

## PHASE II CLINICAL TRIAL FOR A HUMAN INFLUENZA VACCINE INITIATED

### KAKETSUKEN TO CONDUCT A PHASE II HUMAN CLINICAL STUDIES WITH A VACCINE CANDIDATE PRODUCED IN EB66<sup>®</sup> CELL LINE

**Nantes, Lyon (France) – May 24th, 2012**, VIVALIS (NYSE Euronext: VLS) today announced that Kaketsuken has commenced a phase 2 clinical trial in Japan in April 2012, for the cell culture based pandemic flu vaccine being co-developed with GlaxoSmithKline (GSK) and using Vivalis' EB66<sup>®</sup> cell line.

In the "Program for preparing pandemic influenza vaccine development and production system" (hereinafter referred to as the "Program"), the Japanese Ministry of Health, Labour and Welfare is taking the lead in establishing domestic production and supply of pandemic influenza vaccine using "cell-culture technology". It is anticipated that cell-culture technology has the potential to enable a vaccine to be available for use in advance of an imminent pandemic.

In order to contribute to the Program, Kaketsuken is aiming to early establish in Japan a domestic production and supply system for influenza vaccines co-developed with GSK, which vaccines are produced in Vivalis proprietary EB66<sup>®</sup> cell line in combination with GSK antigen-sparing adjuvant technology.

Franck Grimaud, CEO, and Majid Mehtali, CSO, co-managers of VIVALIS jointly stated, *"We have now two clinical trials on-going, including one in phase II, with an influenza vaccine produced on our EB66<sup>®</sup> cell line in two of the world largest markets, the USA and Japan. More than ever we are convinced that EB66<sup>®</sup> cells will be the cell line of choice as the new production platform for human and animal vaccines. We will continue to promote the EB66<sup>®</sup> cell line both for the production of vaccines and therapeutic proteins with the objective to expand our worldwide partnering activities."*

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#### **Next Financial Press Release:**

**July 19, 2012, after NYSE Euronext market closing: Second Quarter 2012 Revenues**

#### **About KAKETSUKEN ([www.kaketsuken.or.jp](http://www.kaketsuken.or.jp))**

Based in Kumamoto, Japan, Kaketsuken has pursued the preventive medicine fields of microbiology, immunology and serology, towards the improvement of health and hygiene, and is a leading company in the fields of human vaccines, animal vaccines, and blood plasma derivatives respectively in Japan. In the field of human vaccines, Kaketsuken is currently manufacturing more than 10 kinds of vaccines for humans, such as Influenza vaccine, DTaP vaccine, recombinant Hepatitis B vaccine and Hepatitis A vaccine.

Kaketsuken is also developing a therapeutic monoclonal antibody for HIV, a cell-cultured Japanese encephalitis vaccine and Influenza vaccine.

## **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 unmet medical needs. VIVALIS' expertise and intellectual property are leveraged in three main areas:

### **EB66<sup>®</sup> Cell Line**

VIVALIS offers research and commercial licenses for its EB66<sup>®</sup> cell line, derived from duck embryonic stem cells, to pharmaceutical and biotechnology companies for the production of therapeutic and prophylactic viral vaccines, virosomes, VLP's, and recombinant proteins (with a focus on monoclonal antibodies having enhanced cytotoxic activity). EB66<sup>®</sup> cell line based vaccines are currently in clinical trials in the USA and Japan. Through these programs VIVALIS receives upfront, clinical stage milestone payments along with royalties on licensees net sales.

### **VIVA|Screen<sup>™</sup> Human Antibody Discovery Platform**

Customized solutions for the discovery, development, and production of fully human monoclonal antibodies are now offered by VIVALIS. Through these programs VIVALIS receives upfront, clinical stage milestone payments along with royalties on licensees net sales.

### **3D-Screen<sup>™</sup> Drug Discovery Platform**

VIVALIS performs discovery and development, up to pre-clinical evaluation, of original small chemical molecules identified with its proprietary platform, 3D-Screen<sup>™</sup>. This unique screening platform is designed to identify original molecules that alter the three-dimensional structure of a target protein, thus modulating its biological function through an innovative mode of action. VIVALIS is building a portfolio of proprietary new chemical entities for the treatment of hepatitis-C virus infection. VIVALIS also offers on a service basis to develop ready-to-use customized 3D-Screen<sup>™</sup> HTS assays directed against target proteins of interest.

Based in Nantes & Lyon (France) and in Toyama (Japan) VIVALIS was founded in 1999 by the Grimaud Group (ca. 1,600 employees), a worldwide leader in animal genetic selection. VIVALIS has established more than 30 partnerships and licenses with world leaders in this sector, including Sanofi Pasteur, GlaxoSmithKline, Transgene, Pfizer Animal Health, Kaketsuken, Kitasato Daiichi Sankyo Vaccine, Merial, Merck Animal Health, and SAFB Biosciences. VIVALIS is a member of the French ATLANPOLE BIOTHERAPIES and LYON BIOPOLE bioclusters and a member of the Japanese HOKURIKU INNOVATION CLUSTER FOR HEALTH SCIENCE in Toyama.

#### **VIVALIS**

Listed on Euronext Paris – Compartment C of NYSE Euronext

Reuters: VLS.PA – Bloomberg: VLS FP

Included in NYSE Euronext's SBF 250, CAC Small 90 and Next Biotech indexes



*This document contains forward-looking statements and comments on the company's objectives and strategies. No guarantee can be given as to any of the events anticipated by the forward-looking statements, which are subject to inherent risks, including the risk factors described in the company's document de référence, changes in economic conditions, the financial markets or the markets in which the company operates.*

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