

# A prospective, randomized, multicenter, double-blinded, placebo-controlled phase III trial of the HER2/neu peptide GP2 + GM-CSF (GLSI-100) versus saline placebo as adjuvant therapy after trastuzumab-based therapy in HER2-positive women with operable breast cancer (FLAMINGO-01)

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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, no recurrences were observed in the HER2/neu positive adjuvant setting after median 5 years of follow-up, if the HLA-A\*02+ patient received the 6 primary intradermal GP2 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 immunotherapy 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 trial and will explore the use of GP2 + GM-CSF (GLSI-100) as adjuvant therapy to increase invasive disease-free survival in HER2/neu positive and HLA-A\*02+ patients, post-surgery and following the first year of treatment with any trastuzumab-based therapy.

Phase III Trial Status: Actively recruiting investigators and initiation of study is imminent.

## 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, 6 intradermal injections of GLSI-100 or saline placebo will be administered for the primary immunization series over the first 6 months and 5 subsequent boosters will be administered 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 1 additional year follow-up for a total of 4 years following the first year of treatment with trastuzumab-based therapy. An interim analysis is planned, and patients will be stratified based on prior and current treatments.

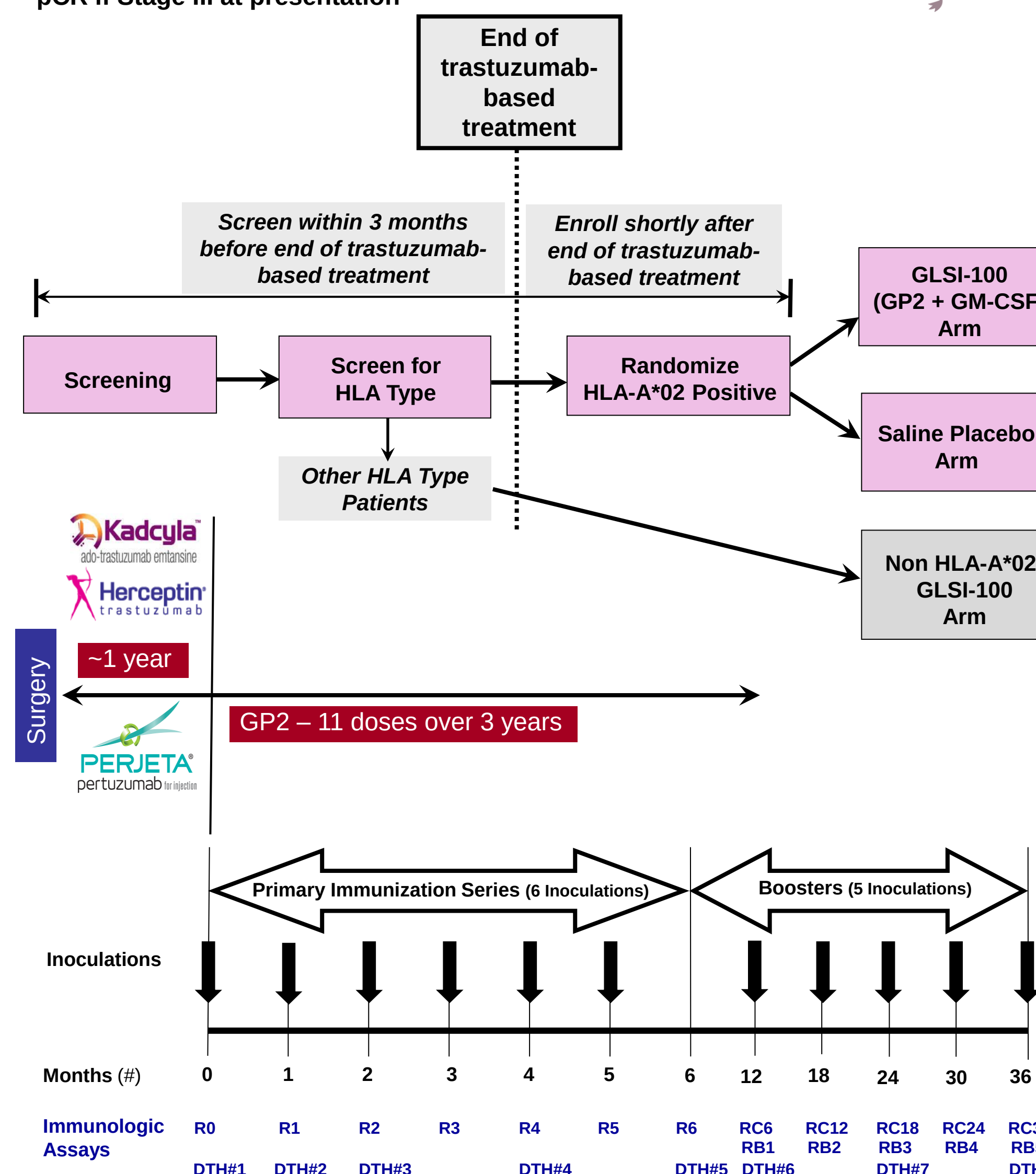
## FLAMINGO-01 SCHEMA

### Major Screening Criteria:

- HER2/neu Positive
- HLA-A\*02+
- Residual disease post neo-adjuvant therapy and surgery
- pCR if Stage III at presentation

### Stratified by:

- Residual disease/pCR
- Prior pertuzumab
- Geographic region



- Measure immune response by DTH and/or immunological assays (potential biomarkers)
- Peak immune response after 6 months and completion of first 6 doses

## PATIENT POPULATION

The patient population is defined by these key eligibility criteria:

- HER2/neu positive and HLA-A\*02+
- Residual disease or high risk pCR (Stage III at presentation) post appropriate neo-adjuvant therapy
- Exclude Stage IV
- Completed at least 70% of planned trastuzumab therapy

## TRIAL OBJECTIVES

1. To determine if GP2 therapy increases invasive disease-free survival (IDFS)
2. To assess the safety profile of GP2
3. To monitor immunologic responses to treatment and assess relationship to efficacy and safety

## STUDY SIZE – INTERIM ANALYSIS

Approximately 498 subjects will be enrolled. To detect a hazard ratio of 0.3 in IDFS, 28 events will be required. An interim analysis for superiority and futility will be conducted when at least half of those events, 14, have occurred. This sample size provides 80% power if the annual rate of events in placebo-treated subjects is 2.4% or greater.

## CONTACT INFORMATION

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