



PRESS RELEASE  
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FOR IMMEDIATE RELEASE

## **IMMUTEP INITIATES PHASE I CLINICAL TRIAL IN RENAL CELL CANCER**

Immutep S.A. announced today that it has initiated a Phase I clinical trial of its lead product *ImmuFact*<sup>®</sup> IMP321 in metastatic renal cell carcinoma. This is the Company's first clinical trial targeting cancer. Immutep is already carrying out trials of IMP321 to show safety and immune response to infectious disease antigens in healthy volunteers. *ImmuFact*<sup>®</sup> IMP321 is a potent natural human T cell immunostimulatory factor designed to amplify the T cell immune response through activation of dendritic cells and more efficient antigen presentation to T cells.

The single-centre open-label escalating-dose Phase I study is designed to show first, safety and tolerability, and second, to assess the T cell immune response with *ImmuFact*<sup>®</sup> IMP321 alone. The Company has a state-of-the-art immunomonitoring facility for measuring a wide range of immune response parameters. Recruitment of 12 patients started in September and the trial will be completed in Q2 2006. Each patient will receive 6 subcutaneous injections of IMP321 at two-weekly intervals. Dose levels will range from 50 µg to 1250 µg per injection. Additional patients may be recruited into the trial if useful to provide more data on safety or response rates.

Immutep and its partners will use the resulting data in the development of immunostimulatory treatments of cancer. *ImmuFact*<sup>®</sup> IMP321 can be used either alone or in combination with chemotherapy, or as an immunopotentiator in therapeutic vaccines.

"We are delighted to be starting our third clinical trial which will establish the safety and some immunological parameters of IMP321 for the first time in oncology," said Frédéric Triebel, Scientific & Medical Director of Immutep. "Metastatic renal cell carcinoma patients have no effective drugs that prolong survival at their disposal. However, we know that tumour-specific T cells accumulate at the tumour site in these patients and we believe that mobilizing the dendritic cell network with our highly potent LAG-3 molecule can make a difference for these patients".

The clinical study is being carried out at the Institut Gustave Roussy (IGR, Villejuif, France), the largest cancer clinic in Europe, under the supervision of Dr Bernard Escudier, a leading specialist in renal cell carcinoma. The CRO is Umanis Clinical Research. Claude Dubois, who manages IGR&D, IGR's technology transfer company, one of the founding shareholders of Immutep, said: "We are looking forward to this strengthening of the links between IGR and Immutep, a venture in which we believed from the very start."

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 a key human mediator of the T cell immune response. Immutep is developing its products both in-house and in partnership with pharmaceutical and biotech companies.

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).

## **Immutep S.A.**

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*<sup>®</sup> 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 is conducting two randomised single-blind escalating-dose Phase I/II studies designed first, to show safety and tolerability, and second, to assess T cell immune response in 108 healthy individuals with IMP321 alone and combined with two well-defined standard types of antigens: soluble influenza virus antigens and particulate hepatitis B surface antigen. The clinical phase of the first study in 60 subjects is complete and has shown good tolerability with no adverse events. As announced here, a Phase I clinical trial in cancer patients started in September with IMP321 injected alone.

## **Umanis Clinical Research**

Umanis Clinical Research is a contract research organisation which is part of the Umanis Group (Eurolist C FR0000066771 – UMS). Umanis ([www.umanis.com/cro](http://www.umanis.com/cro)) provides to the pharmaceutical/ biotechnology industry a full range of services for managing clinical trials including monitoring, data management, statistics, medical writing and information technology solutions (e-CRF, PDA).