From cells to therapeutics Vivalis

# VIVALIS ANNOUNCES THE PHASE III ADVANCEMENT OF THE EB66<sup>®</sup> CELL BASED HUMAN INFLUENZA VACCINE

**Nantes & Lyon (France) – 14 September 2012** – VIVALIS (NYSE Euronext: VLS) announced today the advancement of a human influenza vaccine into Phase III clinical trials being jointly developed by the Chemo-Sero-Therapeutic Research Institute of Japan ("Kaketsuken"), GlaxoSmithKline K.K. ("GSK Japan"), and GlaxoSmithKline Biologicals ("GSK Bio").

Franck Grimaud, CEO, and Majid Mehtali, CSO, co-managers of VIVALIS jointly stated, "This is a major development for the EB66<sup>®</sup> platform and we are happy that Kaketsuken and GlaxoSmithKline have achieved this significant milestone. EB66<sup>®</sup> is an innovative cell-line that is now used as a production platform for a vaccine that reaches Phase III, the last step of clinical development. Having worked together with GSK and Kaketsuken, over the last several years, it is gratifying for Vivalis to see this investigational product progress using a technology developed with this type of dedication envisioned. We look forward to continuing these relationships and are confident that our EB66<sup>®</sup> technology will continue to provide the demands exacted upon it."

A copy of the press release per Kaketsuken (announced on 14 SEPTEMBER 2012) is provided after the following paragraph.

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## <u>Next Financial Press Release</u> 23 October 2012, after NYSE Euronext market closing: Third Quarter 2012 Revenues

### About VIVALIS (www.vivalis.com)

VIVALIS (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 two 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). Through these programs VIVALIS receives upfront, clinical, and 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 rare, fully human monoclonal antibodies is offered by VIVALIS. Through these programs VIVALIS receives upfront, clinical, and milestone payments along with royalties on licensees net sales under both service agreements and partnered programs.

Based in Nantes & Lyon (France) and in Toyama (Japan) VIVALIS, VIVALIS was founded in 1999 by the Grimaud group (ca. 1,700 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, Pfizer Animal Health, Kaketsuken, Kitasato Daiichi Sankyo Vaccine, Merial, Intervet, and SAFC Biosciences. VIVALIS is a member of the French ATLANTIC BIOTHERAPIES and LYON BIOPOLE bio-clusters 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 indices

This document contains forward-looking statements and comments on the company's objectives and strategies. No guarantees can be given to any of the events anticipated by the forward-looking statements contained in this document, which are subject to inherent risks, including 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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# Start of phase 3 clinical trial for EB66® cell culture based pandemic vaccine

The Chemo-Sero-Therapeutic Research Institute

The Chemo-Sero-Therapeutic Research Institute (Head Office: Kumamoto city, Kumamoto, Director General: Seiji Miyamoto, hereinafter referred to as Kaketsuken) announces that it has commenced a phase 3 clinical trial in September 2012 for the EB66® cell culture based pandemic vaccine being co-developed with GlaxoSmithKline K.K. (Head Office: Shibuya-ku Tokyo, President: Philippe Fauchet, hereinafter referred to as "GSK Japan"), and GlaxoSmithKline Biologicals (Belgium, hereinafter referred to as "GSK Bio").

## 1. Development Objective

In the "Program for preparing pandemic influenza vaccine development and production system" (hereinafter referred to as the "Program"), the Ministry of Health Labour and Welfare is taking the lead in establishing domestic production and supply of pandemic influenza vaccine using "cell-culture technology," which is expected to shorten the production time required in the event of an imminent pandemic.

In order to contribute to the Program Kaketsuken, in collaboration with GSK Bio, is aiming to establish early in Japan a domestic production and supply system for influenza vaccines by i) utilizing The Vivalis EB66<sup>®</sup> in-licensed cell line and ii) applying their cell culture technologies in combination with the GSK Bio antigen-sparing adjuvant technology.

## 2. Outline of Study

### Development Phase: Phase 3 clinical study

Objective of the study: The study investigates the safety and immunogenicity of the vaccine in healthy adults in Japan.

# [Reference]

For more than 50 years, Kaketsuken has contributed to the preventive and therapeutic areas of infectious diseases both domestic and overseas through the development and supply of biological medications such as vaccines. Kaketsuken aims to further contribute to the pandemic influenza preparedness plan, a nationwide risk management program.

As a part of the government program on pandemic influenza preparedness, Kaketsuken started clinical trials for its egg-based H5N1 (pre-) pandemic influenza vaccine in 2004 and obtained approval for the vaccine on October 27, 2010. Kaketsuken is also contributing to the government stockpile of H5N1 (pre-) pandemic antigen produced with egg-based technology. Furthermore, Kaketsuken contributed to the production and supply of vaccine in Japan for the 2009 H1N1 pandemic influenza.

Cell culture technology may have the potential to shorten the production time after the pandemic virus is identified, support vaccine production capability in the event of an avian influenza pandemic (where the egg supply may be in jeopardy) and realise quick production and supply of the vaccine. Kaketsuken aims to utilize the production technology and know-how it possesses, combined with the knowledge acquired from the collaboration with GSK Bio and GSK Japan, to contribute to the pandemic preparedness plan of Japan.

The EB66<sup>®</sup> cell line, which is used for this present project, is a proprietary technology of Vivalis (Nantes, France), and has been exclusively licensed to GSK Bio for influenza vaccine production. Capable of proliferation in serum-free suspension culture, EB66<sup>®</sup> cells support the efficient production of influenza and other virus-based vaccines used in both human and animal health.

[End of Kaketsuken press release.]

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