ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 07/23/2014

ClinicalTrials.gov ID: NCT00925548

Study Identification

Unique Protocol ID:	EMR 200038-010
Brief Title:	STRIDE - STimulating Immune Response In aDvanced brEast Cancer
Official Title:	A Randomized, Double-blind, Controlled Phase III Study of Stimuvax® (L-BLP25 or BLP25 Liposome Vaccine) in Combination With Hormonal Treatment Versus Hormonal Treatment Alone for First-line Therapy of Post-menopausal Women With Estrogen Receptor (ER)-Positive and/or Progesterone Receptor (PgR)-Positive, Inoperable Locally Advanced, Recurrent, or Metastatic Breast Cancer
Secondary IDs:	2008-005544-17 [EudraCT Number]

Study Status

Record Verification:	July 2014
Overall Status:	Terminated
Study Start:	September 2009
Primary Completion:	August 2010 [Actual]
Study Completion:	August 2010 [Actual]

Sponsor/Collaborators

Sponsor:	EMD Serono
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	Yes
Applicable Trial?:	Section 801 Clinical Trial? Yes Delayed Posting? No
IND/IDE Protocol?:	Yes
IND/IDE Information:	Grantor: CBER IND/IDE Number: BB-IND 7787 Serial Number: 121 Has Expanded Access? No
Review Board:	Approval Status: Approved Approval Number: ICO1-09-156 Board Name: Copernicus Group IRB Board Affiliation: Dana Farber Cancer Institute Phone: 888-303-2224 (toll-free) Email: irb@cgirb.com
Data Monitoring?:	Yes
Plan to Share Data?:	
Oversight Authorities:	United States: Food and Drug Administration Argentina: Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica Australia: Department of Health and Ageing Therapeutic Goods Administration Austria: Agency for Health and Food Safety Belgium: Federal Agency for Medicinal Products and Health Products Brazil: Ministry of Health Canada: Health Canada China: Food and Drug Administration Czech Republic: State Institute for Drug Control France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Germany: Paul-Ehrlich-Institut Greece: National Organization of Medicines Hungary: National Institute of Pharmacy India: Ministry of Health Ireland: Irish Medicines Board Israel: Ministry of Health Italy: The Italian Medicines Agency Mexico: Ministry of Health Netherlands: The Central Committee on Research Involving Human Subjects (CCMO) Norway: Norwegian Medicines Agency Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products Portugal: National Authority of Medicines and Health Products (INFARMED, I.P.) Russia: Ministry of Health of the Russian Federation

Slovakia: State Institute for Drug Control
South Africa: Department of Health
South Korea: Korea Food and Drug Administration (KFDA)
Spain: Spanish Agency of Medicines
Sweden: Medical Products Agency
Switzerland: Swissmedic
Taiwan: Department of Health
United Kingdom: Medicines and Healthcare Products Regulatory Agency

Study Description

Brief Summary: EMD Serono has decided to permanently terminate the trial EMR 200038-010 (STRIDE) in the indication of breast cancer following the clinical hold on the investigational new drug application for tecemotide (L-BLP25).

Detailed Description: The purpose of the study is to determine whether the addition of the experimental mucinous glycoprotein 1 (MUC1) antigen-specific cancer immunotherapy tecemotide (L-BLP25) to hormonal treatment is effective in prolonging progression-free survival in postmenopausal women with endocrine-sensitive inoperable locally advanced, recurrent or metastatic breast cancer.

Conditions

Conditions: Breast Cancer

Keywords: Phase III trial
randomized
cancer vaccine
MUC1
BLP25
advanced breast cancer
postmenopausal breast cancer
immunotherapy of breast cancer
Inoperable locally advanced, recurrent, or metastatic endocrine-sensitive Breast Cancer

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Intervention Model: Parallel Assignment

Number of Arms: 2

Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)

Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	16 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Investigational Arm Investigational Arm: • Pretreatment (Single Dose): 300 milligrams per square meter (mg/m^2) up to a maximum dose of 600 mg of intravenous cyclophosphamide • tecemotide (L-BLP25) plus Hormonal Therapy (Standard Dose)	Biological/Vaccine: Tecemotide (L-BLP25) and Hormonal Treatment Investigational Arm: Pretreatment (Single Dose) 300 mg/m^2 of intravenous cyclophosphamide in investigational arm to a maximum of 600 milligrams (mg). Primary treatment phase: Hormonal treatment plus 8 consecutive weekly subcutaneous vaccinations with tecemotide (L-BLP25) 1000 micrograms (actual delivered dose was 930 micrograms)* (Week 1 to 8). Maintenance treatment phase: Hormonal treatment plus vaccinations with tecemotide (L-BLP25) 1000 micrograms (actual delivered dose was 930 micrograms)* at six-week intervals beginning at Week 14 and continued until Progressive Disease (PD). *calculated as mass of lipopeptide (antigen) Drug: cyclophosphamide 300 mg/m^2 (to a maximum of 600 mg) of intravenous cyclophosphamide.
Active Comparator: Control Arm Control Arm: • Pretreatment (Single Dose): sodium chloride (NaCl) 9 grams per liter (g/L) infusion • Placebo plus Hormonal Therapy (Standard Dose)	Biological/Vaccine: Placebo of tecemotide (L-BLP25) and Hormonal Treatment Control Arm: Pretreatment (Single Dose) NaCl 9 g/L infusion as a substitute for cyclophosphamide. Primary treatment phase: Hormonal therapy plus 8 consecutive weekly subcutaneous placebo doses (Week 1 to 8). Maintenance treatment phase: Hormonal therapy plus placebo doses at six-week intervals beginning at Week 14 and continued until Progressive Disease (PD). Drug: sodium chloride (NaCl) NaCl 9 g/L infusion

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	18 Years
Maximum Age:	
Gender:	Female

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Postmenopausal women as defined in the protocol
- Estrogen receptor (ER)-positive and/or progesterone receptor (PgR)-positive, histologically or cytologically confirmed primary carcinoma of the breast
- Expressing at least one of the following five human leukocyte antigen (HLA) haplotypes, as centrally assessed by HLA genotyping from whole blood: HLA-A2, -A3, -A11, -B7, or -B35
- Locally advanced, recurrent, or metastatic breast cancer (Subject must have at least one lesion not located in bone)
- Measurable disease by Response Evaluation Criteria in Solid Tumors (RECIST), and inoperable
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- Adequate hematologic, hepatic, and renal function within two weeks prior to initiation of therapy, as defined by the protocol
- Other protocol-defined inclusion criteria may apply

Exclusion Criteria:

Disease Status

- PD either during hormonal therapy for early breast cancer (adjuvant therapy) or within 48 months from the initiation of such therapy
- Human epidermal growth factor receptor 2-positive (HER2+) breast cancer as defined in the protocol
- Autoimmune disease that in the opinion of the investigator could compromise the safety of the subject in this study (Exception will be granted for well-controlled Type I diabetes mellitus)
- Recognized immunodeficiency disease, including cellular immunodeficiencies, hypogammaglobulinemia or dysgammaglobulinemia; hereditary or congenital immunodeficiencies
- Past or current history of malignant neoplasm other than breast cancer (BRCA), except for curatively treated non-melanoma skin cancer, in situ carcinoma of the cervix, or other cancer curatively treated and with no evidence of disease for at least five years
- Known active Hepatitis B infection or carrier state and/or Hepatitis C infection, known Human Immunodeficiency Virus infection, or any other infectious process that in the opinion of the investigator could compromise the subject's ability to mount an immune response or could expose her to the likelihood of more and/or severe side effects

Pre-therapies

- Receipt of immunotherapy (for example [e.g.], interferons; tumor necrosis factor; interleukins; growth factors granulocyte macrophage-colony stimulating factor [GM-CSF], granulocyte-colony stimulating factor [G-CSF], macrophage-colony stimulating factor [M-CSF], or monoclonal antibodies), or chemotherapy, within four weeks (28 days) prior to randomization. Note: Subjects who have received monoclonal antibodies for imaging are eligible
- Prior receipt of investigational systemic drugs (including off-label use of approved products) or any kind of systemic treatment (chemotherapy, or immunotherapy), with the exception of hormonal therapy (HT) when given for a period not exceeding 4 weeks (28 days) prior to randomization, for treatment of inoperable, locally advanced, recurrent, or metastatic breast cancer
- Prior radiotherapy to the site of cancer, if only one site will be used for evaluation of tumor response

Prior use of bisphosphonates or concurrent use while on study treatment is allowed

Physiological Function

- Central nervous system disease or brain metastases, as documented by computed tomography (CT) or magnetic resonance imaging (MRI)
- Medical or psychiatric conditions that would interfere with the ability to provide informed consent, communicate side effects, or comply with protocol requirements
- Clinically significant cardiac disease, e.g., cardiac failure of New York Heart Association (NYHA) classes III-IV; uncontrolled angina pectoris, uncontrolled arrhythmia, uncontrolled hypertension, or myocardial infarction in the previous six months, as confirmed by an electrocardiogram (ECG)
- Splenectomy

Standard Criteria

- Need for concurrent treatment with a non-permitted therapy (e.g., concurrent chemotherapy, radiotherapy, systemic immunosuppressive drugs, use of herbal medicines or botanical formulations intended to treat cancer) while on protocol therapy. Palliative radiation to painful bone lesions is allowed
- Participation in another clinical study within 30 days prior to randomization
- Known hypersensitivity to the study drugs
- Known alcohol or drug abuse
- Legal incapacity or limited legal capacity
- Signs and symptoms suggestive of transmissible spongiform encephalopathy, or family members who suffer(ed) from such.
- Subject who could be regarded as "vulnerable" according to International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) guidelines (e.g., the subject's willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate, plus persons kept in detention; persons in nursing homes; subjects in emergency situations; homeless persons; and nomads)
- Any other reason that, in the opinion of the investigator, precludes the subject from participating in this study

Contacts/Locations

Study Officials: Oscar Kashala, MD, PhD, DSc
Study Director
EMD Serono

Locations: United States, North Carolina
Research Site
Hickory, North Carolina, United States

Australia
Research Site
Bedford Park, SA, Australia

Austria
Research Site
Salzburg, Austria

Research Site

Innsbruck, Austria

Belgium
Research Site
Leuven, Belgium

Czech Republic
Research Site
Praha, Czech Republic

Research Site
Pardubice, Czech Republic

Germany
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Wiesbaden, Germany

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Kiel, Germany

Research Site
München, Germany

Research Site
Hamburg, Germany

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Rostock, Germany

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Tübingen, Germany

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Chemnitz, Germany

Research Site
Frankfurt am Main, Germany

Research Site
Lübeck, Germany

Israel
Research Site

Beer Yaakov, Israel

Korea, Republic of
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Seoul, Korea, Republic of

Research Site
Gyeonggi-do, Korea, Republic of

Poland
Research Site
Opole, Poland

Russian Federation
Research Site
Saint-Petersburg, Russian Federation

Research Site
Tula, Russian Federation

Research Site
Obninsk, Russian Federation

Slovakia
Research Site
Bratislava, Slovakia

Research Site
Poprad, Slovakia

Research Site
Trnava, Slovakia

Research Site
Nitra, Slovakia

South Africa
Research Site
Johannesburg, South Africa

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Reporting Groups

	Description
Tecemotide (L-BLP25) + Hormonal Therapy + Cyclophosphamide	Single dose of cyclophosphamide (300 milligrams per square meter [mg/m^2] to a maximum of 600 mg) was administered intravenously, 3 days prior to the start of vaccination, followed by primary treatment phase in which weekly subcutaneous vaccinations with tecemotide (L-BLP25) 1000 micrograms (actual delivered dose was 930 micrograms) along with hormonal treatment were administered for 8 weeks, followed by maintenance treatment phase starting at Week 14 (6 weeks after the last dosing of the primary treatment phase), in which subcutaneous vaccinations with tecemotide (L-BLP25) 1000 micrograms (actual delivered dose was 930 micrograms) along with hormonal treatment were administered every 6 weeks until progressive disease (PD) was documented.
Placebo + Hormonal Therapy + NaCl 9 g/L	Single dose of sodium chloride (NaCl) 9 grams per liter (g/L) infusion as substitute for cyclophosphamide was administered intravenously, 3 days prior to the start of vaccination, followed by primary treatment phase in which weekly subcutaneous placebo doses matched to tecemotide (L-BLP25) along with hormonal therapy were administered for 8 weeks, followed by maintenance treatment phase starting at Week 14 (6 weeks after the last dosing of the primary treatment phase), in which subcutaneous placebo doses along with hormonal therapy were administered every 6 weeks until progressive disease (PD) was documented.

Overall Study

	Tecemotide (L-BLP25) + Hormonal Therapy + Cyclophosphamide	Placebo + Hormonal Therapy + NaCl 9 g/L
Started	11	5
Completed	1	0
Not Completed	10	5
Discontinuation of trial by sponsor	10	5

Baseline Characteristics

Analysis Population Description

Safety population included all participants who received at least one dose of any study treatment (L-BLP25, placebo, cyclophosphamide, saline, or any of the three hormonal therapies).

Reporting Groups

	Description
Tecemotide (L-BLP25) + Hormonal Therapy + Cyclophosphamide	Single dose of cyclophosphamide (300 milligrams per square meter [mg/m^2] to a maximum of 600 mg) was administered intravenously, 3 days prior to the start of vaccination, followed by primary treatment phase in which weekly subcutaneous vaccinations with tecemotide (L-BLP25) 1000 micrograms (actual delivered dose was 930 micrograms) along with hormonal treatment were administered for 8 weeks, followed by maintenance treatment phase starting at Week 14 (6 weeks after the last dosing of the primary treatment phase), in which subcutaneous vaccinations with tecemotide (L-BLP25) 1000 micrograms (actual delivered dose was 930 micrograms) along with hormonal treatment were administered every 6 weeks until progressive disease (PD) was documented.
Placebo + Hormonal Therapy + NaCl 9 g/L	Single dose of sodium chloride (NaCl) 9 g/L infusion as substitute for cyclophosphamide was administered intravenously, 3 days prior to the start of vaccination, followed by primary treatment phase in which weekly subcutaneous placebo doses matched to tecemotide (L-BLP25) along with hormonal therapy were administered for 8 weeks, followed by maintenance treatment phase starting at Week 14 (6 weeks after the last dosing of the primary treatment phase), in which subcutaneous placebo doses along with hormonal therapy were administered every 6 weeks until progressive disease (PD) was documented.

Baseline Measures

	Tecemotide (L-BLP25) + Hormonal Therapy + Cyclophosphamide	Placebo + Hormonal Therapy + NaCl 9 g/L	Total
Number of Participants	11	5	16
Age, Customized [units: participants]			
Less than (<) 65 years	5	2	7
Greater than or equal to (>=) 65 years	6	3	9
Gender, Male/Female [units: participants]			
Female	11	5	16
Male	0	0	0

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Progression-Free Survival (PFS)

Measure Description	PFS was defined as the duration from randomization to first observation of progressive disease (PD) as confirmed by the independent radiological review or death.
Time Frame	Time from randomization to disease progression, death or last tumor assessment, reported between day of first participant randomized i.e. 30 Sep 2009, until end of trial i.e. 27 Aug 2010
Safety Issue?	No

Analysis Population Description

Data were not collected as no independent read took place, due to low numbers: the trial was prematurely terminated following the clinical hold on the investigational new drug application for tecemotide (L-BLP25).

Reporting Groups

	Description
Tecemotide (L-BLP25) + Hormonal Therapy + Cyclophosphamide	Single dose of cyclophosphamide (300 milligrams per square meter [mg/m^2] to a maximum of 600 mg) was administered intravenously, 3 days prior to the start of vaccination, followed by primary treatment phase in which weekly subcutaneous vaccinations with tecemotide (L-BLP25) 1000 micrograms (actual delivered dose was 930 micrograms) along with hormonal treatment were administered for 8 weeks, followed by maintenance treatment phase starting at Week 14 (6 weeks after the last dosing of the primary treatment phase), in which subcutaneous vaccinations with tecemotide (L-BLP25) 1000 micrograms (actual delivered dose was 930 micrograms) along with hormonal treatment were administered every 6 weeks until progressive disease (PD) was documented.
Placebo + Hormonal Therapy + NaCl 9 g/L	Single dose of sodium chloride (NaCl) 9 g/L infusion as substitute for cyclophosphamide was administered intravenously, 3 days prior to the start of vaccination, followed by primary treatment phase in which weekly subcutaneous placebo doses matched to tecemotide (L-BLP25) along with hormonal therapy were administered for 8 weeks, followed by maintenance treatment phase starting at Week 14 (6 weeks after the last dosing of the primary treatment phase), in which subcutaneous placebo doses along with hormonal therapy were administered every 6 weeks until progressive disease (PD) was documented.

Measured Values

	Tecemotide (L-BLP25) + Hormonal Therapy + Cyclophosphamide	Placebo + Hormonal Therapy + NaCl 9 g/L
Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

2. Secondary Outcome Measure:

Measure Title	Overall Survival (OS) Time
Measure Description	OS time was defined as the time from randomization to death. Participants without event were to be censored at the last date known to be alive or at the clinical cut-off date, whichever was earlier.

Time Frame	Time from randomization to death or last day known to be alive reported between day of first participant randomized i.e. 30 Sep 2009, until end of trial i.e. 27 Aug 2010
Safety Issue?	No

Analysis Population Description

Data were not analyzed as the trial was prematurely terminated following the clinical hold on the investigational new drug application for tecemotide (L-BLP25)

Reporting Groups

	Description
Tecemotide (L-BLP25) + Hormonal Therapy + Cyclophosphamide	Single dose of cyclophosphamide (300 milligrams per square meter [mg/m^2] to a maximum of 600 mg) was administered intravenously, 3 days prior to the start of vaccination, followed by primary treatment phase in which weekly subcutaneous vaccinations with tecemotide (L-BLP25) 1000 micrograms (actual delivered dose was 930 micrograms) along with hormonal treatment were administered for 8 weeks, followed by maintenance treatment phase starting at Week 14 (6 weeks after the last dosing of the primary treatment phase), in which subcutaneous vaccinations with tecemotide (L-BLP25) 1000 micrograms (actual delivered dose was 930 micrograms) along with hormonal treatment were administered every 6 weeks until progressive disease (PD) was documented.
Placebo + Hormonal Therapy + NaCl 9 g/L	Single dose of sodium chloride (NaCl) 9 g/L infusion as substitute for cyclophosphamide was administered intravenously, 3 days prior to the start of vaccination, followed by primary treatment phase in which weekly subcutaneous placebo doses matched to tecemotide (L-BLP25) along with hormonal therapy were administered for 8 weeks, followed by maintenance treatment phase starting at Week 14 (6 weeks after the last dosing of the primary treatment phase), in which subcutaneous placebo doses along with hormonal therapy were administered every 6 weeks until progressive disease (PD) was documented.

Measured Values

	Tecemotide (L-BLP25) + Hormonal Therapy + Cyclophosphamide	Placebo + Hormonal Therapy + NaCl 9 g/L
Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

3. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Objective Tumor Response
Measure Description	Percentage of participants with objective tumor response was to be reported. An objective response (OR) was defined as a participant having a best overall response of either confirmed complete response (CR) or confirmed partial response (PR) according to Response Evaluation Criteria in Solid Tumors Version 1.0 (RECIST 1.0) as assessed by independent radiological review.

Time Frame	Randomization until the date of first documented progression, until end of trial i.e. 27 Aug 2010
Safety Issue?	No

Analysis Population Description

Data were not analyzed as the trial was prematurely terminated following the clinical hold on the investigational new drug application for tecemotide (L-BLP25)

Reporting Groups

	Description
Tecemotide (L-BLP25) + Hormonal Therapy + Cyclophosphamide	Single dose of cyclophosphamide (300 milligrams per square meter [mg/m^2] to a maximum of 600 mg) was administered intravenously, 3 days prior to the start of vaccination, followed by primary treatment phase in which weekly subcutaneous vaccinations with tecemotide (L-BLP25) 1000 micrograms (actual delivered dose was 930 micrograms) along with hormonal treatment were administered for 8 weeks, followed by maintenance treatment phase starting at Week 14 (6 weeks after the last dosing of the primary treatment phase), in which subcutaneous vaccinations with tecemotide (L-BLP25) 1000 micrograms (actual delivered dose was 930 micrograms) along with hormonal treatment were administered every 6 weeks until progressive disease (PD) was documented.
Placebo + Hormonal Therapy + NaCl 9 g/L	Single dose of sodium chloride (NaCl) 9 g/L infusion as substitute for cyclophosphamide was administered intravenously, 3 days prior to the start of vaccination, followed by primary treatment phase in which weekly subcutaneous placebo doses matched to tecemotide (L-BLP25) along with hormonal therapy were administered for 8 weeks, followed by maintenance treatment phase starting at Week 14 (6 weeks after the last dosing of the primary treatment phase), in which subcutaneous placebo doses along with hormonal therapy were administered every 6 weeks until progressive disease (PD) was documented.

Measured Values

	Tecemotide (L-BLP25) + Hormonal Therapy + Cyclophosphamide	Placebo + Hormonal Therapy + NaCl 9 g/L
Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

4. Secondary Outcome Measure:

Measure Title	Duration of Response
Measure Description	Duration of response is defined as the time from the first assessment of CR or PR until the date of the first occurrence of PD, or until the date of death.
Time Frame	Time from first assessment of CR or PR until PD, death or last tumor assessment, reported between day of first participant randomized i.e. 30 Sep 2009, until end of trial i.e. 27 Aug 2010
Safety Issue?	No

Analysis Population Description

Data were not analyzed as the trial was prematurely terminated following the clinical hold on the investigational new drug application for tecemotide (L-BLP25)

Reporting Groups

	Description
Tecemotide (L-BLP25) + Hormonal Therapy + Cyclophosphamide	Single dose of cyclophosphamide (300 milligrams per square meter [mg/m^2] to a maximum of 600 mg) was administered intravenously, 3 days prior to the start of vaccination, followed by primary treatment phase in which weekly subcutaneous vaccinations with tecemotide (L-BLP25) 1000 micrograms (actual delivered dose was 930 micrograms) along with hormonal treatment were administered for 8 weeks, followed by maintenance treatment phase starting at Week 14 (6 weeks after the last dosing of the primary treatment phase), in which subcutaneous vaccinations with tecemotide (L-BLP25) 1000 micrograms (actual delivered dose was 930 micrograms) along with hormonal treatment were administered every 6 weeks until progressive disease (PD) was documented.
Placebo + Hormonal Therapy + NaCl 9 g/L	Single dose of sodium chloride (NaCl) 9 g/L infusion as substitute for cyclophosphamide was administered intravenously, 3 days prior to the start of vaccination, followed by primary treatment phase in which weekly subcutaneous placebo doses matched to tecemotide (L-BLP25) along with hormonal therapy were administered for 8 weeks, followed by maintenance treatment phase starting at Week 14 (6 weeks after the last dosing of the primary treatment phase), in which subcutaneous placebo doses along with hormonal therapy were administered every 6 weeks until progressive disease (PD) was documented.

Measured Values

	Tecemotide (L-BLP25) + Hormonal Therapy + Cyclophosphamide	Placebo + Hormonal Therapy + NaCl 9 g/L
Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

5. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Clinical Benefit
Measure Description	Clinical Benefit is defined as having achieved at least disease stabilization; that is participants with confirmed CR, PR, or stable disease (SD,) lasting for at least 22 weeks.
Time Frame	Randomization until the date of first documented progression assessed up to end of trial i.e. 27 Aug 2010
Safety Issue?	No

Analysis Population Description

Data were not analyzed as the trial was prematurely terminated following the clinical hold on the investigational new drug application for tecemotide (L-BLP25)

Reporting Groups

	Description
Tecemotide (L-BLP25) + Hormonal Therapy + Cyclophosphamide	Single dose of cyclophosphamide (300 milligrams per square meter [mg/m^2] to a maximum of 600 mg) was administered intravenously, 3 days prior to the start of vaccination, followed by primary treatment phase in which weekly subcutaneous vaccinations with tecemotide (L-BLP25) 1000 micrograms (actual delivered dose was 930 micrograms) along with hormonal treatment were administered for 8 weeks, followed by maintenance treatment phase starting at Week 14 (6 weeks after the last dosing of the primary treatment phase), in which subcutaneous vaccinations with tecemotide (L-BLP25) 1000 micrograms (actual delivered dose was 930 micrograms) along with hormonal treatment were administered every 6 weeks until progressive disease (PD) was documented.
Placebo + Hormonal Therapy + NaCl 9 g/L	Single dose of sodium chloride (NaCl) 9 g/L infusion as substitute for cyclophosphamide was administered intravenously, 3 days prior to the start of vaccination, followed by primary treatment phase in which weekly subcutaneous placebo doses matched to tecemotide (L-BLP25) along with hormonal therapy were administered for 8 weeks, followed by maintenance treatment phase starting at Week 14 (6 weeks after the last dosing of the primary treatment phase), in which subcutaneous placebo doses along with hormonal therapy were administered every 6 weeks until progressive disease (PD) was documented.

Measured Values

	Tecemotide (L-BLP25) + Hormonal Therapy + Cyclophosphamide	Placebo + Hormonal Therapy + NaCl 9 g/L
Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

6. Secondary Outcome Measure:

Measure Title	Time to Progression (TTP)
Measure Description	TTP is defined as the time from date of randomization to the date of radiological diagnosis of PD (censoring for death without progression).
Time Frame	Time from randomization to PD, reported between day of first participant randomized i.e. 30 Sep 2009, until end of trial i.e. 27 Aug 2010
Safety Issue?	No

Analysis Population Description

Data were not collected as no independent read took place, due to low numbers: the trial was prematurely terminated following the clinical hold on the investigational new drug application for tecemotide (L-BLP25).

Reporting Groups

	Description
Tecemotide (L-BLP25) + Hormonal Therapy + Cyclophosphamide	Single dose of cyclophosphamide (300 milligrams per square meter [mg/m^2] to a maximum of 600 mg) was administered intravenously, 3 days prior to the start of vaccination, followed by primary treatment phase in which weekly subcutaneous vaccinations with tecemotide (L-BLP25) 1000 micrograms (actual delivered dose was 930 micrograms) along with hormonal treatment were administered for 8 weeks, followed by maintenance treatment phase starting at Week 14 (6 weeks after the last dosing of the primary treatment phase), in which subcutaneous vaccinations with tecemotide (L-BLP25) 1000 micrograms (actual delivered dose was 930 micrograms) along with hormonal treatment were administered every 6 weeks until progressive disease (PD) was documented.
Placebo + Hormonal Therapy + NaCl 9 g/L	Single dose of sodium chloride (NaCl) 9 g/L infusion as substitute for cyclophosphamide was administered intravenously, 3 days prior to the start of vaccination, followed by primary treatment phase in which weekly subcutaneous placebo doses matched to tecemotide (L-BLP25) along with hormonal therapy were administered for 8 weeks, followed by maintenance treatment phase starting at Week 14 (6 weeks after the last dosing of the primary treatment phase), in which subcutaneous placebo doses along with hormonal therapy were administered every 6 weeks until progressive disease (PD) was documented.

Measured Values

	Tecemotide (L-BLP25) + Hormonal Therapy + Cyclophosphamide	Placebo + Hormonal Therapy + NaCl 9 g/L
Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

7. Secondary Outcome Measure:

Measure Title	Time to Chemotherapy
Measure Description	Time to chemotherapy is defined as the time from date of randomization to the start date of chemotherapy.
Time Frame	Time from randomization to start of chemotherapy, reported between day of first participant randomized i.e. 30 Sep 2009, until end of trial i.e. 27 Aug 2010
Safety Issue?	No

Analysis Population Description

Data were not analyzed as the trial was prematurely terminated following the clinical hold on the investigational new drug application for tecemotide (L-BLP25)

Reporting Groups

	Description
Tecemotide (L-BLP25) + Hormonal Therapy + Cyclophosphamide	Single dose of cyclophosphamide (300 milligrams per square meter [mg/m^2] to a maximum of 600 mg) was administered intravenously, 3 days prior to the start of vaccination, followed by primary treatment phase in which weekly subcutaneous vaccinations with tecemotide (L-BLP25) 1000 micrograms (actual delivered dose was 930 micrograms) along with hormonal treatment were administered for 8 weeks, followed by maintenance treatment phase starting at Week 14 (6 weeks after the last dosing of the primary treatment phase), in which subcutaneous vaccinations with tecemotide (L-BLP25) 1000 micrograms (actual delivered dose was 930 micrograms) along with hormonal treatment were administered every 6 weeks until progressive disease (PD) was documented.
Placebo + Hormonal Therapy + NaCl 9 g/L	Single dose of sodium chloride (NaCl) 9 g/L infusion as substitute for cyclophosphamide was administered intravenously, 3 days prior to the start of vaccination, followed by primary treatment phase in which weekly subcutaneous placebo doses matched to tecemotide (L-BLP25) along with hormonal therapy were administered for 8 weeks, followed by maintenance treatment phase starting at Week 14 (6 weeks after the last dosing of the primary treatment phase), in which subcutaneous placebo doses along with hormonal therapy were administered every 6 weeks until progressive disease (PD) was documented.

Measured Values

	Tecemotide (L-BLP25) + Hormonal Therapy + Cyclophosphamide	Placebo + Hormonal Therapy + NaCl 9 g/L
Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

8. Secondary Outcome Measure:

Measure Title	Functional Assessment of Cancer Therapy-Breast (FACT-B) Questionnaire
Measure Description	FACT-B questionnaire consists of 36 questions; 7 in physical well-being (PWB); 7 in social well-being (SWB); 6 in emotional well-being (EWB); 7 in functional well-being (FWB); 9 in breast cancer subscale (BCS). Trial outcome Index (TOI) was calculated by the sum of the physical well-being (PWB), functional well-being (FWB), and breast cancer scale (BCS) subscales of FACT-B. Total score of subscores or TOI is calculated from each score of question. Higher score means better and lower score means worthier. Score range; 0-28 in PWB; 0-28 in SWB; 0-24 in EWB; 0-28 in FWB; 0-36 in BCS; 0-92 in TOI.
Time Frame	Baseline, Week 9, 20, 32, 44 and end of trial visit
Safety Issue?	No

Analysis Population Description

Data were not analyzed as the trial was prematurely terminated following the clinical hold on the investigational new drug application for tecemotide (L-BLP25)

Reporting Groups

	Description
Tecemotide (L-BLP25) + Hormonal Therapy + Cyclophosphamide	Single dose of cyclophosphamide (300 milligrams per square meter [mg/m^2] to a maximum of 600 mg) was administered intravenously, 3 days prior to the start of vaccination, followed by primary treatment phase in which weekly subcutaneous vaccinations with tecemotide (L-BLP25) 1000 micrograms (actual delivered dose was 930 micrograms) along with hormonal treatment were administered for 8 weeks, followed by maintenance treatment phase starting at Week 14 (6 weeks after the last dosing of the primary treatment phase), in which subcutaneous vaccinations with tecemotide (L-BLP25) 1000 micrograms (actual delivered dose was 930 micrograms) along with hormonal treatment were administered every 6 weeks until progressive disease (PD) was documented.
Placebo + Hormonal Therapy + NaCl 9 g/L	Single dose of sodium chloride (NaCl) 9 g/L infusion as substitute for cyclophosphamide was administered intravenously, 3 days prior to the start of vaccination, followed by primary treatment phase in which weekly subcutaneous placebo doses matched to tecemotide (L-BLP25) along with hormonal therapy were administered for 8 weeks, followed by maintenance treatment phase starting at Week 14 (6 weeks after the last dosing of the primary treatment phase), in which subcutaneous placebo doses along with hormonal therapy were administered every 6 weeks until progressive disease (PD) was documented.

Measured Values

	Tecemotide (L-BLP25) + Hormonal Therapy + Cyclophosphamide	Placebo + Hormonal Therapy + NaCl 9 g/L
Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

9. Secondary Outcome Measure:

Measure Title	European Questionnaire-5 Dimensions (EQ-5D) Questionnaire
Measure Description	EQ-5D questionnaire is a measure of health status that provides a simple descriptive profile and a single index value. The optional part of the questionnaire was not applied. EQ-5D defines health in terms of mobility, self-care, usual activities, pain/discomfort and anxiety/depression. The 5 items are combined to generate health profiles. These profiles were to be converted to a continuous single index score using a one to one matching. The lowest possible score is -0.59 and the highest is 1.00. Higher scores on the EQ-5D represent a better quality of life (QoL) and lower scores on the EQ-5D represent a worst QoL.
Time Frame	Baseline, Week 9, 20, 32, 44 and end of trial visit
Safety Issue?	No

Analysis Population Description

Data were not analyzed as the trial was prematurely terminated following the clinical hold on the investigational new drug application for tecemotide (L-BLP25)

Reporting Groups

	Description
Tecemotide (L-BLP25) + Hormonal Therapy + Cyclophosphamide	Single dose of cyclophosphamide (300 milligrams per square meter [mg/m^2] to a maximum of 600 mg) was administered intravenously, 3 days prior to the start of vaccination, followed by primary treatment phase in which weekly subcutaneous vaccinations with tecemotide (L-BLP25) 1000 micrograms (actual delivered dose was 930 micrograms) along with hormonal treatment were administered for 8 weeks, followed by maintenance treatment phase starting at Week 14 (6 weeks after the last dosing of the primary treatment phase), in which subcutaneous vaccinations with tecemotide (L-BLP25) 1000 micrograms (actual delivered dose was 930 micrograms) along with hormonal treatment were administered every 6 weeks until progressive disease (PD) was documented.
Placebo + Hormonal Therapy + NaCl 9 g/L	Single dose of sodium chloride (NaCl) 9 g/L infusion as substitute for cyclophosphamide was administered intravenously, 3 days prior to the start of vaccination, followed by primary treatment phase in which weekly subcutaneous placebo doses matched to tecemotide (L-BLP25) along with hormonal therapy were administered for 8 weeks, followed by maintenance treatment phase starting at Week 14 (6 weeks after the last dosing of the primary treatment phase), in which subcutaneous placebo doses along with hormonal therapy were administered every 6 weeks until progressive disease (PD) was documented.

Measured Values

	Tecemotide (L-BLP25) + Hormonal Therapy + Cyclophosphamide	Placebo + Hormonal Therapy + NaCl 9 g/L
Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

10. Secondary Outcome Measure:

Measure Title	Number of Participant Utilizing Healthcare Resources
Measure Description	Healthcare Resource Utilization (HRU) parameters included direct medical resources (e.g., nonscheduled procedures, unplanned hospitalization, outpatient visits), nonmedical resources (e.g., travel, paid and unpaid assistance), and occupational resources (e.g., occupational changes and concerns).
Time Frame	Randomization up to end of trial visit
Safety Issue?	No

Analysis Population Description

Data were not analyzed as the trial was prematurely terminated following the clinical hold on the investigational new drug application for tecemotide (L-BLP25)

Reporting Groups

	Description
Tecemotide (L-BLP25) + Hormonal Therapy + Cyclophosphamide	Single dose of cyclophosphamide (300 milligrams per square meter [mg/m^2] to a maximum of 600 mg) was administered intravenously, 3 days prior to the start of vaccination, followed by primary treatment phase in which weekly subcutaneous vaccinations with tecemotide (L-BLP25) 1000 micrograms (actual delivered dose was 930 micrograms) along with hormonal treatment were administered for 8 weeks, followed by maintenance treatment phase starting at Week 14 (6 weeks after the last dosing of the primary treatment phase), in which subcutaneous vaccinations with tecemotide (L-BLP25) 1000 micrograms (actual delivered dose was 930 micrograms) along with hormonal treatment were administered every 6 weeks until progressive disease (PD) was documented.
Placebo + Hormonal Therapy + NaCl 9 g/L	Single dose of sodium chloride (NaCl) 9g/L infusion as substitute for cyclophosphamide was administered intravenously, 3 days prior to the start of vaccination, followed by primary treatment phase in which weekly subcutaneous placebo doses matched to tecemotide (L-BLP25) along with hormonal therapy were administered for 8 weeks, followed by maintenance treatment phase starting at Week 14 (6 weeks after the last dosing of the primary treatment phase), in which subcutaneous placebo doses along with hormonal therapy were administered every 6 weeks until progressive disease (PD) was documented.

Measured Values

	Tecemotide (L-BLP25) + Hormonal Therapy + Cyclophosphamide	Placebo + Hormonal Therapy + NaCl 9 g/L
Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

11. Secondary Outcome Measure:

Measure Title	Serum Carcinoma Antigen (CA) 15-3 Levels
Measure Description	CA 15-3 is a serum marker for breast cancer which is a possible measure for immune response.
Time Frame	Baseline, Week 5, 9, 20, 32, 44 and end of trial visit
Safety Issue?	No

Analysis Population Description

Data were not analyzed as the trial was prematurely terminated following the clinical hold on the investigational new drug application for tecemotide (L-BLP25)

Reporting Groups

	Description
Tecemotide (L-BLP25) + Hormonal Therapy + Cyclophosphamide	Single dose of cyclophosphamide (300 milligrams per square meter [mg/m^2] to a maximum of 600 mg) was administered intravenously, 3 days prior to the start of vaccination, followed by primary treatment phase in which weekly subcutaneous vaccinations with tecemotide (L-BLP25) 1000 micrograms (actual delivered dose was 930 micrograms) along with hormonal treatment were administered for 8 weeks, followed by maintenance treatment phase starting at Week 14 (6 weeks after the last dosing of the primary treatment phase), in which subcutaneous vaccinations with tecemotide (L-BLP25) 1000 micrograms (actual delivered dose was 930 micrograms) along with hormonal treatment were administered every 6 weeks until progressive disease (PD) was documented.
Placebo + Hormonal Therapy + NaCl 9 g/L	Single dose of sodium chloride (NaCl) 9 g/L infusion as substitute for cyclophosphamide was administered intravenously, 3 days prior to the start of vaccination, followed by primary treatment phase in which weekly subcutaneous placebo doses matched to tecemotide (L-BLP25) along with hormonal therapy were administered for 8 weeks, followed by maintenance treatment phase starting at Week 14 (6 weeks after the last dosing of the primary treatment phase), in which subcutaneous placebo doses along with hormonal therapy were administered every 6 weeks until progressive disease (PD) was documented.

Measured Values

	Tecemotide (L-BLP25) + Hormonal Therapy + Cyclophosphamide	Placebo + Hormonal Therapy + NaCl 9 g/L
Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

Reported Adverse Events

Time Frame	Baseline (First treatment dose) up to end of trial i.e. 27 Aug 2010
Additional Description	Adverse event (AE): Any untoward medical occurrence/worsening of pre-existing medical condition, whether or not related to study drug.

Reporting Groups

	Description
Tecemotide (L-BLP25) + Hormonal Therapy + Cyclophosphamide	Single dose of cyclophosphamide (300 milligrams per square meter [mg/m^2] to a maximum of 600 mg) was administered intravenously, 3 days prior to the start of vaccination, followed by primary treatment phase in which weekly subcutaneous vaccinations with tecemotide (L-BLP25) 1000 micrograms (actual delivered dose was 930 micrograms) along with hormonal treatment were administered for 8 weeks, followed by maintenance treatment phase starting at Week 14 (6 weeks after the last dosing of the primary treatment phase), in which subcutaneous vaccinations with tecemotide (L-BLP25) 1000 micrograms (actual delivered dose was 930 micrograms) along with hormonal treatment were administered every 6 weeks until progressive disease (PD) was documented.
Placebo + Hormonal Therapy + NaCl 9 g/L	Single dose of sodium chloride (NaCl) 9 g/L infusion as substitute for cyclophosphamide was administered intravenously, 3 days prior to the start of vaccination, followed by primary treatment phase in which weekly subcutaneous placebo doses matched to tecemotide (L-BLP25) along with hormonal therapy were administered for 8 weeks, followed by maintenance treatment phase starting at Week 14 (6 weeks after the last dosing of the primary treatment phase), in which subcutaneous placebo doses along with hormonal therapy were administered every 6 weeks until progressive disease (PD) was documented.

Serious Adverse Events

	Tecemotide (L-BLP25) + Hormonal Therapy + Cyclophosphamide	Placebo + Hormonal Therapy + NaCl 9 g/L
	Affected/At Risk (%)	Affected/At Risk (%)
Total	1/11 (9.09%)	0/5 (0%)
Gastrointestinal disorders		
Intestinal obstruction [A] *	1/11 (9.09%)	0/5 (0%)

* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA version 12.1

Other Adverse Events
Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Tecemotide (L-BLP25) + Hormonal Therapy + Cyclophosphamide	Placebo + Hormonal Therapy + NaCl 9 g/L
	Affected/At Risk (%)	Affected/At Risk (%)
Total	9/11 (81.82%)	3/5 (60%)
Blood and lymphatic system disorders		
Anaemia [A] *	1/11 (9.09%)	0/5 (0%)
Cardiac disorders		

	Tecemotide (L-BLP25) + Hormonal Therapy + Cyclophosphamide	Placebo + Hormonal Therapy + NaCl 9 g/L
	Affected/At Risk (%)	Affected/At Risk (%)
Bradycardia [A] *	1/11 (9.09%)	0/5 (0%)
Eye disorders		
Eye swelling [A] *	0/11 (0%)	1/5 (20%)
Ocular hyperaemia [A] *	0/11 (0%)	1/5 (20%)
Vision blurred [A] *	1/11 (9.09%)	0/5 (0%)
Gastrointestinal disorders		
Abdominal distension [A] *	1/11 (9.09%)	0/5 (0%)
Abdominal pain [A] *	3/11 (27.27%)	0/5 (0%)
Abdominal pain upper [A] *	1/11 (9.09%)	0/5 (0%)
Constipation [A] *	3/11 (27.27%)	0/5 (0%)
Diarrhoea [A] *	2/11 (18.18%)	0/5 (0%)
Eructation [A] *	1/11 (9.09%)	0/5 (0%)
Nausea [A] *	7/11 (63.64%)	1/5 (20%)
Odynophagia [A] *	1/11 (9.09%)	0/5 (0%)
Vomiting [A] *	3/11 (27.27%)	1/5 (20%)
General disorders		
Asthenia [A] *	1/11 (9.09%)	1/5 (20%)
Chills [A] *	1/11 (9.09%)	0/5 (0%)
Fatigue [A] *	4/11 (36.36%)	0/5 (0%)
Injection site erythema [A] *	3/11 (27.27%)	0/5 (0%)
Injection site haematoma [A] *	0/11 (0%)	1/5 (20%)
Injection site induration [A] *	1/11 (9.09%)	0/5 (0%)

	Tecemotide (L-BLP25) + Hormonal Therapy + Cyclophosphamide	Placebo + Hormonal Therapy + NaCl 9 g/L
	Affected/At Risk (%)	Affected/At Risk (%)
Injection site pain [A] *	1/11 (9.09%)	0/5 (0%)
Injection site pruritus [A] *	1/11 (9.09%)	0/5 (0%)
Injection site swelling [A] *	1/11 (9.09%)	0/5 (0%)
Non-cardiac chest pain [A] *	1/11 (9.09%)	0/5 (0%)
Oedema peripheral [A] *	1/11 (9.09%)	0/5 (0%)
Infections and infestations		
Influenza [A] *	1/11 (9.09%)	0/5 (0%)
Nasopharyngitis [A] *	3/11 (27.27%)	0/5 (0%)
Upper respiratory tract infection [A] *	0/11 (0%)	1/5 (20%)
Urinary tract infection [A] *	1/11 (9.09%)	0/5 (0%)
Injury, poisoning and procedural complications		
Fall [A] *	0/11 (0%)	1/5 (20%)
Metabolism and nutrition disorders		
Decreased appetite [A] *	1/11 (9.09%)	0/5 (0%)
Hypercholesterolaemia [A] *	1/11 (9.09%)	0/5 (0%)
Musculoskeletal and connective tissue disorders		
Arthralgia [A] *	1/11 (9.09%)	0/5 (0%)
Back pain [A] *	2/11 (18.18%)	0/5 (0%)
Musculoskeletal chest pain [A] *	1/11 (9.09%)	0/5 (0%)
Myalgia [A] *	0/11 (0%)	1/5 (20%)
Neck pain [A] *	3/11 (27.27%)	0/5 (0%)
Nervous system disorders		

	Tecemotide (L-BLP25) + Hormonal Therapy + Cyclophosphamide	Placebo + Hormonal Therapy + NaCl 9 g/L
	Affected/At Risk (%)	Affected/At Risk (%)
Dizziness [A] *	2/11 (18.18%)	0/5 (0%)
Headache [A] *	1/11 (9.09%)	0/5 (0%)
Hypoaesthesia [A] *	1/11 (9.09%)	0/5 (0%)
Sinus headache [A] *	1/11 (9.09%)	0/5 (0%)
Transient ischaemic attack [A] *	1/11 (9.09%)	0/5 (0%)
Psychiatric disorders		
Anxiety [A] *	1/11 (9.09%)	1/5 (20%)
Depression [A] *	1/11 (9.09%)	0/5 (0%)
Respiratory, thoracic and mediastinal disorders		
Painful respiration [A] *	1/11 (9.09%)	0/5 (0%)
Rhinorrhoea [A] *	1/11 (9.09%)	0/5 (0%)
Skin and subcutaneous tissue disorders		
Alopecia [A] *	0/11 (0%)	1/5 (20%)
Nail disorder [A] *	1/11 (9.09%)	0/5 (0%)
Night sweats [A] *	2/11 (18.18%)	0/5 (0%)
Swelling face [A] *	0/11 (0%)	1/5 (20%)
Vascular disorders		
Hot flush [A] *	2/11 (18.18%)	0/5 (0%)
Hypertension [A] *	1/11 (9.09%)	0/5 (0%)
Jugular vein thrombosis [A] *	1/11 (9.09%)	0/5 (0%)
Phlebitis [A] *	1/11 (9.09%)	0/5 (0%)
Thrombophlebitis superficial [A] *	1/11 (9.09%)	0/5 (0%)

	Tecemotide (L-BLP25) + Hormonal Therapy + Cyclophosphamide	Placebo + Hormonal Therapy + NaCl 9 g/L
	Affected/At Risk (%)	Affected/At Risk (%)
Thrombosis [A] *	0/11 (0%)	1/5 (20%)

* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA version 12.1

Limitations and Caveats

Efficacy data were not analyzed as the trial was prematurely terminated following the clinical hold on the investigational new drug application for tecemotide (L-BLP25)

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

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