primary endpoint will be the proportion of pts with confirmed objective response, as defined by RECIST v1.1. Secondary endpoints include duration of response, time to disease progression, time to withdrawal due to lack of efficacy, best overall response rate and time to treatment discontinuation. Overall survival and safety will also be evaluated. Pts may receive up to 3 years of study treatment. This study is currently recruiting at 13 sites in the UK. The trial is sponsored by Resolved Therapeutics, Inc. All arms are supported by investigator initiated research. Pts are expected to be followed for 5 years for overall survival.

The objective of the study is to evaluate the efficacy of giredestrant + exemestane, alone or in combination with everolimus, in pts with ER+/HER2- metastatic breast cancer with brain metastases. The primary endpoint will be the proportion of pts with confirmed objective response, as defined by RECIST v1.1. Secondary endpoints include duration of response, time to confirmed disease progression, time to withdrawal due to lack of efficacy, best overall response rate and time to treatment discontinuation. Overall survival and safety will also be evaluated. Pts may receive up to 3 years of study treatment. This study is currently recruiting at 13 sites in the UK. The trial is sponsored by Resolved Therapeutics, Inc. All arms are supported by investigator initiated research. Pts are expected to be followed for 5 years for overall survival.