



## MEDIA RELEASE

### 15-year follow-up study shows strong validation of Ascend's breast cancer vaccine

**December 20th, 2013:** Melbourne-based immunotherapy company Ascend Biopharmaceuticals has today welcomed the results of an investigator led follow-up study of patients who participated in a 1998 trial of breast cancer vaccine OM-MUC-1 – an earlier prototype of Ascend's clinical compound ASN-004.

The study, which investigated breast cancer recurrence in patients 15 years after taking part in an immunotherapy trial of OM-MUC-1, showed evidence of efficacy and substantially reduced rates of breast cancer recurrence. OM-MUC1 was developed by researchers at Melbourne's Austin Research Institute and licensed to Ascend in 2006.

Ascend has since developed, ASN-004, an improved version of OM-MUC-1, and is preparing to commence a Phase 1b trial of the drug in 2015 in breast cancer.

Ascend CEO Clement Leong said the results of the 15-year follow up study were among the most favourable results reported for cancer vaccines in preventing cancer recurrence.

"The results have been compelling to this point," Dr Leong said. "This study showed OM-MUC-1 was found to reduce a patient's cancer returning from 60% to 12.5% chance, which clearly are much better odds for any patient." he said. The study has been published in *Future Medicine*.

Out of 16 patients who received the OM-MUC-1 15 years ago, only two have experienced a recurrence of Stage II breast cancer (12.5%). Of those who received the placebo, nine patients out of 15 experienced a recurrence (60%), consistent with the historical recurrence rate with Stage II breast cancer. The trial showed the time of recurrence in the placebo group ranged from 7 to 180 months (mean: 65.8 months) while in the two patients of the vaccine group, the recurrence appeared at 95 and 141 months (mean: 118 months) after surgery.

Ascend has since developed, ASN-004, an improved version of OM-MUC-1, and is preparing to commence a Phase 1b trial of the drug in 2014 in breast cancer. "Our current clinical strategy builds upon this encouraging clinical data. We will evaluate the new vaccine in breast cancer patient subsets that are clinically relevant to the earlier study, but with a view to generating meaningful clinical data in a shorter time-frame."

OM-MUC-1 has been studied in 100 patients in a number of clinical trials to date. These studies have demonstrated that targeting the mannose receptor on macrophages and dendritic cells leads to both a strong cellular and antibody immune response. Human clinical trials have already demonstrated the effectiveness of oxidized mannan–MUC1 (M-FP) in stimulating both arms of the immune system (e.g., cellular and antibody).

Ascend Biopharmaceuticals has two clinical stage products focused on using the immune system to treat cancer. The company is preparing to advance its first product (ASN-002) in a Phase II clinical trial expected to initiate later in 2014.



-ENDS-

**For more information, please contact:**

Clement Leong  
Ascend Biopharmaceuticals, CEO  
T: + 61 3 8606 3401  
E: [clementleong@ascendbiopharma.com](mailto:clementleong@ascendbiopharma.com)

Ben Oliver  
Buchan Consulting  
T: + 613 9866 4722 / 0402 242 982  
E: [boliver@buchanwe.com.au](mailto:boliver@buchanwe.com.au)

**About Ascend Biopharmaceuticals**

Ascend Biopharmaceuticals is developing immunotherapy products for the treatment of cancer which harness the body's immune system - the body's natural safeguard against infection - to selectively destroy cancer cells. Immunotherapy is an emerging, but proven area of cancer treatment that has the potential to deliver safer and more effective treatment regime than those currently available.

Ascend's two clinical stage products both focus on using the immune system to treat cancers. ASN-002 is a treatment designed for delivery of an immunomodulator into the cancer micro-environment and plans to enter Phase II clinical studies in skin cancer patients later in 2014. ASN-004, a cancer vaccine, based on a well-validated technology from originally invented by Melbourne's Burnet Institute. ASN-004 will be developed as treatment for breast cancer and the Company plans to initiate a Phase Ib clinical study in 2015.