Sanofi−aventis and Oxford Biomedica Report Encouraging Trovax® Phase II Trial Results in Metastatic Renal Cancer

− Presentations at the American Society of Clinical Oncology Annual Meeting −

Paris, France and Oxford, UK − 2 June 2008: Sanofi−aventis (Euronext: SAN and NYSE: SNY) and Oxford BioMedica (LSE: OXB) announced today encouraging updated results from Phase II trials of TroVax in metastatic (advanced) renal cancer.

TroVax is Oxford BioMedica s lead therapeutic cancer vaccine, which is being developed in metastatic renal cancer and other solid cancers in collaboration with sanofi−aventis. The Phase III TRIST (TroVax Renal Immunotherapy Survival Trial) study is ongoing in patients with locally advanced or metastatic clear cell renal carcinoma and is expected to complete in the first half of 2009. Phase III trials in colorectal cancer are expected to start in 2008.

Results from three Phase II trials in metastatic renal cancer were presented by the trials respective Principal Investigators at the 2008 Annual Meeting of the American Society of Clinical Oncology (ASCO) on 31 May and 1 June in Chicago, Illinois.

Oxford BioMedica has completed four Phase II trials of TroVax in metastatic renal cancer in a total of 88 patients to evaluate the safety, immunogenicity and efficacy of TroVax in combination with standard therapy or as a single agent. The ASCO presentations provide mature analyses of three of the four Phase II trials of TroVax in metastatic renal cancer. The three trials enrolled 61 patients in centres in the USA and UK. Although each of these studies had differing patient cohorts in terms of prior treatment, concomitant therapy and histological type of tumour, all studies indicated that TroVax was well tolerated and generated consistent and robust immune responses to the tumour antigen 5T4 (55 of 60 evaluable patients, 92%). Overall there were no serious TroVax−related adverse events. The most frequent TroVax−related side effect was low−grade transient irritation at the injection site. Furthermore, all studies showed encouraging levels of clinical benefit relative to historical controls.

The presentations were as follows:

Phase II trial of TroVax and high−dose interleukin−2 in metastatic renal cancer

Dr. Howard L. Kaufman of the Division of Surgical Oncology, Columbia University, New York, NY, presented results from a Phase II trial of TroVax as a second−line treatment (with a minority of first−line patients) for metastatic renal cancer in combination with high−dose interleukin−2, entitled: Effector and regulatory T cell responses correlate with clinical outcome in metastatic renal cell carcinoma patients treated with MVA−5T4 vaccine and high−dose interleukin−2 , (abstract number: 3004).

The trial enrolled 25 patients with metastatic renal cell carcinoma (RCC). Patients were eligible to receive five TroVax immunisations, which were administered intramuscularly every three weeks followed by cycles of interleukin−2 (600,000 IU/kg). Patients demonstrating objective tumour responses or disease stabilisation received further TroVax immunisations every three months for up to one year as long as there was no evidence of disease progression. Clinical responses were determined by RECIST criteria.

There were no serious TroVax−related adverse events. Although no objective tumour responses were documented, three previously non−resectable patients (12%) were rendered disease−free after nephrectomy or resection of residual metastatic disease following treatment with TroVax and interleukin−2. Including these patients, a total of twelve patients (48%) had disease stabilisation and showed an improved median overall survival compared to patients with progressive disease (median not reached vs. 28 months, p=0.026, *t*−test). One patient withdrew prior to evaluation of immune responses, however, 23 of 24 evaluable patients (96%) developed 5T4−specific antibody responses and 13 patients (54%) had detectable 5T4−specific T cell responses. Despite the survival data being immature, there was a relationship between improvement in overall survival and the presence of a 5T4−specific T cell response. The median progression−free survival of 23 per−protocol patients (i.e. reached the first scan) was 4.8 months. Overall survival appears favourable relative to RCC patients receiving high−dose interleukin−2 alone at this institution.

Phase II trial of TroVax and low−dose interleukin−2 in metastatic renal cancer

Dr. Robert J. Amato of the Methodist Hospital Research Institute, Houston, Texas, presented results from a Phase II trial of TroVax as a second and third−line treatment for metastatic renal cancer in combination with low−dose interleukin−2, entitled: Vaccination of renal cell cancer patients with modified vaccinia ankara delivering the tumour antigen 5T4 (TroVax) and low−dose interleukin−2: A Phase II trial , (abstract number: 5101).

The trial enrolled 25 patients, some heavily pre−treated, with metastatic RCC. The interleukin−2 was administered in eight−week cycles as a subcutaneous injection at doses of 125,000−250,000 IU/kg. Patients received eight TroVax immunisations over 48 weeks or until disease progression or death. Clinical responses were determined by RECIST criteria.

There were no serious TroVax−related adverse events. Two patients showed durable complete tumour responses with progression−free survival of >24 months and another patient had a partial tumour response with progression−free survival of >13 months. A further six patients showed disease stabilisation with progression−free survival ranging from six to >24 months. Median progression−free survival was 3.4 months. Median overall survival has yet to be reached but exceeds 12.9 months and 16 patients (64%) remain alive. In terms of immune responses, 21 of the 25 patients (84%) mounted 5T4 specific antibody responses. There was a statistically significant correlation between the magnitude of 5T4−specific antibody responses and both progression−free survival ($p<0.05$, log rank test) and overall survival ($p<0.05$, log rank test).

Phase II trial of TroVax and interferon−alpha in metastatic renal cancer

Dr. Robert Hawkins of the Christie Hospital, Manchester, UK, presented results from a Phase II trial of TroVax as a first−line treatment for metastatic renal cancer in combination with interferon−alpha, entitled: Vaccination of renal cell cancer patients with TroVax (modified vaccinia ankara delivering the tumour antigen 5T4) plus interferon−alpha: A Phase II trial , (abstract number: 3053).

The trial enrolled 11 first line patients with metastatic RCC. TroVax was administered every two to three weeks for the first four immunisations and, thereafter, every four weeks until the end of the study (week 42). Clinical responses were determined by RECIST criteria.

Administration of TroVax alongside interferon−alpha was well tolerated with no serious adverse events attributed to TroVax. All 11 patients mounted 5T4 specific antibody responses and of these five[1] patients (45%) also mounted 5T4−specific T cell responses. No objective tumour responses were seen, but ten patients (91%) showed disease stabilisation for periods ranging from 3.9 to >16.8 months. The median time to disease progression was 9.5 months. Median overall survival has yet to be reached and nine patients (82%) remain alive with a minimum follow−up period of 15.6 months.

Dr Mike McDonald, Oxford BioMedica s Chief Medical Officer, commented on the new data: *With our partner, sanofi−aventis, we continue to be encouraged by the Phase II results of TroVax. These updated analyses of three trials in metastatic renal cancer further support the mechanistic rationale that the immune response induced by TroVax has potential for clinical use in this setting. In addition, the results provide important safety and immunogenicity data for TroVax when administered in combination with two standard therapies for metastatic renal cancer. Future trials will determine whether TroVax could play an important role in the treatment of metastatic renal cancer and other solid cancers, and thus potentially address significant unmet needs for patients. We look forward to the results from the ongoing Phase III TRIST study of TroVax in metastatic renal cancer, anticipated in the first half of 2009.*

The abstracts can be accessed online at http://www.asco.org.

1. One of the five patients showing 5T4−specific T cell responses had no baseline sample available for testing, so cannot confirm whether this is a de novo or pre−existing response

TroVax®

TroVax is Oxford BioMedica s novel therapeutic cancer vaccine, which is being developed in collaboration with sanofi−aventis. It is designed specifically to stimulate an anti−cancer immune response and has potential application in most solid tumour types. TroVax targets the tumour antigen 5T4, which is broadly distributed throughout a wide range of solid tumours. The presence of 5T4 is correlated with poor prognosis. The product consists of a Modified Vaccinia Ankara vector, which delivers the gene for 5T4 and stimulates a patient s body to produce an anti−5T4 immune response. This immune response destroys tumour cells carrying the 5T4.

Renal Cell Carcinoma

Renal cell carcinoma (RCC) accounts for 2% of all new cancer cases worldwide. More than 150,000 people are newly diagnosed with RCC worldwide each year. Prognosis is very poor. If RCC has metastasised to other organs at the time of first diagnosis, the five−year survival rate is less than 5%. In the USA and Europe, RCC accounts for more than 33,000 deaths each year. There are several types of RCC, but the most common is called clear cell, which accounts for 80% of diagnoses. In RCC, cancer cells develop in the lining of the kidney's tubes and grow into a tumour.

About sanofi−aventis

Sanofi−aventis, a leading global pharmaceutical company, discovers, develops and distributes therapeutic solutions to improve the lives of everyone. Sanofi−aventis is listed in Paris (EURONEXT : SAN) and in New York (NYSE : SNY).

Forward−looking statements sanofi−aventis

This press release contains forward−looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward−looking statements are statements that are not historical facts. These statements include product development, product potential projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future events, operations, products and services, and statements regarding future performance. Forward−looking statements are generally identified by the words expects, anticipates, believes, intends, estimates, plans and similar expressions. Although sanofi−aventis management believes that the expectations reflected in such forward−looking statements are reasonable, investors are cautioned that forward−looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of sanofi−aventis, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward−looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMEA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such products candidates, the absence of guarantee that the products candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives as well as those discussed or identified in the public filings with the SEC and the AMF made by sanofi−aventis, including those listed under Risk Factors and Cautionary Statement Regarding Forward−Looking Statements in sanofi−aventis annual report on Form 20−F for the year ended December 31, 2007. Other than as required by applicable law, sanofi−aventis does not undertake any obligation to update or revise any forward−looking information or statements.

About Oxford BioMedica

Oxford BioMedica (LSE: OXB) is a biopharmaceutical company specialising in cancer immunotherapy and gene−based therapies. The Company was established in 1995, as a spin−out from Oxford University, and is listed on the London Stock Exchange.

The Company has a platform of gene delivery technologies, which are based on highly engineered viral systems. Oxford BioMedica also has in−house clinical, regulatory and manufacturing know−how. The lead product candidate is TroVax®, a therapeutic vaccine for multiple solid cancers, which is licensed to sanofi−aventis for global development and commercialisation. TroVax is in Phase III development. Oxford BioMedica has three other products in clinical development, including ProSavin®, a novel gene−based treatment for Parkinson s disease, in a Phase I/II trial. The Company is underpinned by over 80 patent families, which represent one of the broadest patent estates in the field. The Company has a staff of approximately 85. Oxford BioMedica has collaborations with sanofi−aventis, Wyeth, Sigma−Aldrich, MolMed and Virxsys. Technology licensees include Biogen Idec, Merck & Co, GlaxoSmithKline and Pfizer.

Further information is available at www.oxfordbiomedica.co.uk

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