

## **STALLERGENES AND CMC BIOPHARMACEUTICALS SIGN MANUFACTURING AGREEMENT FOR RECOMBINANT Bet v 1**

**Antony, France; Copenhagen, Denmark (May 14, 2007)** – STALLERGENES SA and CMC Biopharmaceuticals A/S announce today that they have entered into an agreement for development and supply of recombinant Bet v 1 (rBet v 1) purified bulk.

Bet v 1 is the protein that embodies most of the allergenicity of birch pollen, so called the major allergen of birch pollen.

CMC Biopharmaceuticals will scale up the manufacturing of GMP purified recombinant Bet v 1 and produce batches for Phase III clinical trials and commercial supply.

“CMC will allow us to benefit not only from its experienced management and its state-of-the-art fermentation facilities but also from its compliance with EMEA<sup>1</sup> and FDA<sup>2</sup> requirements”, said Albert Saporta, Chairman and CEO of STALLERGENES. “This agreement will speed our ORALAIR<sup>®</sup> Bet v 1 project towards late stage clinical trials and registration while securing the supply of active ingredients for commercial batches”.

“CMC is pleased to establish such a partnership with STALLERGENES in this truly innovative field of recombinant allergens; It is also a great opportunity to leverage our cGMP manufacturing capabilities with the short term prospect of an EMEA / FDA registration of a tablet for desensitization” said Mads Laustsen, CEO of CMC Biopharmaceuticals.

### **About ORALAIR<sup>®</sup> Bet v 1**

According to World Health Organization (WHO) estimates, 20% to 25% of the world population is suffering from respiratory allergic symptoms, rhinitis and/or asthma. Birch pollen is a major cause of those allergic symptoms, especially in the Northern countries of the Northern hemisphere. For instance, in Germany, up to 16% of the patients are sensitized to birch pollen.

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<sup>1</sup> EMEA: European Agency for the Evaluation of Medicinal Products

<sup>2</sup> FDA: Food and Drug Administration

STALLERGENES has carried out a Proof Of Concept trial aiming at demonstrating the ability of Bet v 1 to reduce the symptoms in patients allergic to birch pollen. This double blind placebo controlled study conducted in 150 patients in 5 countries was highly significant in efficacy and has also shown a good safety profile in the rBet v 1 group versus placebo, similar to the natural extract group.

Henceforth, STALLERGENES has decided to pursue the ORALAIR<sup>®</sup> Bet v 1 project to fully develop, register, and commercialize a desensitization tablet with rBet v 1 as active ingredient instead of natural birch pollen extract. STALLERGENES plans to submit a license application to the EMEA in 2010.

## **About STALLERGENES**

STALLERGENES is a European biopharmaceutical company dedicated to desensitization therapies for the prevention and treatment of allergy-related respiratory diseases, e.g. rhino-conjunctivitis and allergic asthma.

Pioneer and leader in sublingual desensitization treatments, STALLERGENES devotes more than 15% of its sales to Research and Development and is fully involved in the development of a new therapeutic class, the sublingual desensitization tablets.

Headquartered in France, STALLERGENES markets its products through its subsidiaries or joint-ventures in Europe and through distribution agreements in other countries. In 2006, STALLERGENES reached a turnover of 126.6 million euros, mainly achieved in the European markets.

STALLERGENES is listed on the Eurolist Compartment B of the Euronext Paris Stock Exchange.

ISIN Code:FR0000065674

Reuters Code:GEN.PA

Bloomberg Code: GEN.FP

Additional information is available on <http://www.stallergenes.com>

## **About CMC Biopharmaceuticals A/S**

Based in Copenhagen, Denmark, CMC is a contract development and manufacturing organization with sales offices located in both Europe and the U.S.

CMC specializes in process and analytical development as well as the scale-up and cGMP manufacture of Active Pharmaceutical Ingredients for pre-clinical, clinical trials and in-market production. CMC's competitive strength is centered on the flexibility it can offer to customers combined with the extensive experience of its management and key personnel in the field of biopharmaceutical manufacture and development.

Additional information is available on [www.cmcbio.com](http://www.cmcbio.com)

For more information please contact:



**Investors and analysts relations:**

Christian Thiry  
Chief Financial Officer  
Phone: +33 1 55 59 20 95  
Email: investorrelations@stallergenes.fr

Richard Hart  
VP Business Development  
Phone: +44 1491 681 823  
Email: rh@cmcbio.com

Lucile de Fraguier  
Investor & Analyst Relations  
Pavie Finance  
Phone: +33 1 42 15 04 39  
Email: contact@pavie-finance.com

**Press relations:**

Lise Lemonnier  
Communication Manager  
Phone: +33 1 55 59 23 10  
Email: llemonnier@stallergenes.fr