DBV Technologies Reports Full Year 2012 Topline and Provides an Update on R&D Activities

- DBV closes 2012 with €37.8 million in net cash
- All Viaskin® programmes progressing on schedule
- Significant pre-clinical and clinical data published in 2012 will lead to a significant news flow in 2013


Dr. Pierre-Henri Benhamou, Chairman & CEO of DBV Technologies, said: “It has been an extremely exciting year for the evolution of DBV, which I look back on with great pride. We have strengthened our team with a number of new talents, successfully completed an IPO that provided us with the cash necessary to conduct our three main development programmes, and made scientific advances which have been praised in major international allergy circles. We are now fully geared-up to face the challenge ahead, and I cannot think of 2013 being any less exciting, with an intense pre-clinical and clinical news flow.”

DBV is focused on Viaskin®, an epicutaneous immunotherapy skin patch that has the potential to address high unmet medical needs in the field of allergy. Viaskin® offers a pharmaceutical treatment to the most vulnerable patient populations: food allergic patients and young children. DBV is targeting the following programmes:
1- Peanut allergy, the most dangerous food allergy;
2- Milk allergy, the first allergy in the life, and a major cause of a rare and severe condition;
3- House Dust Mites allergy in young children, the main cause of allergic asthma in children.

Update on R&D activities

Pr. Christophe Dupont, Head of Pediatrics, Necker Hospital, Paris, and Chairman of DBV’s Scientific Advisory Board said: “DBV has made - throughout 2012 - tremendous progress in the understanding of epicutaneous immunotherapy and I warmly congratulate DBV’s research team for their contribution to this promising mechanism of action. New pre-clinical data will be published by DBV’s research team in major conferences, whilst I will soon have the opportunity to present the results of the AP-HP-sponsored efficacy study, Arachild.”

Throughout 2012, DBV was one of the most active companies in the field of immunotherapy and had several major pre-clinical and clinical development accomplishments, which are summarized below:

Clinical results in 2012

- DBV announced the results of its phase Ib US clinical study1 of Viaskin® Peanut, which demonstrated that the patch is “safe and well-tolerated” by adults, adolescents and children with peanut allergy regardless the severity of the allergy.

- Assistance Public-Hôpitaux de Paris (AP-HP) and DBV announced the 6-month interim data of Arachild phase II study2, showing statistically significant efficacy of Viaskin® Peanut versus placebo on the primary efficacy endpoint of at least a 10-fold increase of initial reactive dose, in addition to the strong safety data. More information on the Arachild study can be found in the ClinicalTrials.gov website at http://clinicaltrials.gov/show/NCT01197053

---

Recent pre-clinical publications

- Two new papers in major scientific journals were published recently. The first paper\(^3\) shows in a pre-clinical setting that epicutaneous allergen-specific immunotherapy needs the integrity of superficial layers of the stratum corneum to ensure the safety of treatment and to induce a tolerogenic profile of the immune response.

- The second paper\(^4\) suggests that, in a study comparing Viaskin\(^\circledast\) with Finn chamber patch tests in dogs hypersensitized to mite allergens, Viaskin\(^\circledast\) induces stronger allergen-specific response and that, as a consequence, Viaskin\(^\circledast\) may offer a better alternative for screening cellular hypersensitivity to food and environmental allergens.

2013 clinical study outlook

- DBV Technologies will present at two major allergy conferences: the American Academy of Allergy, Asthma and Immunology (AAAAI; [http://annualmeeting.aaaai.org/](http://annualmeeting.aaaai.org/)) and the European Allergy And Clinical Immunology congress (EAACI; [http://www.eaaci-wao2013.com](http://www.eaaci-wao2013.com)).

- In 1Q 2013, DBV will collaborate with the Consortium for Food Allergy Research (‘CoFAR’) for the launch of an important NIH-sponsored efficacy study, CoFAR6, in peanut allergic patients.

- In 2013, DBV will continue its partnership with the University of Geneva in the field of vaccination, and expects to make good progress in a very promising joint development programme.

- The topline results of the on-going phase IIb VIPES study are expected to be available in mid-2014 ([http://clinicaltrials.gov/ct2/show/NCT01675882](http://clinicaltrials.gov/ct2/show/NCT01675882)).

Full year 2012 topline

For the full year 2012, total revenues reached €2,776,588, up from €1,873,571 a year earlier, driven by an increase in Research tax credit. This 48.2% increase reflects DBV’s intense R&D activities, on both pre-clinical research and clinical development fronts. Revenues from Diallertest\(^\circledast\) stood at €174,360, with four batches sold to DBV’s commercial partner over the period. In-market sales of Diallertest\(^\circledast\) reached 22,085 units in France in 2012, reflecting a stable demand overall year-on-year.

As of December 31, 2012, DBV’s cash position amounted to €37.8 million, compared with €41.7 million three months earlier.

---

\(^3\) “Intact skin - and not stripped skin - is crucial for the safety and efficacy of peanut epicutaneous immunotherapy (EPIT\(^\circledast\))” in *Clin Transl Allergy. Mondoulet and al; 2012 Nov 12;2[1]:22.*

\(^4\) “Validation of a novel epicutaneous delivery system for patch testing of house dust mite-hypersensitive dogs” in *Vet Dermatol 2012; Olivry and al; 23: 525–e106.*
About peanut allergy: a life-threatening risk for millions of people

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

About DBV Technologies:

DBV Technologies is developing Viaskin®, an innovative new approach to the treatment of allergies – a major public health issue that is constantly increasing in prevalence. Food allergies represent a true handicap in everyday life for millions of people, constituting a major unmet medical need. DBV Technologies, incorporated in France in 2002, has developed a proprietary, worldwide-patented technology for administering an allergen to intact skin while avoiding 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 peanuts, and thus considerably lowers the risk of a systemic, allergic reaction in the event of accidental exposure. The product’s clinically proven safety profile enables the application of effective desensitization techniques in the most severe forms of the allergy.

DBV Technologies is focusing on food allergies, including milk and peanut, for which there are currently no effective treatments. DBV Technologies has designed 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 and is currently being studies in Phase II program. 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 a primary 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

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.

Contacts

DBV Technologies
David Schilansky
Chief Financial Officer
Tél. : +33(0)1 55 42 78 75
david.schilansky@dbv-technologies.com

US & UK investors
The Trout Group
Investor Relations
Alan S. Roemer
Tél. : +1 (212) 531-3315
aroemer@troutgroup.com

French investors
NewCap.
Financial Communication and investor relations
Emmanuel Huynh / Valentine Brouchot
Tél. : +33(0)1 44 71 94 94
dbv@newcap.fr

US press & media
Ronald Trahan, APR
Press relations
Ronald Trahan
Tél. : +1 508 359 4005
rctrahan@ronaldtrahan.com