Press release

From cells to therapeutics Vivalis

A MAJOR STEP TAKEN IN THE DEVELOPMENT OF VIVALIS:

FILING OF THE EB66® CELL LINE BMF WITH THE AMERICAN FDA

CONFIRMATION OF BREAKTHROUGH TECHNOLOGY STATUS FOR THE PRODUCTION OF VACCINES AND PROTEINS

Nantes (France) – 30 June 2008

VIVALIS (NYSE Euronext: VLS) announces that on 27 June 2008 it filed the BMF (Biologics Master File), for registration of the EB66® cell line with the FDA (Food and Drug Administration), the American health regulation authority. The EB66® cell line results from the EBx® technology developed by VIVALIS from duck embryonic stem cells for use in the production of vaccines and therapeutic proteins.

VIVALIS has thus taken a decisive step towards regulatory approval of EBx® technology by the health authorities.

This file covers all the tests and controls carried out over the last few months in order to characterise the EB66® cell line and demonstrate the high level of health standards of the innovative technology developed by VIVALIS for the production of vaccines and therapeutic proteins. Subsequent to this file being filed, all partners of VIVALIS having signed a commercial licence with the company may file requests for clinical trials for their products based on the EB66® cell line. In this way, VIVALIS is showing its capacity to meet its commitments and its development schedule announced at the time of its IPO. Following this registration, the first authorisation requests for clinical trials should take place in the course of 2009 or early 2010.

Characteristics of the "BMF" file.

This "BMF" file contains three main sections:

- A precise description of the process of establishing the EB66® cell line, from the duck eggs from which were obtained the embryonic stem cells up to the derivation of the EB66® cell line. This process, which is the final outcome of 15 years of academic and internal research, required 5 years of research and characterisation for its final development;
- An exhaustive description of all the raw materials used in this process, the laboratories where the EB66® cell line was developed, and the environmental safeguards implemented to protect the cells during their manipulation;
- The characterisation strategy and the description of all the tests carried out on the EB66® cell line. This section brings together the results of the many highly advanced tests on the EB66® intended to demonstrate that the cell is exempt from any viral and bacterial contaminants and that it has perfect genetic stability.

Over 100 tests proving the unique and innovative nature of VIVALIS EBx® technology, which can be used in the production of a very large number of vaccines and proteins.

All results obtained to date are compliant with the specifications defined by the regulatory health authorities, and confirm that the EB66® cell line is a unique cell line. Today, it is the only immortal cell line to have been produced naturally, without genetic, chemical or viral modification. Furthermore, although immortal, the EB66® cell line remains diploid and genetically stable, unlike existing cell lines, which are genetically unstable and tumorigenic.

More importantly, the EB66® cell line is the only known cell line able to replicate almost all viruses currently produced in embryonated eggs, i.e. more than 25 families of virus, with an even greater number of vaccines. The EB66® cell line therefore confirms its status as the benchmark cell line to replace embryonated eggs, the system used for decades to produce vaccines such as those against influenza, measles, mumps or yellow fever, as well as a very large number of new-generation vaccines against various types of cancer or infectious diseases such as AIDS.

By way of reminder, the vaccine market is currently worth over 18 billion dollars, and is set to reach 25 billion by 2012. The market is growing by over 15% per year, double the growth in the pharmaceuticals market as a whole.

Developments are on going on the EB66® cell line for the production of monoclonal antibodies, representing a second application for this technology. This second market is currently worth 20 billion dollars, and is also experiencing growth of 15% per year.

Confirmation of schedule with the major world players in vaccines.

EBx® technology, which is currently used or tested by 75% of the world players in vaccines, notably **Sanofi Pasteur**, **GSK**, **Novartis Vaccines**, **CSL**, **Schering Plough (Nobilon)**, **Bavarian Nordic**, **Kaketsuken**, **Geovax**, **Merial**, **Intervet Schering Plough**, **Fort Dodge (Wyeth)**, and **Virbac,** has therefore taken a major step in regulatory terms.

Tests have also begun on it for the production of monoclonal antibodies by companies such as **Sanofi-Aventis, Innate Pharma** and **MAT Biopharma**.

VIVALIS's partners worldwide will now be able to file requests for clinical trials of their vaccines or antibodies produced using the EB66® cell line. The regulatory authorities will analyse the regulatory file describing the therapeutic product and the "BMF" file which characterises the EB66® cell line. The first authorisations for clinical trials are expected in the course of 2009 or early 2010.

Majid MEHTALI, VIVALIS' CSO, states: *"The scientific and regulatory departments at VIVALIS are delighted to be able to announce that the "BMF" file characterising the EB66® cell line has been filed with the FDA. This very important step makes concrete several years of intense research, and we firmly believe that the EB66® cell line will meet the requirements of the regulatory authorities for all potential uses of the cell line. This filing represents a decisive step in the establishment of the EBx® platform as a benchmark cellular substrate for the industrial production of a very large number of vaccines, as well as monoclonal antibodies with increased cytotoxic activity".*

Franck GRIMAUD, VIVALIS' CEO, concludes: "*One year after its IPO, VIVALIS is taking a major step in its development through this registration with the FDA. This regulatory step makes concrete more than 5 years of work by all VIVALIS's research teams and confirms the trust placed in this new technology by the world largest pharmaceutical companies. The positive results of the tests carried out demonstrate the unique and innovative character of this breakthrough technology. Finally, this registration confirms our initial schedule, and development will continue in the coming months.*"

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Next press release:

13 August 2008, after closure of the Euronext Paris market: Turnover for the 2nd quarter of 2008

About VIVALIS (www.vivalis.com)

VIVALIS (NYSE- Euronext: VLS) is a biopharmaceutical company that provides innovative cell-based solutions to the pharmaceutical industry for the manufacture of vaccines and proteins, and develops drugs for the prevention and treatment of viral diseases. VIVALIS's expertise and intellectual property are exploited in three main areas:

1. The development and manufacturing of vaccines. VIVALIS offers research and commercial licenses for its EB66® cell line, derived from duck embryonic stem cells, to pharmaceutical and biotechnology companies for the production of viral vaccines. Vivalis receive up front, milestones, and royalties on its licensees net sales.

2. The development of production systems for recombinant proteins and monoclonal antibodies. VIVALIS licenses its EB66® cell line for the production of recombinant proteins to biotechnology and pharmaceutical companies. Vivalis receive up front, milestones, and royalties on its licensees net sales. Vivalis receive up front, milestones, and royalties on its licensees net sales.

3. The construction of a portfolio of proprietary products in the area of vaccines and anti-viral molecules (hepatitis C).

Based in Nantes (France), VIVALIS was founded in 1999 by the Grimaud group (1,450 employees), the second largest group worldwide in animal genetic selection. VIVALIS has established numerous partnerships with world leaders in this sector, including Sanofi Pasteur, GlaxoSmithKline, Novartis Vaccines, Kaketsuken, Merial and SAFC Biosciences. VIVALIS is a member of the French ATLANTIC BIOTHERAPIES bio-cluster.

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