



## **Immutep Announces Oral Presentation at ASCO Annual Meeting of IMP321 Final Results In Phase I/II Chemoimmunotherapy Trial**

### ***IMP321 associated with paclitaxel in first-line metastatic breast cancer***

**Orsay, France, May 18, 2010**, Immutep S.A. announced today that the final results from its Phase I/II chemoimmunotherapy clinical trial in metastatic breast carcinoma will be shown in an oral presentation at the 46th Annual Meeting of the American Society of Clinical Oncology (ASCO). The ASCO meeting will be held at McCormick Place in Chicago from June 4 through June 8, 2010.

The oral presentation is entitled ".First-line chemoimmunotherapy in metastatic breast carcinoma: effect of a combination of paclitaxel and LAG-3Ig (IMP321), a novel MHC class II agonist, on T cell responses and anti-tumor activity" and is scheduled for Tuesday, June 8 from 11:45 to 12 a.m. CDT in room E354a.

IMP321 is a T cell immunostimulatory agent. Repeated IMP321 injections lead to strong anti-tumour T cell responses. In synergistic combination with first-line chemotherapy, IMP321 may increase the clinical response rate. This therapeutic strategy is called chemoimmunotherapy.

The study was carried out in three cancer centres in the Paris region. The lead centre was the René Huguenin Cancer Centre in Saint Cloud. The other centres were Tenon Hospital and the Georges Pompidou European Hospital in Paris

The abstract can be accessed after May 20, 2010 through the ASCO website, [www.asco.org](http://www.asco.org) and will be accessible from Immutep's website at [www.immutep.com](http://www.immutep.com) after the presentation

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## Notes to Editors

### **ImmuFact<sup>®</sup> - T cell Immunostimulatory Agent for amplifying the T cell response**

ImmuFact<sup>®</sup> IMP321 is a first-in-class antigen-presenting cell (APC) agonist. It is a soluble form of the LAG-3 ("lymphocyte activation gene-3") T cell surface receptor that binds, with high affinity, to MHC ("major histocompatibility complex") class II molecules on APC such as monocytes and dendritic cells. Repeated IMP321 injections lead to strong anti-tumour CD8 T cell responses in cancer patients especially in combination with chemotherapy.

### **Metastatic Breast Cancer and Chemoimmunotherapy**

Metastatic breast cancer remains incurable. The failure of current approaches is generally attributed to the outgrowth of breast tumour cells that are inherently resistant to standard treatments. Manipulating the immune system to recognize and eradicate breast tumour cells is a highly attractive alternative approach to disease management. Active immunization offers multiple theoretical advantages over all other therapies, including low toxicity. The sustained antitumour effect due to *immunological memory* would obviate the requirement for prolonged, repetitive cycles of therapy.

The objective of chemoimmunotherapy is to amplify *natural pre-existing* T cell responses specific for any known or unknown tumour antigen and to recruit and amplify *new* tumour-specific T cell responses resulting from the use of cytotoxic drugs. The direct cytolytic effect of some cytotoxic drugs, such as paclitaxel, can enhance antigen presentation by inducing tumour cell apoptosis. This mechanism of therapeutic synergy has been shown with cyclophosphamide, doxorubicin, or paclitaxel when given with dendritic cell-based vaccines. Until 8 years ago, it was thought that the T cell depletion caused by chemotherapy would make immunotherapy ineffective. However it has now been shown that, on the contrary, the vigorous T cell repopulation following depletion can be directed against the tumour.

### **Soluble LAG-3 protein is a prognostic factor in breast cancer**

ImmuFact IMP321 is closely related to the soluble form of the LAG-3 (Lymphocyte Activation Gene-3) protein which is a prognostic indicator for survival in breast cancers expressing oestrogen or progesterone receptors. This was shown in a study carried out by researchers at the René Huguenin Cancer Centre and Pr. Frédéric Triebel when he was at the Pharmacy Faculty of University Paris 11. These results paved the way for the current clinical trial. (Immutep Press Release No 6, April 2006)

### **Centre René Huguenin de Lutte contre le Cancer**

The René Huguenin Centre for the Fight against Cancer is a comprehensive cancer centre that treats more than 3,000 new cases of cancer each year, with more than 2,000 new cases of breast cancer. It has a medical staff of 66 practitioners. Besides participation in therapeutic trials, the Centre has developed special expertise in the field of tumorigenesis and pharmacogenetics of breast cancers. Professor Jean-Nicolas Munck is the Directeur-Général of the Centre.

### **Immutep S.A.**

Immutep S.A. is a biopharmaceutical company developing immunostimulatory factors for the treatment of cancer and chronic infectious diseases and immunomodulatory therapeutic antibodies for the treatment of cancer or autoimmune disease. The Company's technologies are based on the LAG-3 immune control mechanism that mediates T cell immune responses.

### **ImmuFact<sup>®</sup> - Clinical Development**

More than 600 s.c. injections of IMP321 have been administered to date in Europe and the USA at doses up to 30 mg with no clinically significant drug-related adverse events. A Phase I trial in metastatic renal cell carcinoma with IMP321 alone has been completed. A Phase I/II trial in metastatic breast cancer combining IMP321 with weekly paclitaxel in a chemo-immunotherapy protocol has been completed (<http://clinicaltrials.gov/ct/gui/show/NCT00349934?order=1>). Three Phase I/II clinical trials are in progress: in pancreatic cancer combining IMP321 with gemcitabine in chemoimmunotherapy (<http://www.clinicaltrials.gov/ct2/show/NCT00732082?term=07-0265&rank=1>), a disease-free melanoma study with IMP321 as a therapeutic vaccine adjuvant to peptide antigens and a lympho-depletive/adoptive transfer metastatic melanoma study.