

### GlaxoSmithKline signs an agreement with Kaketsuken to codevelop cell-culture based influenza vaccines in Japan based on Vivalis EB66® cell line

Nantes (France) – 29 September 2009: VIVALIS (NYSE Euronext Paris: VLS), announces today that its partners GlaxoSmithKline K.K. (Head Office: Shibuya-ku, Tokyo, President: Marc Dunoyer, hereinafter referred to as GSK), GlaxoSmithKline Biologicals (Belgium), its licensee of EB66® cell line for the production of flu vaccine, and The Chemo-Sero-Therapeutic Research Institute (Head Office: Kumamoto-shi, Kumamoto, Director General: Akinobu Funatsu, hereinafter referred to as "Kaketsuken"), have signed an agreement to co-develop influenza vaccines, including pandemic influenza vaccines, produced using EB66® cell-culture technology in Japan.

The agreement aims to integrate cell-culture technology and know-how owned by or licensed to GSK and Kaketsuken (including the EB66<sup>®</sup> cell line in-licensed by GSK from Vivalis) with GSK's adjuvant technology in order to co-develop, manufacture and supply a cell-culture based pandemic influenza vaccine as early as possible in Japan.

With this collaboration, GSK and Kaketsuken are committed to contributing to Japan's pandemic plan through developing and making available as quickly as possible a cell-culture based pandemic influenza vaccine to as many people as possible in need of this vaccine.

GSK has extensive experience and a track record in manufacturing and supplying influenza vaccines as well as in adjuvant technology. From GSK's experience with an H5N1 pandemic influenza vaccine in Europe, using GSK's adjuvant promotes stronger and longer immune response. Thus, influenza vaccines that use the adjuvant are expected to induce high immune response against the virus even at a low dose of antigen, sparing the amount of antigen required per vaccination. Furthermore, the addition of the adjuvant has demonstrated to stimulate an immune response even if the influenza strain changes slightly (drifts), providing a substantial level of cross-protection. Also, the safety of the adjuvant has been confirmed by large-scale clinical trials.

Marc Dunoyer, president of GSK said, "This agreement with Kaketsuken, a leader in research and manufacturing of vaccines in Japan, is an extremely important milestone in developing and providing a stable supply of vaccines necessary to combat pandemic influenza. This collaboration is a good example that reflects the policy of the Vaccine Industry Vision, which refers to the collaboration between domestic makers and foreign-affiliated companies, and this project has been submitted for the Health Labour Sciences Research Grant for research and development of a cell culture based pandemic influenza vaccine, as a joint project between a foreign and domestic company. I am pleased that we will be able to actively contribute to influenza measures in Japan in this way."

Kaketsuken has been fulfilling its responsibilities of supplying seasonal influenza vaccines in Japan over the years and as a part of the country's pandemic response plan, it is manufacturing pandemic vaccine solutions for H5N1, contributing to the government's stockpiling. It is also currently manufacturing vaccines for the swine-derived H1N1 influenza that continues to spread.

GlaxoSmithKline continues to be committed to doing all it can to support governments and health authorities around the world in planning to respond to a global influenza pandemic, both ahead of an outbreak and once it has officially been declared. GSK has made substantial progress in its vaccine development programme and continues to investigate ways to further improve its pre-pandemic and pandemic vaccine strategies. To this end more than \$2 billion has already been invested in developing a vaccine to combat H5N1 influenza,

increasing the production capacity for influenza vaccines and its antiviral flu treatment *Relenza*<sup>®</sup> (zanamivir hydrate), in addition to ensuring the continuity of critical business operations and processes.

Franck Grimaud, CEO and Majid Mehtali, CSO, co-managers of VIVALIS said: "VIVALIS is very pleased of this agreement between GSK and Kaketsuken in the flu field. It is a further evidence that the EB66® vaccine production technology should establish its position as a new global industry standard in the coming years in the vaccine field. In the current environment, the risk of a flu pandemic has increased the determination of public authorities and manufacturers in possessing a technology offering more rapid, effective and safer performances."

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## Financial press release: 21 October 2009 after NYSE Euronext market closing: 2009 third-quarter revenue

#### About the EB66® line

The EB66<sup>®</sup> cell line, derived from duck embryonic stem cells, presents unique industrial and regulatory characteristics such as long-term genetic stability, immortality and cell growth to high cell densities in suspension in a serum-free medium (>20 millions cells/mL).

The BMF (Biologics Master File) for the registration of the EB66<sup>®</sup> cell line with the FDA (U.S. Food and Drug Administration) was filed on June 27, 2008.

The EB66<sup>®</sup> cell line is currently used or being tested by 75% of the major players in vaccines. VIVALIS has furthermore demonstrated that the EB66<sup>®</sup> cell line can be easily genetically modified, permitting the expression of recombinant proteins of potential interest. Moreover the glycosylation profile of monoclonal antibodies produced through EB66<sup>®</sup> cell lines is similar to the glycosylation profiles of human monoclonal antibodies with the added benefit of being distinguished by reduced fucose content. This latter characteristic is known to be associated with a higher level of antibody cytotoxic activity, particularly useful in the treatment of cancer cells.

#### About GlaxoSmithKline Biologicals (GSK Biologicals)

GSK Biologicals is a global vaccine company which has shown itself to be a leader in innovation. The business is active in the fields of vaccine research, development and production with over 30 vaccines approved for marketing and 20 more in development. Based in Belgium, GSK Biologicals has 14 manufacturing sites strategically positioned around the globe. In 2007 GSK Biologicals distributed 1.1 billion doses of vaccines to 169 countries in both developed and the developing world – an average of 3 million doses a day.

GSK Biologicals employs over 9000 people worldwide including more than 1600 scientists actively engaged in research aimed at discovering innovative vaccines that contribute to the health and well-being of people of all generations around the world.

Relenza® is a trademark of GSK. <Media enquiries> GlaxoSmithKline K.K. Yoshiaki Komatsu TEL: 03-5786-5030

About VIVALIS (www.vivalis.com)

are exploited in three main areas:

# 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' expertise and intellectual property

1. The development and manufacturing of vaccines. VIVALIS offers research and commercial licenses for its EB66® cell line, derived from duck stem cells, to pharmaceutical and biotechnology companies

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for the production of vaccines. Vivalis receives upfront fees, milestone payments 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 receives upfront fees, milestone payments 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 more than 30 partnerships and licenses with world leaders in this sector, including Sanofi Pasteur, GlaxoSmithKline, Novartis Vaccines, Merck, CSL Kaketsuken, Merial, Intervet, SAFC Biosciences. VIVALIS is a member of the French ATLANTIC BIOTHERAPIES bio-cluster.

VIVALIS
Listed on Euronext Paris – Compartment C of NYSE Euronext
Reuters: VLS.PA – Bloomberg: VLS FP
Included in NYSE Euronext's Next Biotech index



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