CHOA Clinical Trial Master List

BREAST CANCER:

D5336C00001: A Phase II, Open Label, Randomized, Multi-Centre Study to Assess the Safety and Efficacy of Agents Targeting DNA Damage Repair in Combination with Olaparib (Lynparza) versus Olaparib (Lynparza) Monotherapy in the Treatment of Metastatic Triple Negative Breast Cancer Patients Stratified by Alterations in Homologous Recombinant Repair (HRR)-related Genes (including *BRCA1/2*) (VIOLETTE)	
Sponsor: Astra Zeneca Arm A – Olaparib plus AZD1775 Arm B – Olaparib plus AZD6738 Arm C – Olaparib Alone **Must send tissue for HRR Gene Panel Testing** If BRCA 1-2 is known then can submit report in lieu of tissue	Therapy Line**: 2nd or 3rd Line Metastatic** Drug Classification: **Olaparib -** PARP inhibitor **AZD1775** – WEE 1 inhibitor; **AZD6738** - Ataxia Telangiectasia Inhibitor & Rad3 related protein ****Can sign consent for Part I to send tissue while on current treatment****
Principal Investigator: David Ellison, MD	**CRC:** Jacqueline Showalter ext. 293
Basic Enrollment Criteria: ECOG PS 0-1 within 28 days of randomization, Progressive cancer at the time of study entry, Histologically or cytologically confirmed TNBC with evidence of metastatic disease, Patients must have received at least 1 and no more than 2 prior lines of treatment for metastatic disease with an anthracycline (eg, doxorubicin, epirubicin) and/or a taxane (eg, paclitaxel, docetaxel) unless contraindicated, in either the neo-adjuvant, adjuvant or metastatic setting, Patients who have received platinum (cisplatin or carboplatin, either as monotherapy or in combination) for advanced breast cancer are eligible to enter the study provided there has been no evidence of disease progression during the platinum chemotherapy, Patients who have received prior platinum based chemotherapy are eligible if platinum was given either as potentially curative treatment for a prior non breast cancer (eg, ovarian cancer) with no evidence of disease for ≥5 years prior to study entry or as adjuvant/neoadjuvant treatment for breast cancer provided at least 12 months have elapsed between the last dose of platinum-based treatment and randomization, Confirmed presence of qualifying HRR mutation or absence of any HRR mutation in tumor tissue by the Lynparza HRR assay, at least one measurable lesion that can be accurately assessed at baseline by computed tomography (CT) (magnetic resonance imaging [MRI] where CT is contraindicated) and is suitable for repeated assessment as per RECIST 1.1. Patients must have a life expectancy of ≥16 weeks. **Exclusion criteria:** Cytotoxic chemotherapy, hormonal or non-hormonal targeted therapy within 21 days of Cycle 1 Day 1 is not permitted. Palliative radiotherapy must have been completed 21 or more days before Cycle 1 Day 1. The patient can receive a stable dose of bisphosphonates or denosumab for bone metastases, before and during the study as long as these were started at least 5 days prior to study treatment, More than 2 prior lines of cytotoxic chemotherapy for metastatic disease, Previous treatment with a PARP inhibitor (including olaparib) or other DDR inhibitor (unless treatment was for less than 3 weeks duration and at least 12 months have elapsed between the last dose and randomization. Patients that did not tolerate prior treatment are excluded). Exposure to a small molecule IP within 30 days or 5 half-lives (whichever is longer) prior to randomization. The minimum washout period for immunotherapy shall be 42 days.	

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INO-VT-464-CL-006: A Phase 1/2 Open-Label Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Efficacy of VT-464 in Patients with Advanced Breast Cancer	
Sponsor: Innocrin Precision Patient type: As of 11Jan18 *** Cohort 3: Male ER(+) BC Patients** o If a patient has local AR+ results, they do not need to sign the Screening consent, but they still must have tissue submitted to the central lab for AR staining o Locally confirmed AR+ patients do not have to wait on the results from the central lab to begin treatment o Patients with unknown AR status must have AR positivity confirmed prior to enrollment (this can be done locally or through the central lab); if performed locally, tissue must also be submitted to the central lab**	Drug Classification: **Lyase selective inhibitor of CYP17** **Patient may start a line of therapy while waiting for AR status to be confirmed. There must be a 2 week wash prior to starting VT-464.**
Principal Investigator: David Ellison, MD	**CRC:** Ashley Morrill ext. 291
Basic Enrollment Criteria: Patients must have documented histological or cytological evidence of invasive cancer of the breast. Measureable disease is not required. Phase 1 patients must have TNBC normal breast cancer and Phase 2 patients must have AR(+) TNBC or ER(+) HER2 normal breast cancer. ECOG PS of 0 or 1. **Exclusion**: Patients who have received anti-androgens within 4 weeks of study entry. Patients who have received palliative radiotherapy within 4 weeks of study entry. Patients who have received any other therapeutic treatment for breast cancer within 2 weeks of study entry, except for LHRH agonists or antagonists in patients undergoing ovarian suppression enrolled in the Female ER(+) BC cohort and patients undergoing gonadal suppression enrolled in the Male ER(+) BC cohort. Patients with bone metastases who have initiated denosumab or bisphosphonate therapy within 28 days of Cycle 1 Day 1.	

CX-839-007: A Multicenter Phase 2 Study of the Glutaminase Inhibitor CB-839 in Combination with Paclitaxel (Taxol) in Patients with Advanced Triple Negative Breast Cancer (TNBC) Including Patients of African Ancestry and Non-African Ancestry	
Sponsor: Calithera	Therapy Line: Cohort 1 – 3rd line or greater African Ancestry Cohort 2 – 1st Line Metastatic African Ancestry Cohort 3 – 3rd Line + Metastatic Non-African Cohort 4 – 1st Line Metastatic Non-African Drug Classification: **Glutaminase Inhibitor**
Principal Investigator: James M. Orcutt, MD	**CRC:** Ashley Morril ext. 291
Basic Enrollment Information Criteria: TNBC, defined as ER and PR negative (< 1% by immunohistochemistry) and HER2-negative (immunohistochemistry 0 to 1+ or fluorescence *in situ* hybridization [FISH] negative). Metastatic disease or locally-advanced disease not amenable to curative intent treatment. ECOG 0-1. Estimated Life Expectancy of at least 3 mo. **Cohort 1:** Patients must self-identify as African ancestry (AA; includes African American). At least 2 prior lines of systemic therapy for advanced/metastatic disease including a taxane. Prior taxane (paclitaxel, docetaxel, or nab-paclitaxel) for advanced/metastatic disease is required but must not have been received in the immediate prior line of therapy. Systemic neoadjuvant and/or adjuvant therapy is considered a line of therapy for advanced/metastatic disease if the time to recurrence from completion of treatment was ≤ 12 mo. **Cohort 2 - African ancestry 1st line Metastatic**: Patients must self-identify as African ancestry (includes African American). No prior systemic therapy for advanced or metastatic disease. Systemic neoadjuvant or adjuvant therapy, including taxane, is allowed if time to recurrence was > 12 mo. **Cohort 3 – Non-African ancestry 3rd line+ Metastatic:** Patients do not self-identify as African ancestry. Otherwise have the same criteria as Cohort 1.**Cohort 4 – Non-African ancestry 1st line Metastatic:** Patients do not self-identify as African ancestry. Otherwise have the same criteria as Cohort 2. **Exclusion Criteria:** Prior treatment with CB-839, Receipt of any anticancer therapy within 4 weeks before C1D1 EXCEPT for the following: Targeted/small molecule or investigational therapy within 4 weeks or 5 halflives, whichever is shorter. Radiation therapy for bone metastasis within 2 weeks, any other external radiation therapy within 4 weeks before C1D1 or systemic treatment with radionuclides within 6 weeks before C1D1. Patients with clinically relevant ongoing complications from prior radiation therapy are not eligible. Any other current or previous malignancy within the past three years except a) adequately treated basal cell or squamous cell skin cancer, b) carcinoma *in situ* of the cervix, or c) other neoplasm that, in the opinion of the Principal Investigator and with the agreement of the Medical Monitor, will not interfere with study-specific endpoints. Known brain metastases or CNS cancer unless adequately treated with radiotherapy and/or surgery and stable by symptoms and radiographic imaging and not requiring corticosteroids for at least 2 mo before C1D1. **Cohort-specific Exclusion Criteria - Cohorts 1 and 3:** Taxane (paclitaxel, docetaxel or nab-paclitaxel) in the immediate prior metastaticline of therapy. **Cohorts 2 and 4:** Prior metastatic therapy	