



## **VIVALIS ANNOUNCES THE STRATEGIC ACQUISITION OF HUMALYS AND THE ADDITION OF A NEW PLATFORM FOR GENERATING HUMAN MONOCLONAL ANTIBODIES**

**Nantes (France) – 11 January 2010** – VIVALIS (NYSE Euronext: VLS), a biopharmaceutical company that provides the pharmaceutical industry innovative cell-based solutions for the manufacture of vaccines and proteins and develops drugs to prevent and treat viral diseases, today announces the acquisition HUMALYS SAS (“HUMALYS”), a private French biotech research and development company, based in Lyon, specialised in the generation of human monoclonal anti-bodies.

Founded in 2007 in Lyon by a group of scientists recognised in the field of immunology and biology of human B lymphocytes with the support of Parteurop, HUMALYS developed a unique platform, the HUMALEX<sup>®</sup> technology capable of efficiently generating human monoclonal antibodies for therapeutic and diagnostic applications.

**This strategic acquisition will complete and accelerate VIVALIS’ business development model by:**

- **Considerably increasing the generation of cash flow by isolating and licensing human monoclonal antibodies targeting specific therapeutic indications, supplementing its current EB66<sup>®</sup> cell line licensing for the production of vaccines and monoclonal antibodies;**
- **Proposing customers a complete service and product offering, including the generation of human monoclonal antibodies specific to the therapeutic indication or diagnostic targeted by the customer (HUMALEX<sup>®</sup>), a cell line providing competitive advantages for the production of anticancer antibodies (EB66<sup>®</sup> cell line) and industrial production capacity for pre-clinical and clinical batches production from EB66<sup>®</sup> cell lines or CHO;**
- **Identifying and developing proprietary products without increasing the company's risk profile.**

### **A powerful and unique technology**

HUMALYS has developed a proprietary technology platform, HUMALEX<sup>®</sup>, capable of identifying and effectively generating fully human monoclonal antibodies against the therapeutic target or diagnostic objective. This technology is one of the last independent platforms in the world. In effect, demonstrating the considerable interest by world players in the human monoclonal antibody market and its associated technologies, most platforms have been recently acquired by large pharmaceutical groups (ex: Abgenix, acquired by Amgen in 2005 for US\$2.2 billion, CAT acquired by AstraZeneca in 2006 for US\$1 billion, Medarex acquired by BMS in 2009 for US\$2.4 billion).

The attractiveness of the HUMALEX<sup>®</sup> technology is enhanced by its ability to isolate fully human monoclonal antibodies from human B lymphocytes isolated directly from selected donors for the targeted pathology. This platform has already demonstrated its scientific potential for infectious diseases with the successful identification of human monoclonal antibodies directed against viral and bacterial pathologies, including nosocomial infections, but also in the area of anti-immune diseases, by isolating human monoclonal antibodies directed against the natural anti-immune repertory. By leveraging their combined resources, the new Vivalis-Humalys venture will be able to accelerate the industrialisation and commercialisation of the HUMALEX<sup>®</sup> platform and extend its applications to other areas of therapeutic interest (ex: cancer, inflammatory and degenerative diseases).

HUMALYS’ technology has already received its first validation by the industrial agreement signed with a

world leader in the field of diagnostics.

### **A high growth target market with significant prospects for added commercial value**

The market for monoclonal antibodies is currently in a phase of strong growth. In 2006 it represented US\$20 billion and is expected to increase on average 14.2% per year to reach US\$30 billion by 2011. This particularly active market includes several blockbusters in the marketing phase, highlighting the strategic and scientific interest of these products. While monoclonal antibodies currently on the market are still predominantly chimeric or humanised (human antibodies including mouse trace elements), most monoclonal antibodies under development are fully human. This in turn guarantees a lower immunogenicity for the patient combined with better pharmacokinetics properties. The HUMALEX<sup>®</sup> platform is thus ideally positioned to benefit from these scientific and commercial trends.

HUMALYS is currently in discussion with several large pharmaceutical groups that have expressed serious interest in the HUMALEX<sup>®</sup> technology. In this market of monoclonal antibodies, amounts represented by licenses are much higher than those normally registered for technology platforms, frequently exceeding the level of €50 million per indication.

VIVALIS has accordingly positioned itself in an important growth market where it already is familiar with many players through the commercialisation of its EB66<sup>®</sup> cell line platform for the production of monoclonal antibodies.

The commercial model will be very similar to that developed for the EB66<sup>®</sup> line:

- Signature of agreements for the generation and development of antibodies for third parties in exchange for upfront fees, milestone payments and royalties to generate short-term and medium-term revenue streams and to finance research expenditures;
- Developing proprietary antibodies for licensees up to the early clinical phases to capture more added value.

VIVALIS HUMALYS' objective in this area is to sign a commercial agreement for HUMALEX<sup>®</sup> within the next 18 months.

### **Very significant synergies with VIVALIS' historic activities**

HUMALYS provides a perfect economic as well as scientific and commercial fit with the VIVALIS business model.

This acquisition will allow VIVALIS to propose an increasingly broad commercial offering ranging from the generation of monoclonal antibodies through the HUMALEX<sup>®</sup> technology to their industrial production based on the proprietary EB66<sup>®</sup> cell line or through the standard CHO cell line, in its GMP biomanufacturing unit located in Nantes. In addition, VIVALIS' sales teams already have a substantial knowledge of the major players of the monoclonal antibodies sector that will provide them with a competitive advantage to capture additional value.

From an economic standpoint, VIVALIS' limited risk profile and low cash burn model remain unchanged. The commercialisation of a new technology platform provides a beneficial fit with its EB66<sup>®</sup> proprietary cell line platform. In this way, HUMALYS should provide a positive contribution to VIVALIS' cash flow starting in 2010.

Finally, the HUMALEX<sup>®</sup> platform will make it possible to considerably strengthen activities focusing on the generation and development of proprietary products to be developed internally up to the clinical phase and subsequently licensed.

## Financial terms and conditions

Under the terms of the agreement, HUMALYS shareholders will receive €10.4 million through several instalments with a first payment of €3.6 million in January 2010 in exchange for the acquisition on that date of 100% HUMALYS shares by VIVALIS. In addition, VIVALIS will pay a maximum of €15 million over 15 years for payments relating to licenses of the HUMALEX<sup>®</sup> technology to third parties.

In light of this acquisition, VIVALIS anticipates net cash at 2010 year-end exceeding €15 million, confirming its low cash burn model.

Franck Grimaud, CEO and Majid Mehtali, CSO, co-managers of VIVALIS, noted: *"We are very pleased that the HUMALYS team has decided to join us and participate in our development project. Through this strategic acquisition VIVALIS will achieve a new dimension with a very comprehensive and innovative offering in the field of human monoclonal antibodies, one of the pharmaceutical market segments with the highest growth potential. This new strategic milestone will enable VIVALIS to capture more value while increasing its medium and long-term cash flow generation without modifying its risk profile. This acquisition will also enable us to develop proprietary products that will be co-developed or developed by VIVALIS up to the clinical phase."*

Philippe Guillot-Chêne, Chairman of HUMALYS SAS, remarked: *"We are very happy to join the VIVALIS Group. The complementary fit of our technologies and know-how will enable us to industrialise the HUMALEX<sup>®</sup> platform and optimise its potential. This major advance is highly motivating for the entire HUMALYS team who will remain very involved in the development and commercialisation of the HUMALEX<sup>®</sup> technology."*

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### **Next financial press release:**

**27 January 2010, after NYSE Euronext market closing: 2009 annual revenue**

### **About the EB66<sup>®</sup> 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 VIVALIS ([www.vivalis.com](http://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' expertise and intellectual property are exploited in three main areas:

1. VIVALIS offers research and commercial licenses for its EB66® cell line, derived from duck stem cells, to pharmaceutical and biotechnology companies for the production of vaccines. VIVALIS receives upfront fees, milestone payments and royalties on its licensees' net sales.
2. Through the Humalex® platform, VIVALIS proposes customers solutions for the generation, development and production of human antibodies. 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 SBF 250, CAC Small 90 and Next  
Biotech indexes



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