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A prospective, randomized, multicenter, double-blinded, placebo-controlled phase III trial of the HER2/neu peptide GP2 + GM-CSF versus bacteriostatic saline/WFI placebo as adjuvant therapy after any trastuzumab-based therapy in HER2-positive women with operable breast cancer

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BACKGROUND

GP2 is a biologic nine amino acid peptide of the HER2/*neu* protein delivered in combination with an FDA-approved immunoadjuvant Granulocyte-Macrophage Colony Stimulating Factor (GM-CSF, Sargramostim, Leukine) that stimulates an immune response targeting HER2/neu expressing cancers. In a prospective, randomized, single-blinded, placebo-controlled, multicenter Phase IIb clinical trial completed in 2018, no recurrences were observed in the HER2/neu positive adjuvant setting after median 5 years of follow-up, if the HLA 2+ patient received the 6 primary intradermal injections over the first 6 months ($p = 0.0338$) in a pre-specified subgroup analysis.

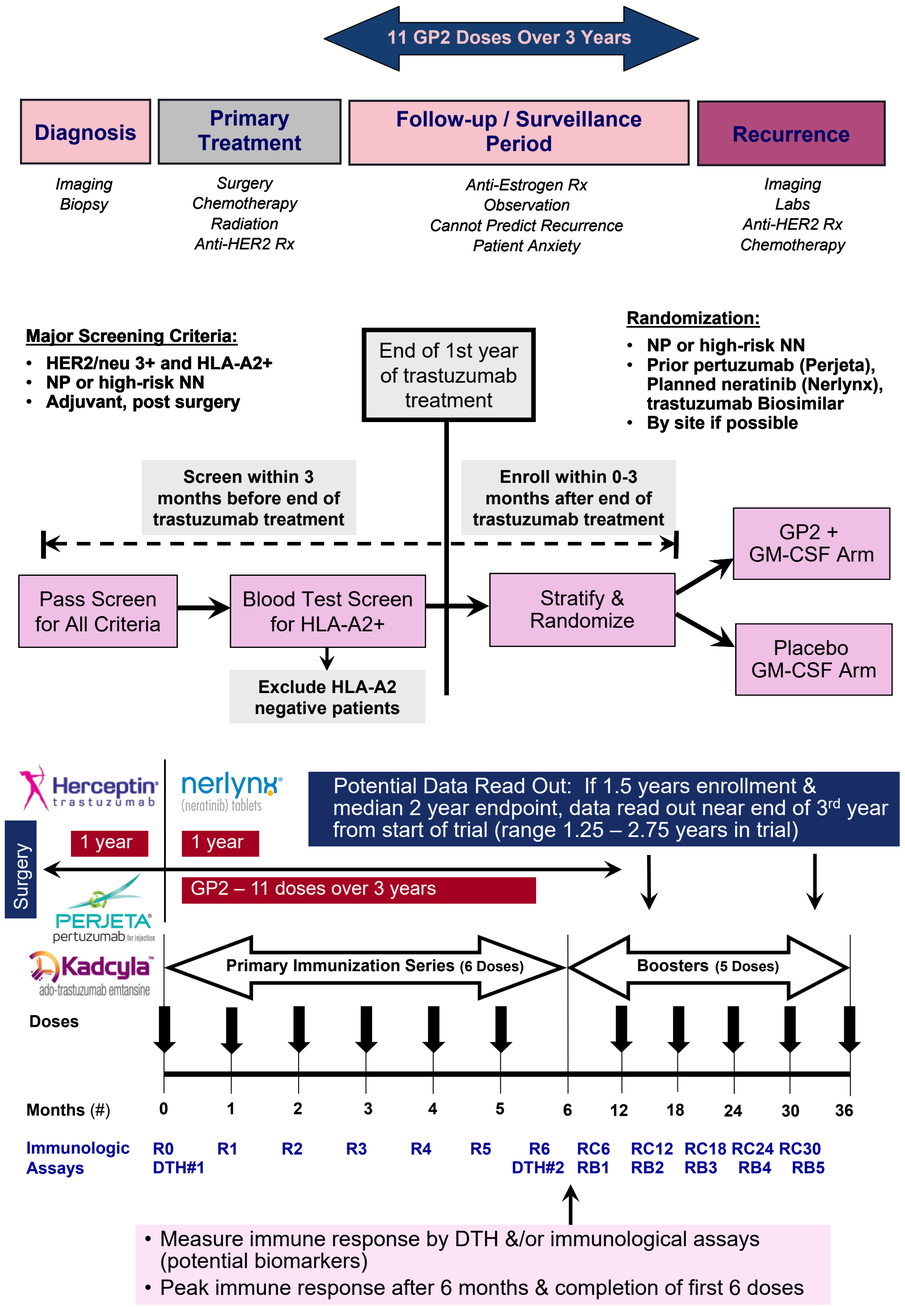
Furthermore, the GP2 immunotherapy elicited a potent immune response measured by local skin tests and immunological assays. Of the 138 patients that have been treated with GP2 to date over 4 clinical trials, GP2 treatment was well tolerated and no serious adverse events were observed related to the GP2 immunotherapy.

This Phase III trial aims to reproduce the Phase IIb study and will explore the use of GP2 + GM-CSF as adjuvant therapy to prevent the recurrence of breast cancer in HER2/neu positive and HLA 2+ patients, post-surgery and following the first year treatment with any trastuzumab-based therapy.

TRIAL DESIGN

This Phase III trial is a prospective, randomized, double-blinded, multi-center study. After 1 year of trastuzumab-based therapy or an approved biosimilar, treatment with GP2 + GM-CSF or placebo (Bacteriostatic Saline/WFI) will be administered intradermally for the 6 primary immunization series over the first 6 months and 5 subsequent boosters over the next 2.5 years for a total of 11 injections over 3 years of treatment. The participant duration of the trial will be 3 years treatment plus 2 years follow-up for a total of 5 years following the first year treatment with trastuzumab-based therapy or approved biosimilar. An interim analysis is planned and patients will be stratified based on prior and current treatments, among other factors.

SCHEMA



ELIGIBILITY CRITERIA

The majority of breast cancer patients will be HER2/neu positive and HLA 2+, disease-free, conventionally treated node-positive, post breast tumor removal surgery and following the first year treatment with trastuzumab-based therapy.

TRIAL OBJECTIVES

1. To determine if GP2 therapy reduces recurrence in HER2/neu positive breast cancer patients.
2. To monitor the in vitro and in vivo immunologic responses to GP2 therapy and correlate these responses with the clinical outcomes.
3. To monitor for any unexpected adverse events and toxicities related to GP2 therapy.

ACCRUAL

The target enrollment is up to approximately 500 patients, pending the planned interim analysis.

CONTACT INFORMATION

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