DBV Technologies and Mount Sinai Hospital Enter Research Collaboration for Crohn’s Disease

BAGNEUX, FRANCE, February 18, 2014 - DBV Technologies (Euronext: DBV – ISIN: FR0010417345), creator of Viaskin®, a new standard in the treatment of allergies, and the Icahn School of Medicine at Mount Sinai announced today that they entered into a research collaboration agreement to investigate the efficacy and mechanism of epicutaneous tolerance utilizing Viaskin® for the treatment of Crohn’s disease.

Crohn’s disease is a chronic condition for which there is currently no satisfactory cure able to increase the quality of life for people who have Crohn’s disease. DBV has already proven, in several pre-clinical studies that repeated epicutaneous immunotherapy (EPIT™) leads to increase natural and induced immune regulatory cells. Preliminary studies already showed that these immune regulatory cells play an essential role in by protecting the gut from inflammation. DBV partnered with the Mount Sinai team, which has world-class expertise in cellular mechanisms involved in Crohn’s disease, having already demonstrated that administration of Tregs to patients with severe Crohn’s disease was well tolerated and efficacious. DBV has established that Induction of immune regulatory cells can be achieved by epicutaneous exposure. The combination of DBV’s technology with Mount Sinai’s expertise could lead to a first-in-class approach to induce tolerance and decrease gut inflammation.

Pr. Jean-Frédéric Colombel, Director of the Leona M. and Harry B. Helmsley Charitable Trust Inflammatory Bowel Disease Center at Mount Sinai Hospital (New-York, NY, USA), said, “We are very excited with this collaboration. There is still a huge unmet need in the treatment of Crohn’s disease. This new technology could offer to our patients’ new opportunities and pave the way for an original approach aiming at amplifying the effect of immune regulatory cells instead of targeting immune suppression and its associated potential side effects”.

Dr. David Dunkin, Assistant Professor of Pediatrics in the Division of Pediatric Gastroenterology The Icahn School of Medicine at Mount Sinai (New-York, NY, USA), said, “This collaboration is exciting because it develops a new possibility for a treatment for Crohn’s disease by utilizing a patient’s normal immune response to treat disease. Through the technology at DBV and the scientific expertise at both institutions working in collaboration we hope to one day offer our patients a new safe therapy for the treatment of Crohn’s disease”

Dr. Pierre-Henri Benhamou, Chairman and CEO of DBV Technologies, said, “Mount Sinai is a leading center in gastroenterology worldwide, at the forefront of Crohn’s disease research initiatives. We are extremely proud to contribute, along with Pr. Colombel and Dr. Dunkin, to a novel approach using Viaskin® in a severe condition, with no therapeutic alternative. We believe this new research area with such a center of excellence further emphasizes the potential of the Viaskin platform, positioning it as a technology enabling a deep and durable modulation of the immune system.”

The Collaboration will explore a novel approach to treat Crohn’s disease based on epicutaneous delivery with Viaskin® to induce regulatory cells (Treg).

Pre-clinical studies will aim at:
- Evaluating the ability of epicutaneous tolerance induction with Viaskin® to treat inflammatory colitis
- Demonstrating the functional ability of antigen-specific Tregs induced by epicutaneous exposure with Viaskin® in suppressing inflammatory responses in the gut,
- Acquiring a better knowledge of cellular mechanisms involved.

These activities and studies are expected to last at least 12 months.
About Crohn’s disease

Crohn’s disease (CD) is a chronic inflammatory disease of the gastrointestinal tract, mainly characterized by abdominal pain, diarrhea and various digestive or non-digestive complications, with alternating eruptions and remissions. The incidence of CD is increasing especially in young children and infants posing an increasing burden on society. CD is more common in northwestern countries where the incidence ranges between 1 and 10/100,000, and a prevalence of approximately 1-0.5/1,000. Both men and women can have Crohn’s disease. Crohn’s disease is usually diagnosed in people between the ages of 20 - 30.

About Investigators at Icahn School of Medicine at Mount Sinai

Pr. Colombel is best known for his participation in the identification of NOD2 as a susceptibility gene for Crohn’s disease, and the identification of a new subtype of Escherichia coli associated with Crohn’s disease, as well as the development of the Anti-Saccharomyces Cerevisiae Antibody (ASCA) test, which remains the most sensitive and specific marker for Crohn's disease. He has authored or coauthored more than 500 peer-reviewed articles, books, and book chapters on IBD.

Dr. Dunkin is an Assistant Professor of Pediatrics in the Division of Pediatric Gastroenterology. Dr. Dunkin obtained his undergraduate degree from Cornell University, and received his MD from Sackler School of Medicine. He completed his Pediatric residency at Yale Children’s Hospital followed by a fellowship in Pediatric Gastroenterology at Mount Sinai. Dr. Dunkin completed addition research training under the mentorship of Dr. Lloyd Mayer. His research seeks to understand the mechanism by which the human body develops or fails to develop tolerance to foreign antigens including food and intestinal flora that leads to diseases such as allergies and inflammatory bowel disease. He has published work on protein sensitization through the skin and has published multiple manuscripts with his collaborators in the Center for Chinese Medicine investigating the use of Chinese herbal therapies for the treatment of IBD.

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: www.dbv-technologies.com

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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