ALEXANDRA - IMPASSION 030 (dernière mise à jour : 02/03/2020)

http://archimaid.fr/index.php?action=show&id=594

Informations générales

Titre de l'étude : Etude de phase III, multicentrique, randomisée, en ouvert, comparant l'atézolizumab (Anticorps anti-PDL1) en association à la chimiothérapie adjuvante à base d'anthracycline/taxane versus chimiothérapie seule chez des patients atteints d'un cancer du sein triple négatif opérable

Traitement : Adjuvant

Type d'étude : Ciblage moléculaire / Innovation thérapeutique

Phase : III **Stade** : Localisé à Localement avancé **Ligne(s)** : 1

Schéma : This study will evaluate the efficacy, safety, and pharmacokinetics of adjuvant atezolizumab in combination with paclitaxel, followed by atezolizumab, dose-dense doxorubicin or epirubicin (investigator's choice), and cyclophosphamide, compared with paclitaxel followed by dose-dense doxorubicin or epirubicin (investigator's choice) and cyclophosphamide alone in patients with Stage II-III TNBC (Triple Negative Breast Cancer)

2 treatment arms:
- Experimental: Atezolizumab + Chemotherapy
Participants will receive atezolizumab (in combination with chemotherapy as described below) every 2 weeks for 10 doses, followed by atezolizumab maintenance therapy every 3 weeks to complete 1 year of treatment from the first dose
Chemotherapy will consist of paclitaxel every week for 12 weeks, followed by dose-dense doxorubicin +cyclophosphamide or dose-dense epirubicin + cyclophosphamide every 2 weeks, for 4 doses supported with Granulocyte Colony-Stimulating Factor (G-CSF) or Granulocyte-Macrophage Colony Stimulating Factor (GM-CSF)
- Active Comparator: Chemotherapy
Chemotherapy will consist of paclitaxel every week for 12 weeks, followed by dose-dense doxorubicin +cyclophosphamide or dose-dense epirubicin + cyclophosphamide every 2 weeks, for 4 doses supported with Granulocyte Colony-Stimulating Factor (G-CSF) or Granulocyte-Macrophage Colony Stimulating Factor (GM-CSF)

Spécialités / Localisations

Spécialité n°1 : Seins, organes génitaux de la femme

CIM10 - Localisation n°1 : **C50** - Tumeur maligne du sein

Critères

Critères d'inclusion : - Non-metastatic operable Stage II-III breast cancer
- Histologically documented TNBC (Triple Negative Breast Cancer)
- Confirmed tumor PD-L1 evaluation as documented through central testing of a representative tumor tissue specimen
- Adequately excised: Patients must have undergone either breast-conserving surgery or mastectomy/nipple- or skin-sparing mastectomy
- Adequate hematologic and end-organ function
- For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures
- For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures and agreement to refrain from donating sperm.

- No more than 8 weeks (56 days) may elapse between definitive breast surgery and randomization.
- Representative formalin-fixed, paraffin embedded (FFPE) tumor specimen from surgical resection in paraffin blocks (preferred) or at least 25 unstained slides.

Critères de non-inclusion : - Prior history of invasive breast cancer
- For the currently diagnosed breast cancer, any previous systemic anti-cancer treatment (e.g., neoadjuvant or adjuvant), including, but not limited to, chemotherapy, anti-HER2 therapy.
- Previous therapy with anthracyclines or taxanes for any malignancy
- Cardiopulmonary dysfunction
- Prior malignancies within 5 years prior to randomization, with the exception of those with a negligible risk of metastasis or death and treated with expected curative outcome
- Active or history of autoimmune disease or immune deficiency
- History of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis on screening chest computed tomography (CT) scan
- Urinary outflow obstruction
- Active tuberculosis
- Major surgical procedure other than for diagnosis within 4 weeks prior to initiation of study treatment or anticipation of need for a major surgical procedure during study treatment or within 5 months following the last dose of Atezolizumab (for patients randomized to Atezolizumab)
- Prior allogeneic stem cell or solid organ transplant
- Treatment with systemic immunosuppressive medications within 2 weeks prior to initiation of study treatment or anticipation of need for systemic immunosuppressive medication during the study

Informations promoteur

Nom du promoteur : HOFFMANN-LA ROCHE

Type de promoteur : Industriel

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Informations centre investigateur n°1

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Ouverture de l'essai : OUVERT

Liens utiles

ClinicalTrials : https://clinicaltrials.gov/ct2/show/NCT03498716?titles=impassion&cntry=FR&rank=1