

## **FAST FACTS**

### **WF 97116: A Phase 3 Randomized Placebo Controlled Clinical Trial of Donepezil in Chemotherapy Exposed Breast Cancer Survivors with Cognitive Impairment**

#### **Inclusion Criteria**

1. Women  $\geq 18$  years old with history of invasive breast cancer
2. Must have completed at least 4 cycles of adjuvant/neo-adjuvant cytotoxic chemotherapy between 1 and 5 years prior to enrollment (Ongoing herceptin or other chronic HER 2 directed therapies are allowed).
3. Patients receiving ongoing hormonal therapy for breast cancer must be on the same hormonal agent for at least 3 months prior to study enrollment and plan to continue for the duration of the study (9 months)
4. Use of psychotropic medications (anti-depressants, anxiolytics, sleeping aids, narcotics) is permitted (patient will be asked to list any that have been taken within the last 3 days on the recent medication sheet) if dose is stable over previous 12 weeks.
5. Self-reported cognitive problem plus a measured memory deficit (score  $\leq 7$  on single trial of Eligibility Pre-screen HVL-T-R Form C).
6. ECOG performance status 0-2
7. Ability to understand and the willingness to sign a written informed consent document.
8. Must be able to speak English.

#### **Exclusion Criteria**

1. Evidence or suspected recurrent or metastatic disease. Prior brain irradiation is not allowed.
2. Patients may not currently be taking Quinidine, Certinib, Highest Risk QTc-Prolonging Agents, MiFEPRISone, or Succinylcholine
3. History of dementia, Alzheimer's disease, multi-infarct dementia or CVA (history of transient ischemic attack (TIA is allowed)
4. Current use of donepezil, galantamine, rivastigmine, tacrine, memantine, methylphenidate, dextroamphetamine, or any other specific cognition enhancing drugs are not allowed. For patients who have used these medications they must not have used them within 4 weeks prior to enrollment.
5. History of allergic reactions attributed to compounds of similar chemical or biologic composition to donepezil. Hypersensitivity to donepezil.
6. Uncontrolled intercurrent illness including, but not limited to, ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, recent myocardial infarction, cardiac arrhythmia,
7. Traumatic brain injury, multiple sclerosis, acute severe fatigue, chronic fatigue syndrome or fibromyalgia.
8. Psychiatric illness/social situations that would limit compliance with study requirements including but not limited to a history of schizophrenia, psychosis or substance abuse.
9. Untreated current severe depression. Currently treated depression is permitted if treatment is stable.
10. Patients with bradycardia, seizure disorder or peptic ulcer disease (PUD)
11. Pregnant women are excluded from this study. The effects of donepezil on the developing human fetus at the recommended therapeutic dose are unknown. For this reason and because donepezil is known to be teratogenic, women of child-bearing potential must agree to use adequate contraception (hormonal or barrier method of birth control; abstinence) prior to study entry and

- for the duration of study participation. Should a woman become pregnant or suspect she is pregnant while participating in this study, she should inform her study physician immediately.
12. It is unknown whether donepezil is excreted in breast milk, for this reason women who are currently breast-feeding are not eligible for this study.

**SCHEMA**

