



DBV Technologies and INRA receive funding to develop pediatric bronchiolitis ('RSV') vaccine: RSV-NanoViaSkin

'RSV' (Respiratory Syncytial Virus) is the first cause of hospitalization under 2 years old and the leading cause of bronchiolitis, pneumopathy, and the common cold in children

Bagneux, FRANCE, January 15th 2013 - DBV Technologies (Euronext: DBV – ISIN: FR0010417345), creator of Viaskin[®], a new standard in the treatment of allergies, announced today that the Company and the French Institute for Agricultural Research-INRA (Molecular Virology and Immunology Unit, VIM-U892) have been awarded a research grant of nearly €600.000 from the French National Research Agency (ANR) to develop an innovative, efficient and safe pediatric 'RSV' bronchiolitis ('RSV') vaccine. RSV-NanoViaSkin is intended to become the world's first non-invasive and adjuvant-free epicutaneous RSV pediatric vaccine.

Respiratory syncytial virus is the major cause of lower respiratory tract infection in infants and children. It is highly contagious, and it is estimated that 95% of children test seropositive for RSV by two years of age. Outbreaks occur annually throughout the world. Symptomatic infections may recur because natural RSV infection produces limited immunity.

Dr. Pierre-Henri Benhamou, Chairman and CEO of DBV Technologies, said: *"We are very proud to announce this new collaboration with INRA and especially the VIM unit. Indeed, this partnership represents undoubtedly a real breakthrough on multiple fronts, notably because two cutting edge technologies are associated to address newborns, a very vulnerable patient population. DBV is thereby positioned to fulfill another very high unmet medical need: there is a growing concern that severe RSV infections may adversely affect pulmonary development and lead to long-term respiratory problems for infants and children; infants who are exposed to even mild RSV-diseases are at much higher risk to develop recurrent wheeze and asthma up to their teenage years. There is no doubt that a safe, painless and effective RSV vaccine in the first six months of life would be a major advance in reducing the severe burden of respiratory diseases and hospitalization. Once again, Viaskin® reveals its versatility and amazing capacity to induce a protecting immune profile without adjuvant."*

Dr. Sabine Riffault, Scientist and deputy director of VIM-U892 at INRA, said, "We are very proud that our efforts to put this project together with DBV Technologies are finally successful. We believe in the strength of our partnership based upon complementary skills that together will open the way to a new generation of pediatric vaccine delivered via the skin and targeting for the first time RSV bronchiolitis. We are addressing with special care all the delicate issues of pediatric vaccination, favoring a non invasive administration of safe non replicating antigens."

DBV Technologies has developed and patented the Viaskin[®] technology which appears to be totally adapted to the development of a new RSV vaccine, for infants. Indeed, the Viaskin[®] technique allows epicutaneous application of the vaccine (non-traumatic for 0-6 months newborn babies, efficient in stimulating the immune system) and compensates the lack of adequate response of the intranasal injection route of administration. The RSV-NanoViaSkin project aims at delivering a pre-clinical-proof of concept for a novel efficient and safe pediatric RSV vaccine that is able to find original solutions to all problems of current RSV vaccination strategies, in a 30-month study. The project aims at developing a full pre-clinical package in several animal models. The INRA innovation stands around a new immunogenic antigen (N-eF proteins), targeting CTL and neutralizing antibody-mediated immunity to RSV, using well characterized immunogenic nanostructures (Nring) decorated with epitopes from the fusion protein based on patented/published pre-clinical results, carried out by VIM-INRA. The epicutaneous route of administration using Viaskin[®] enables to overcome the hurdles of interference of maternal antibodies and the immaturity of the immune system.

About RSV

Respiratory syncytial virus (RSV) is a very common virus that leads to mild, cold-like symptoms in adults and older healthy children. It can be more serious in young babies, especially to those in certain high-risk groups. RSV is the most common germ that causes lung and airway infections in infants and young children. Most infants have had this infection by age 2. Outbreaks of RSV infections most often





begin in the fall and run into the spring. The infection can occur in people of all ages. RSV often spreads very rapidly in crowded households and day care centers. The virus can live for half an hour or more on hands. The virus can also live for up to 5 hours on countertops. Infants under age 1 may have more severe symptoms and often have the most trouble breathing. Antibiotics do not treat RSV. Mild infections go away without treatment. Infants and children with a severe RSV infection may be admitted to hospital. In young children, RSV can cause bronchiolitis, croup, ear infections, lung failure and pneumonia. Children who have had RSV bronchiolitis may be more likely to develop asthma.

About VIM-INRA

The Molecular Virology and Immunology Unit (VIM-U892) is part of the Animal Health division at INRA. VIM-U892 studies **pathogens** affecting farm animals, some of them being zoonotic pathogens. Our research activities range from the molecular characterization of pathogens to host-defense mechanisms. We are mainly interested in respiratory viruses in mammals and birds, fish viruses and bacteria, and non-conventional agents such as prions. We study host-pathogen interactions in target species (swine, cattle, sheep, trout) or model species (mice, zebra fish).

Our main scientific issues are:

- 1) Structure and expression of pathogen genomes
- 2) Structure-function relationships of macro-molecular complexes
- 3) Virulence-pathogenicity factors and escape from host defenses
- 4) Plasticity of host responses during evolution and development
- 5) Fighting strategies: vaccination and therapeutical approaches
- For more information, please visit our website: www.jouy.inra.fr/vim

About DBV Technologies

DBV Technologies is opening up a decisive new approach to the treatment of allergy – a major public health issue that is constantly increasing in prevalence. Food allergies represent a true handicap in everyday life for millions of people and thus constitute a major unmet medical need. DBV Technologies has developed a unique, proprietary, worldwide-patented technology for administering an allergen to intact skin and avoiding massive transfer to the blood. The Viaskin[®] technology combines efficacy and safety as part of a treatment that seeks to improve the patient's tolerability of peanut and thus considerably lower the risk of a systemic, allergic reaction in the event of accidental exposure to the allergen. The company's significant development program has taken this revolutionary method through to the industrial stage in Europe, initially. The product's clinically proven safety of use enables the application of effective desensitization techniques (the efficacy of which is acknowledged worldwide) in the most severe forms of the allergy. DBV Technologies is focusing on food allergies (milk and peanut) for which there are currently no effective treatments. It has developed two products: Viaskin[®] Peanut and Viaskin[®] Milk. The clinical development program for Viaskin[®] Peanut has received Fast Track designation from the US Food and Drug Administration. The company will subsequently develop a Viaskin[®] patch for young children with house dust mite allergy – a true public health issue because this pathology is one of the main risk factors for childhood asthma. DBV Technologies shares are traded on segment C of Euronext Paris (Ticker: DBV, ISIN code: FR0010417345).

For more information on DBV Technologies, please visit our website: <u>www.dbv-technologies.com</u>. CAUTION: Viaskin[®] is not approved for sale in the USA.

Forward Looking Statement

The forward-looking statements, objectives and targets contained herein are based on the Company's management strategy, current views and assumptions. Such statements involve known and unknown risks and uncertainties that may cause actual results, performance or events to differ materially from those anticipated herein. Furthermore, the Research and Development process involves several stages each of which involve the substantial risk that the Company may fail to achieve its objectives and be forced to abandon its efforts with regards to a product in which it has invested significant sums. Therefore, the Company cannot be certain that favorable results obtained during pre-clinical trials will be confirmed subsequently during clinical trials, or that the results of clinical trials will be sufficient to demonstrate the safe and effective nature of the product concerned. DBV technologies' business is subject to the risk factors outlined in its registration documents filed with the French Autorité des Marchés Financiers.





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