

# VIVALIS ANNOUNCED THE FIRST EVER MARKETING AUTHORIZATION FOR A VACCINE PRODUCED IN EB66® CELL LINE

Nantes (France) – 09 October 2012 – Vivalis (NYSE Euronext: VLS) announced today that The Chemo-Sero Therapeutic Research Institute (Kaketsuken) has received a marketing authorization in Japan from the Ministry of Agriculture, Forestry and Fisheries for a prophylactic veterinary vaccine produced in Vivalis' EB66® cells against Egg Drop Syndrome (EDS) for use in egg laying hens. It is the first vaccine produced in EB66® cells to be approved by any regulatory authority in the world.

Vivalis EB66<sup>®</sup> cell line was used in veterinary applications for over five years. A key benefit seen with EB66<sup>®</sup> cell line is the ability to migrate away from traditional egg-based or chicken embryo-based production systems where inefficiencies make some viral vaccines difficult to produce or economically unviable due to high production costs. The EB66<sup>®</sup> cells, with their ability to grow to high cell densities, their rapid 14 hours population doubling time, and their ability to grow in suspension in single- and multi-use bioreactor systems, make them a desirable substrate for viral vaccine production when costs are a significant concern.

Today, over 30 EB66<sup>®</sup> commercial and research licenses have been signed with 20 different vaccine companies world-wide, corresponding to more than 70 vaccines under development produced on the EB66<sup>®</sup> cell line.

Half of these companies represent the veterinary field with the expectation of up to five market approvals within the next three years. The veterinary vaccine market which was established to more than US\$ 5 billion in 2012, is representing a very important segment for Vivalis.

In the field of human health, 20 human vaccines are currently under development; the most advanced vaccine is in Phase III clinical trials for human influenza prevention in Japan.

Franck Grimaud, CEO, and Majid Mehtali, CSO, co-managers of Vivalis jointly stated, "We are very happy that Kaketsuken has achieved the approval for this vaccine produced in the EB66® cell line. Having been thoroughly reviewed in a full regulatory context, our Japanese partner has successfully shown that products can be produced and approved in a novel cell substrate, something few organizations have achieved. We have always been enthusiastic of the strong and trustful relationship with the Kaketsuken team here at Vivalis. This first market approval, in a demanding regulatory environment, demonstrates that the shift from traditional egg-based production systems to a cell substrate like the EB66® cell line, is possible and ongoing. We expect other vaccine companies to follow this example in the months to come, in both the veterinary and human vaccine field."

Financial terms of the agreement were not disclosed.

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

#### 23 October 2012, after NYSE Euronext market closing: Third Quarter 2012 Revenues

# 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 recombinant proteins, and develops monoclonal antibodies for the prevention and treatment of pathologies with unmet medical needs. Vivalis' expertise and intellectual property are leveraged in two main areas:

# 1. EB66® 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. Clinical trials of EB66 produced vaccines are currently ongoing in the USA and Japan. Through these programs Vivalis receives an upfront payment, clinical stage milestone payments along with royalties on licensees net sales.

## 2. VIVA|Screen™ Human Antibody Discovery Platform

Customized solutions for the discovery development and production of rare, fully human monoclonal antibodies are offered by Vivalis. Through these programs, Vivalis receives payments associated with the funding of discovery phase, and an upfront payment, clinical stage milestone payments along with royalties on net sales of licensed antibodies that are commercially developed and sold by our clients.

Based in Nantes & Lyon (France) and in Toyama (Japan) Vivalis, Vivalis was founded in 1999 by the Grimaud group (ca. 1,700 employees), one of the worldwide leaders 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 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



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