Study Finds ABRAXANE Combination Chemotherapy is Superior to Other Chemotherapy Combinations in Women with Metastatic Triple Negative Breast Cancer

Phase 2 tnAcity trial found a significantly longer Progression-Free Survival with ABRAXANE + carboplatin compared to ABRAXANE + gemcitabine or carboplatin + gemcitabine regimens

Melbourne, Australia and Singapore, 23 December 2016: An international study has found that women with metastatic triple-negative breast cancer (mTNBC) demonstrated improved progression-free survival when treated with a combination of ABRAXANE (nanoparticle albumin-bound paclitaxel) and carboplatin, compared to other chemotherapy combinations.[1]

Results from the randomised phase 2 study known as tnAcity were presented at the prestigious San Antonio Breast Cancer Symposium (SABCS) earlier this month.

Researchers found that an investigational weekly combination regimen of ABRAXANE + carboplatin had significantly longer progression-free survival (PFS) (7.4 months) compared to weekly regimens of either ABRAXANE + gemcitabine (5.4 months; P=0.02, HR 0.60 (95% CI, 0.39-0.93)) or carboplatin + gemcitabine (6.0 months; P= 0.03, HR 0.61 (95% CI, 0.39-0.94)) as first-line treatment of patients with mTNBC .[1]

Australian oncologist and trial investigator Dr Nicole Potasz said these results

reaffirmed the belief that an ABRAXANE/carboplatin combination was an active regimen in the first-line metastatic triple-negative breast cancer setting.

“This is a very practical study. We have never really known what the best first-line regimen is for women with triple-negative breast cancer,” she said. “We can use this phase 2 data to guide us in our choices and this study supports the safety and efficacy of the ABRAXANE/carboplatin combination.”

ABRAXANE is made available to Australian and New Zealand patients by Specialised Therapeutics Australia.

Chief Executive Officer Mr Carlo Montagner said these results were “extremely encouraging” and followed a recent qualitative survey of Australian oncologists.[2]

This survey revealed that almost one-third of women being treated for metastatic triple negative breast cancer were prescribed a gemcitabine/carboplatin chemotherapy combination as first line therapy.

“Results from this tnAcity study now provide more information to help guide treatment decisions,” he said.

“Moving forward, we are eagerly anticipating the results of several pivotal phase 3 clinical studies that are examining ABRAXANE in combination with potent immunotherapy agents to treat women with metastatic triple negative breast cancer. These immunotherapy agents have already been approved for use in other cancers.

“While our data indicates that ABRAXANE is already Australia’s most prescribed IV chemotherapy in metastatic breast cancer, we believe it may play an increasingly important role in future therapy regimens, particularly for women with triple-negative breast cancer which remains a very challenging form of breast cancer to treat.”

The tnAcity trial randomised 191 women with mTNBC to receive one of three weekly regimens (dosed 2 out of 3 weeks): ABRAXANE + carboplatin, ABRAXANE + gemcitabine, or carboplatin + gemcitabine as first-line treatment.[3]

The study also reported that those treated with the ABRAXANE + carboplatin regimen experienced a longer median treatment duration (25 weeks) than those

treated with ABRAXANE + gemcitabine (18.1 weeks) or carboplatin + gemcitabine (20.1 weeks).[1]

tnAcity also found an improved overall response rate in patients treated with ABRAXANE + carboplatin (72%) compared with those treated with ABRAXANE + gemcitabine (39%) or carboplatin + gemcitabine (44%).[1] Median overall survival (OS) was longer in the ABRAXANE + carboplatin arm (16.4 months) compared with ABRAXANE + gemcitabine (12.1 months; P = 0.07, HR 0.66 (95% CI, 0.42-1.04)) or carboplatin + gemcitabine (12.6 months; P = 0.18, HR 0.74 (95% CI, 0.48-1.16)), however these differences did not reach statistical significance.[1]

The most common grade ≥3 treatment emergent adverse events (TEAEs) observed in the ABRAXANE + carboplatin, ABRAXANE + gemcitabine, and carboplatin + gemcitabine arms, respectively, during the study were mainly haematologic and included neutropenia (42%, 27%, 52%), anaemia (13%, 12%, 27%), thrombocytopenia (9%, 7%, 28%), leukopenia (6%, 3%, 11%), febrile neutropenia (5%, 2%, 0%), peripheral neuropathy (5%, 7%, 2%) and fatigue (3%, 15%, 3%).[1] A median of 8 treatment cycles were initiated for the ABRAXANE + carboplatin arm and 6 cycles for both the ABRAXANE + gemcitabine and carboplatin + gemcitabine arms. The percentage of patients that discontinued any study drug due to a TEAE was 45% for ABRAXANE + carboplatin and 25% for each of the other arms. The most common AEs leading to discontinuation of any study drug included thrombocytopenia, anaemia, neutropenia and drug hypersensitivity.[1]

About tnAcity[1,3]

tnAcity is a phase 2/3 multicentre, open-label, randomised clinical trial conducted in 139 centres in 12 countries. The study evaluated the safety and efficacy of the investigational use of a weekly treatment regimen of ABRAXANE in combination with carboplatin or gemcitabine as a first-line treatment of women with metastatic triple-negative breast cancer (mTNBC) compared to a gemcitabine + carboplatin regimen.[3]

The phase 2 portion of the tnAcity trial evaluated 191 patients with mTNBC who had received no prior systemic chemotherapy treatment for their mTNBC and had an ECOG performance status of 0 or 1. Patients were randomised to one of three treatment arms: ABRAXANE 125 mg/m^2 + carboplatin AUC 2, ABRAXANE 125 mg/m^2 + gemcitabine 1000 mg/m^2, or carboplatin AUC 2 + gemcitabine 1000 mg/m^2 dosed weekly on days 1 and 8 of a 21-day cycle. The median age in each treatment arm was 55 (ABRAXANE + carboplatin), 53 (ABRAXANE + gemcitabine) and 59 (carboplatin + gemcitabine) years. The primary endpoint of the phase 2 trial was investigator-assessed progression free survival. Secondary endpoints evaluated in the study included overall survival and objective response rate (ORR).[3]

About Specialised Therapeutics Asia

Specialised Therapeutics Asia Pte Ltd (ST Asia) is an international biopharmaceutical company established to provide pioneering healthcare solutions to patients throughout South East Asia, as well as in Australia and New Zealand. The company is a close affiliate of Specialised Therapeutics Australia (STA), which also collaborates with leading global pharmaceutical and diagnostic companies to bring novel, innovative and life changing healthcare solutions to patients affected by a range of diseases. ST Asia is committed to making new and novel therapies available to patients around the world, with a broad therapeutic portfolio spanning oncology, hematology, urology and ophthalmology. Additional information can be found at www.stabiopharma.com

References:

1. Yardley D, et al. nab-Paclitaxel + Carboplatin or Gemcitabine vs Gemcitabine + Carboplatin as First-Line Treatment for Patients With Triple-Negative Metastatic Breast Cancer: Results From the Randomized Phase II Portion of the tnAcity Trial. Poster 874. Presented at the 2016 San Antonio Breast Cancer Symposium (SABCS), December 6-10, 2016.

2. Data on file.
3. Clinicaltrials.gov. Evaluate Risk/Benefit of Nab Paclitaxel in Combination With Gemcitabine and Carboplatin Compared to Gemcitabine and Carboplatin in Triple Negative Metastatic Breast Cancer (or Metastatic Triple Negative Breast Cancer) (tnAcity). Available at: https://www.clinicaltrials.gov/ct2/show/NCT01881230?term=tnacity&rank=1. Accessed November 29, 2016.