

## Communiqué de presse

From cells to therapeutics **Vivalis**

### VIVALIS : NOUVELLE ETAPPE DANS LE DEVELOPPEMENT DE LA LIGNEE CELLULAIRES EB66® DANS LE CADRE DU PARTENARIAT ENTRE GLAXOSMITHKLINE (GSK) ET TEXAS A&M UNIVERSITY SYSTEM VISANT AU DEVELOPPEMENT DE VACCINS CONTRE LA GRIPPE PRODUITS SUR LIGNEE CELLULAIRE AUX ETATS-UNIS.

**Nantes et Lyon (France)** 26 Mars 2013 - VIVALIS (NYSE Euronext : VLS) annonce la diffusion du communiqué de presse distribué par GSK détaillant leurs efforts continus avec Texas A&M University System (Tamus) pour le développement de vaccins contre la grippe, produits sur la lignée cellulaire EB66® et financés par le Ministère américain de la Santé et des Services sociaux (HHS). En vertu de ce programme, le HHS a approuvé la mise en place d'une installation pour la fabrication de vaccins antigrippaux pour un montant de 91 millions de dollars qui sera situé à Bryan-College Station, Texas.

Une copie intégrale du communiqué de presse de GSK est présentée ici.

## PRESS RELEASE



THE TEXAS A&M  
UNIVERSITY SYSTEM



### Texas A&M System and GlaxoSmithKline receive U.S. Government approval to establish influenza vaccine facility in Texas

**Team will develop and manufacture GSK's next generation influenza vaccines to protect the nation against global pandemics**

GlaxoSmithKline plc (GSK) and The Texas A&M University System announced today that the U.S. Department of Health and Human Services (DHHS) has approved the establishment of a \$91 million influenza-vaccines manufacturing facility as the anchor of the Center for Innovation in Advanced Development and Manufacturing (CIADM) in Bryan-College Station, Texas.

The announcement was hosted by Governor Rick Perry at the Texas State Capitol, and was attended by a number of dignitaries including Texas A&M System Chancellor John Sharp, Dr. Robin Robinson, DHHS Deputy Assistant Secretary and Director of the Biomedical Advanced Research and Development Authority (BARDA), and Antoon Loomans, Senior Vice President, GSK Vaccines.

"Today's announcement is a huge win for Texas and for the nation," Governor Perry said. "The Texas A&M Center, anchored by this facility, is expected to bring more than \$41 billion in expenditures within the State of Texas over the next 25 years, and will add more than 6,800 direct and related jobs to Texas."

The TAMUS influenza vaccines manufacturing center will afford GSK the capabilities to eventually manufacture influenza vaccine based on a proprietary cell-culture line, 'EB66®. Most existing influenza vaccine is manufactured using fertilized chicken eggs. The cell-culture process will supplement the vaccine supply from eggs, and facilitate a rapid national vaccine response in the event of a pandemic.

<sup>1</sup> \*EB66® exclusively licensed from Vivalis by GSK Biologicals S.A. for the field of Influenza and sublicensed use at the Texas A&M Center for Innovation in Advanced Development and Manufacturing (CIADM).

GSK Vaccines produces 30 vaccines worldwide, eleven of which are licensed by the FDA. The Texas A&M-GSK venture will complement and support the company's existing influenza vaccines operations, based in

Quebec, Canada, and Dresden, Germany. GSK's operations hub in Marietta, Pennsylvania will package, inspect and distribute influenza vaccine manufactured at the Texas A&M Center. In 2012, GSK provided more than 20 million flu shots for the U.S. market and recently became the first major U.S. vaccines provider to gain FDA-approval for a broader-protection, four-strain (quadrivalent) influenza vaccine shot that will be available in time for the 2013-14 flu season.

"GSK is privileged to deepen our commitment to U.S. public health, as part of this unprecedented public-private collaboration to protect against pandemics and bio-threats," noted Loomans. "In Texas A&M we have found a partner with a rich tradition of service, and with pioneering technologies that will benefit the entire pharmaceutical industry in making vaccines available and accessible to all in need."

One of only three CIADMs to be developed in the U.S., the Texas A&M Center is at the vanguard of U.S. pandemic-preparedness efforts and represents unprecedented public-health collaboration among state and federal governments, academia and private industry. Once constructed and operational, the Center's influenza manufacturing facility will be able to supply 50 million doses of pandemic influenza vaccine within four months of an outbreak. BARDA conceived the public-private formula to assure a strong biosecurity product development and manufacturing base on U.S. soil, ensuring that the nation would have rapid access to vaccines and therapeutics in the advent of influenza pandemics, or chemical, biological, radiological, and nuclear attacks.

"We are honored to welcome GSK to Texas A&M as a key partner in the Center for Innovation," said Sharp. "GSK's dedication to public service is well-aligned with the Texas A&M tradition of serving the nation and defining its future through research and scholarship. Equally important is the cultural and philosophical match between GSK and the A&M System, as reflected by GSK's desire to collaborate with academia and the U.S. government, and their ongoing commitment to helping address global health scourges such as pandemic influenza and malaria."

The Texas A&M Center for Innovation is lead by Dr. Brett Giroir, Vice Chancellor for Strategic Initiatives at the Texas A&M System, and a core team of A&M experts in biotechnology, infectious diseases, facilities planning and construction, federal acquisitions/contracting, and government affairs. The partnership with GSK was founded on a long, collaborative relationship between Texas A&M and the Wallonia Region of Belgium, with specific planning for this project beginning in the spring of 2010.

"GSK's decision to partner with Texas A&M and bring their vaccine manufacturing to our state is a testament to the investments that the A&M System and the State of Texas have made in the people, infrastructure and technologies, much of which came from critical state programs such as the Emerging Technology Fund," Giroir said. "GSK brings unequaled influenza vaccine development, manufacturing, and regulatory expertise to our Center. Equally important, GSK brings its cell based influenza vaccine development program, which we have assessed to be the most promising near term influenza vaccine technology to improve upon current egg based vaccines."

The Texas A&M Center for Innovation represents the largest commitment of a global biopharmaceutical company to partner within Texas, and will be an important catalyst to the future growth of this industry within the State.

### **U.S. Government Funding**

Efforts highlighted in this release have been funded in whole or in part with Federal Funds from the DHHS/ASPR/BARDA, under contract numbers HHSO100200600011C, HHSO100200700029C and HHSO100201200002I.

### **About the A&M System**

The A&M System is one of the largest systems of higher education in the nation, with a budget of \$3.5 billion. Through a statewide network of 11 universities, seven state agencies and a comprehensive health science center, the A&M System educates more than 120,000 students and makes more than 22 million additional educational contacts through service and outreach programs each year. Externally funded research expenditures exceed \$780 million and help drive the state's economy.

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## About the Texas A&M Center for Innovation

The Texas A&M Center for Innovation in Advance Development and Manufacturing (CIADM) is one of three centers established in June, 2012 by the US Department of Health and Human Services to enhance the nation's emergency preparedness against emerging infectious diseases, including pandemic influenza, and chemical, biological, radiological and nuclear threats. The Center is founded on an initial \$285.6 million investment, including a \$176.6 million contribution from the US Department of Health and Human Services, with the remainder cost-shared by commercial and academic proposal partners.

The Center will perform research and advanced development to accelerate vaccines and other medical products through pre-clinical and clinical development and produce these products in cases of pandemics or other national emergencies. Through these activities, the Center will address a recognized shortcoming in preparedness and response to known and unknown threats, and will improve our nation's ability to protect the health of its citizens in emergency situations.

With GSK and other partners, TAMUS also will utilize CIADM capabilities to develop and transition platform technologies to accelerate new treatments for conditions as diverse as cancer and cardiovascular disease.

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**GlaxoSmithKline** – one of the world's leading research-based pharmaceutical and healthcare companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For further information please visit <http://us.gsk.com/>

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### **Cautionary statement regarding forward-looking statements**

GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Factors that may affect GSK's operations are described under Item 3.D 'Risk factors' in the company's Annual Report on Form 20-F for 2012.

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### **Prochaine communication financière :**

**26 mars 2013, après fermeture du marché : résultats annuels 2012**

### **À propos de VIVALIS ([www.vivalis.com](http://www.vivalis.com))**

7 Mars 2013, Vivalis SA (NYSE Euronext: VLS) et Intercell AG (VSE: ICLL) annoncent que les actionnaires des deux groupes réunis en Assemblées générales extraordinaires se sont prononcés en faveur de la fusion entre égaux de Vivalis S.A. et d'Intercell AG pour former Valneva SE. La fusion devrait être effective en Mai 2013

VIVALIS (NYSE- Euronext: VLS) est une société biopharmaceutique qui fournit à l'industrie pharmaceutique des solutions cellulaires innovantes pour la production de vaccins viraux et de protéines recombinantes, et qui développe

des anticorps monoclonaux pour le traitement et la prévention de pathologies sans réponse médicale. Le savoir-faire et la propriété intellectuelle de Vivalis sont principalement exploités dans 2 domaines :

1. Lignée cellulaire EB66<sup>®</sup>

VIVALIS propose des licences de recherche et des licences commerciales de sa lignée cellulaire EB66<sup>®</sup>, dérivée de cellules souches embryonnaires de canard, à des sociétés de biotechnologies et à l'industrie pharmaceutique pour la production de vaccins thérapeutiques et prophylactiques viraux, virosomes, VLPs et protéines recombinantes, notamment d'anticorps monoclonaux. Des essais cliniques sur des vaccins produits sur la lignée cellulaire EB66<sup>®</sup> sont en cours aux Etats-Unis et au Japon et en 2012 un vaccin vétérinaire produit sur la lignée cellulaire EB66<sup>®</sup> a reçu une autorisation de mise sur le marché au Japon. Au travers de ces programmes, la société reçoit des paiements initiaux, des paiements à certaines étapes cliniques et des royalties sur les ventes de ses clients.

2. Plateforme VIVA|Screen™ de découverte d'anticorps humains

VIVALIS propose à ses clients des solutions sur mesure pour la découverte, le développement et la production d'anticorps monoclonaux 100% humains. Au travers de ces programmes, la société reçoit des paiements associés aux activités de découvertes ainsi que des paiements initiaux, des paiements d'étapes et des royalties sur les ventes des anticorps licenciés et développés commercialement par ses clients.

Basée à Nantes & Lyon (France) et à Toyama (Japon), VIVALIS a été créée en 1999 par le Groupe Grimaud (environ 1 700 personnes), l'un des leaders mondiaux de la sélection génétique animale. VIVALIS a établi plus de 30 partenariats et licences avec les leaders mondiaux du secteur, notamment Sanofi Pasteur, GlaxoSmithKline Biologicals, Transgene, Zoetis, Kaketsukan, Kitasato Daiichi Sankyo Vaccine, Merial, Merck Animal Health, SAFC Biosciences. VIVALIS est membre des pôles de compétitivité ATLANPOLE BIOTHERAPIES et LYON BIOPOLE en France et membre de HOKURIKU INNOVATION CLUSTER FOR HEALTH SCIENCE à Toyama au Japon.

VIVALIS

Compartiment B d'Euronext Paris de NYSE Euronext

Reuters : VLS.PA – Bloomberg : VLS FP

Membre des indices SBF 250, Small Cap 90 et NextBiotech de NYSE Euronext

**VLS**  
LISTED  
**NYSE**  
**EURONEXT**

*Le présent document contient des commentaires relatifs aux stratégies de la société. Aucune garantie ne peut être donnée quant à la réalisation de ces stratégies qui sont soumises à des risques dont les facteurs de risques décrits dans le Document de référence et le Document E de la société, à l'évolution de la conjoncture économique, des marchés financiers et des marchés sur lesquels la société est présente.*

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