



## **Immutep Announces That ImmuFact<sup>®</sup> IMP321 Has Entered a Phase I Therapeutic Vaccine Trial in Melanoma**

**Orsay, September 25, 2006,** Immutep S.A. announced today that its lead product, ImmuFact<sup>®</sup> IMP321, has entered a Phase I clinical trial in disease-free melanoma. ImmuFact IMP321 is a potent natural human T cell immunostimulatory factor designed to amplify the T cell immune response. It can be used either as an immunopotentiator in therapeutic vaccines or alone in monotherapy or in combination with chemotherapy.

The Cancer Centre at the St Luc University Clinic, Brussels, is conducting the clinical trial. The design is a randomised open-label four-arm trial comparing a selected set of 8 HLA-A2 melanoma peptide antigens with or without IMP321 and/or Montanide. The study is being carried out by Dr. Jean-François Baurain as Principal Investigator and Pr. Pierre Coulie (Université Catholique de Louvain) for the immunomonitoring part of the study. Most of these HLA-A2 melanoma peptide antigens were first discovered by Pr. Thierry Boon's team at the Ludwig Institute for Cancer Research in Brussels, a world-class leading group in the field of cancer vaccines.

The primary objectives of the study are i) to determine whether immunization with 8 HLA-A2 peptides in PBS, or emulsified in Montanide, results in detectable cytotoxic T lymphocyte (CTL) responses in disease-free (absence of detectable melanoma lesions after surgery) melanoma patients when IMP321 is added as an immunological adjuvant and, ii) to establish safety of the addition of IMP321 to these two peptide formulations. Secondary objectives are to analyse the kinetics of any detectable CTL response and disease-free survival.

"We are very pleased to start this randomised trial in disease-free melanoma patients which should provide information about the potency of IMP321 as an adjuvant for the induction of CTL responses in patients," said Jean-François Baurain, PI of this study. "Disease-free melanoma is certainly an indication of choice to test these innovative vaccine formulations because there will be more time to administer the multiple shot vaccine and to carry out the sophisticated T cell response immunomonitoring. It will also minimise the inhibitory effects that tumour masses may exert on the development of tumour-specific immune responses".

"We are delighted to announce the first cancer vaccine trial using our immunopotentiator agent, IMP321," said Frédéric Triebel, Scientific & Medical Director of Immutep. "This new class of non-TLR agonist products has not yet been tested as a T cell response stimulant in vaccinated cancer patients and IMP321 may represent the extra boost that peptide antigens need for a strong and prolonged CTL activity".

For further information please visit the web-site [www.immutep.com](http://www.immutep.com) or e-mail John Hawken, CEO, at [JBHawken@immutep.com](mailto:JBHawken@immutep.com).

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## **Notes to Editors**

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

Immutep S.A. is a biopharmaceutical company developing technologies for novel immunotherapies for the treatment of cancer and chronic infectious diseases and new approaches to immune response modulation. The Company's technologies are based on the properties of LAG-3. Immutep is developing its products both in-house and in partnership with pharmaceutical and biotech companies. The Company was formed in 2001 by Frédéric Triebel, the scientific founder, and John B. Hawken, a specialist in the management of biotech start-ups, and has its headquarters and research facilities near Paris, France. Immutep is backed by the Paris-based venture capital firm Innoven Partenaires and the venture capital fund H2I, a specialist Biotech fund managed by Unicorn Biotutors/Equitis (Paris).

### **The Technology**

The Company's range of products is derived from LAG-3 (CD223), an immunomodulatory protein expressed on the surface of activated T cells. The three unique proprietary product platforms make use of the key roles played by this natural human protein in the regulation of the immune system.

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

The lead product, ImmuFact IMP321, is a highly potent T cell immunostimulatory factor derived from the soluble form of LAG-3 that binds, with high affinity, to MHC class II molecules expressed by dendritic cells (DC). This binding leads to DC maturation, migration to the lymph nodes and enhanced cross-presentation of antigens to T cells. As a result, strong and sustained anti-tumour or anti-viral cytotoxic T cell responses are obtained when IMP321 is injected alone or in combination with antigens.

#### **ImmuCine<sup>®</sup> – Immunostimulatory Vaccines**

The Company is developing a second technology that will make it possible to design novel therapeutic vaccines with even greater potency and efficacy. Covalently linking an antigen to IMP321 in a fusion protein results in both vectorisation of the antigen to the DC as well as the immunostimulatory effect described above. These dual action vaccines will be particularly useful in very difficult cases like HIV.

#### **ImmuTune<sup>®</sup> – Fine Tuning of the Immune Response**

The third technology uses LAG-3-specific antibodies to control signalling of the membrane-bound LAG-3 molecule into activated effector T cells or regulatory T cells (Tregs) to modulate the T cell response.

### **Clinical Development (ImmuFact)**

Immutep has completed two randomised single-blind escalating-dose Phase I studies in 108 healthy individuals with IMP321 alone and combined with two well-defined standard types of antigens to show safety of the product alone and as an adjuvant in therapeutic vaccines. A Phase I clinical trial in metastatic renal cell carcinoma started in September 2005 with IMP321 injected alone. A Phase I study in metastatic breast cancer started in July 2006 combining IMP321 with paclitaxel in a chemoimmunotherapy protocol. The current melanoma study is thus the fifth clinical trial with ImmuFact IMP321 in two years.

### **Oncology Department, Cliniques Universitaires Saint-Luc, Brussels**

The Cancer Centre at St Luc University Clinic, Brussels is one of the major comprehensive cancer centres in Europe. The Centre is running several immunotherapy trials in melanoma and has a long experience in therapeutic approaches in cancer and in translational research.

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