First nine months topline and clinical and business highlights

- EPIT® (EPicutaneous ImmunoTherapy) brand name registered internationally
- VIPES phase II study recruitment on track

Bagneux, France, October 15, 2012 - DBV Technologies (Euronext: DBV – ISIN: FR0010417345), creator of Viaskin®, a new standard in the treatment of allergy, announced today its first nine months topline and its clinical progress as well as the international registration of the EPIT® (Epicutaneous Immunotherapy) brand.

Pierre-Henri Benhamou, M.D., Chairman and CEO of DBV Technologies said: “Our first nine months cash consumption reflects the successful launch of VIPES phase IIb study for Viaskin Peanut as well as the reinforcement of the teams. All execution streams are on track, and we are progressing in the VIPES study according to plan.” Pierre-Henri Benhamou added: “Throughout the year, we have also continued to strengthen our intellectual property and brand portfolios, thereby increasing DBV’s value. We are also extremely proud to have initiated major scientific partnerships that will contribute to increase our knowledge of the cellular mechanism implicated during the specific EPIT process with Viaskin®.” Pierre-Henri Benhamou concluded: “We have a busy plate in front of us, with all programs now running at full speed. In the coming months, our newsflow will show that we deliver on our strategic objectives in the same way we have done since the beginning of the year.”

Update on clinical activities

VIPES, DBV Technologies’ phase IIb clinical study (Double-Blind, Placebo-Controlled, Randomized Phase IIb trial to study Viaskin® Peanut’s Efficacy and Safety in peanut allergy) has now been recruiting for 2 months. Out of the 6 countries planned to participate in the study, 4 are up and running today. The 2 other countries (the Netherlands and Poland) are still awaiting some regulatory or Ethics Committee approvals. 15 sites have effectively been initiated already out of the 22 sites forecasted. In terms of recruitment, 6 sites out of the 15 initiated are active and recruiting patients. In total, 46 subjects were screened, with 17 randomized subjects: 13 children, 2 adolescents and 2 adults. 17 subjects are still in screening. DBV Technologies expects to end the recruitment as planned, early 2013, in order to finalize the VIPES study first half of 2014, in line with the Company’s initial objectives.

Business update

DBV Technologies considerably strengthened its protection pathway with the registration of the EPIT® (Epicutaneous Immunotherapy) brand. The registration has been done under the number 1125219 in class 42 and 44 at the World Intellectual Property Organization (WIPO) until May 14th 2022. This EPIT® innovative method consists of a skin patch that enables specific immunotherapy by placing the allergen in contact with the immune system through the skin whilst avoiding passage into the blood. The protection of this unique proprietary method reinforces DBV Technologies’ position as the first company able to reach the immune system via the epicutaneous route.

First nine months topline

For the first nine months 2012, total revenues reached €1,922,785, up from €1,316,086 in the first six months, mainly driven by an increase in Research tax credit, up €564,609 in the third quarter. This 46.1% increase stems from an intense R&D activity, notably with the launch of the VIPES Phase IIb study in peanut allergy. Revenues from Diallertest stood at €112,595, with three batches sold to DBV’s commercial partner over the period. In-market sales of Diallertest reached 16,001 units in France in the first nine months 2012, reflecting a stable demand overall.

As of September 30, 2012, DBV’s cash position amounted to €41.7 million, compared with €42.2 million three months earlier, reflecting a cash burn partly offset by a €1.7 million payment in Research tax credit over the period.
About peanut allergy: a life-threatening risk for millions of people

In the US about 1.1% of the general population (i.e. over 3 million people) is allergic to peanut. In the US, peanut allergy causes about 100 to 150 deaths per year. This allergy affects both adults and children and it has been estimated that peanut allergy affects 1.8% of young children in the United Kingdom. The prevalence of peanut allergy in other Western countries (e.g. Canada, France and Spain) has been studied by many researchers and ranges from 0.9% to 1.5%. This allergy is generally considered to be persistent; many studies indicate that fewer than 20% of children will outgrow their peanut allergy. Peanut allergy is more severe than other common food allergies (e.g. milk and egg allergies).

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 developmental clinical 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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