ANTIGENICS

23 November 2009

Dr. Eric Abadie
Chairman, Committee for Medicinal Products for Human Use
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

Subject: Withdrawal of Oncophage (Vitespen), 20µg, Solution for Injection
EMEA/H/C/001072

Dear Dr. Abadie,

I would like to inform you that, at this point of time, Antigenics Therapeutics Limited has taken the decision to withdraw the application for Marketing Authorisation of Oncophage (Vitespen), 20µg, Solution for Injection, which was intended to be used as an adjuvant treatment for localized renal cell carcinoma (RCC) patients at increased risk of recurrence with the following features: primary tumour stage T1b or T2 with high-grade (3 or 4) histology with no nodal involvement.

The company has taken this decision based primarily on the CHMP's view that submitted information is not sufficient to demonstrate efficacy of Oncophage at this point in time.

There are currently no patients in the EU receiving Oncophage as part of a clinical trial, a formal compassionate use or named patient programme. However, we reserve the right to respond to bona fide unsolicited requests from healthcare professionals in the EU to supply Oncophage for use by RCC patients under their care in order to fulfill special medical needs pursuant to Article 5(1) of Directive 2001/83/EC or the equivalent provisions in the domestic laws of the Member States. Antigenics has received preliminary inquiry from clinicians who have expressed an interest in Oncophage, given the acceptable safety profile and measurable treatment effects in certain defined RCC patient population.

3 Forbes Road Lexington, MA 02421 T: 781.674.4400 F: 781.674.4200 ANTIGENICS.COM

We also reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

I agree for this letter to be published on the EMEA website.