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MEDIA RELEASE

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Longer survival with daily single agent oral chemotherapy than with a standard combination chemotherapy for silent majority with advanced breast cancer

Researchers from Australia and New Zealand have demonstrated a rare advance in extending survival for women with advanced breast cancer, according to Associate Professor Martin Stockler, Principal Investigator for the ANZ 0001 trial.

“We were delighted by the results, especially because they were obtained using a convenient oral treatment instead of conventional intravenous chemotherapy,” Associate Professor Stockler said. “We now look forward to planning new treatment approaches building on this success.”

Dr Nicholas Wilcken of Westmead Hospital said, “These results are particularly pleasing because the trial was rigorously conducted in accordance with the highest scientific standards – a randomized controlled trial – giving us great confidence that the results are reliable.”

The ANZ 0001 trial, which was conducted by the Australian New Zealand Breast Cancer Trials Group (ANZ BCTG), included 323 women recruited at 34 centres in Australia and New Zealand. Its final results were reported on 17 December 2006 at the San Antonio Breast Cancer Symposium, the world’s premier breast cancer conference.

Participating women were randomly allocated to one of three treatments:

- 107 to capecitabine tablets given for 14 of every 21 days (intermittent capecitabine)
- 107 to capecitabine tablets given for 21 of every 21 days (continuous capecitabine)
- 109 to classical CMF (a standard combination including injections of methotrexate and fluorouracil twice a month, and tablets of cyclophosphamide for 14 days each month)

The aim of the trial was to see if women treated with capecitabine would do and feel better than those treated with CMF. The underlying idea was that capecitabine would be at least as good as CMF at controlling the cancer, but would maintain control for longer because it is better tolerated and can be continued for longer.

The trial focused on women who were starting chemotherapy for advanced breast cancer, but who were unsuited to intensive chemotherapy. These women are rarely included in cancer trials, even though they represent the majority of those affected by breast cancer. Capecitabine and other single agents are widely used in this situation, without strong evidence of their effectiveness from well-conducted clinical trials.

Capecitabine is an oral chemotherapy drug often used for colorectal cancer and further down the line for advanced breast cancer. It is closely related to 5-fluorouracil, an intravenous chemotherapy drug used in a wide range of cancers, and is the ‘F’ in CMF.

In the ANZ 0001 trial, overall survival was significantly longer with capecitabine than CMF. The typical survival time was 22 months on capecitabine versus 18 months on CMF. Results were similar for the two different ways of giving capecitabine. Similar proportions of women had tumour shrinkage or stabilisation on capecitabine and CMF (60%). Control of the cancer over the first six months was similar on capecitabine and CMF, but capecitabine was more likely to control the cancer beyond six months. Chemotherapy was continued for longer than six months in 40% of women on capecitabine but only 21% of women on CMF. Side effects were less severe and more tolerable with capecitabine than with CMF chemotherapy.

The Coordinator of the ANZ BCTG Consumer Advisory Panel, Professor Linda Reaby, welcomed the results, saying “This is a win-win for women with advanced breast cancer – better survival and less side effects.”

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Background notes:

The ANZ 0001 trial is the first large scale, randomized trial targeting the silent majority of women with advanced breast cancer who are unsuited to intensive chemotherapy. Most breast cancer research has focused on testing intensive treatments in women fit enough to withstand them. The aim of this trial was to determine the best treatment for the majority of women who are unsuited to intensive chemotherapy.

The ANZ 0001 trial was conducted by leading breast cancer specialists and researchers from around Australia and New Zealand. It is the largest trial of its kind in the world. It was coordinated by the Australian New Zealand Breast Cancer Trials Group (ANZ BCTG) based at the University of Newcastle. The ANZ BCTG is Australia's national breast cancer research group dedicated entirely to breast cancer research through the conduct of multi-institution clinical trials. The ANZ BCTG collaborates with 300 researchers in 80 of the leading medical institutions in Australia and New Zealand, and with similar research groups in more than 15 countries internationally.

The results of this trial were analysed at the NHMRC Clinical Trials Centre, at The University of Sydney. ANZ 0001 was supported by the Breast Cancer Institute of Australia, The Cancer Council NSW, Roche Australia, and Roche International. Roche had no part in the trial design, conduct, data-collection or analysis. This was solely the responsibility of the ANZ BCTG.

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