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Biovitrum wins contract to manufacture pharmaceutical substance for Resistentia's clinical phase III trials of new protein-based drug candidate for the treatment of allergy

Biopharma company Biovitrum, listed on the Stockholm Stock Exchange since September 15, 2006, has entered an agreement with the Uppsala-based biotech company Resistentia Pharmaceuticals AB for process development and manufacturing of the biopharmaceutical substance RES 08 intended for use in clinical phase III trials of Resistentia's new protein-based drug candidate for the treatment of allergy.

With the onset of an allergic reaction, allergy antibodies (IgE, immunoglobulin E, a specific protein in our immune system) are formed against a specific substance, for example pollen, dust, etc. Resistentia has developed a protein drug candidate (RES 08) that blocks the effect of IgE preventing an allergic reaction. RES 08 is a recombinant fusion protein (a protein with a compound structure produced by biotechnical methods) that initially is intended for the treatment of IgE-mediated allergies. Biovitrum's assignment is to develop the existing process for the biotechnical manufacturing of RES 08 to a standard that meets the high demands of a clinical phase III trial, and furthermore to manufacture sufficient amounts of the substance for the trial. The project will run for more than two years beginning in November 2006.

"We are very pleased with our partnership with the Swedish company Resistentia. This is a complex and extensive assignment which further emphasizes Biovitrum's role as a leading company in the Nordic biopharma industry," says Mats Pettersson, President of Biovitrum.

"The agreement which involves both process development and manufacturing of the biopharmaceutical drug substance for this clinical phase III trial, means that we will utilize our extensive expertise and broad experience in protein pharmaceuticals to the full extent," says Hans Örström, SVP Biovitrum Biopharmaceuticals and Marketing & Sales.

Marcus Bosson, President of Resistentia, says: "Biovitrum's long experience and expertise in the development and manufacturing of phase III processes is of vital importance at this stage to efficiently advance our project one step closer towards the market".

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Biovitrum

Biovitrum is one of the largest biopharma companies in Europe. With operations in Sweden and in the UK Biovitrum conducts research and develops pharmaceuticals for unmet medical needs both for common diseases and conditions that affect smaller patient populations. Biovitrum has a broad and balanced R&D portfolio with several projects in clinical and preclinical phases for the treatment of obesity, diabetes, inflammation and eye and blood diseases as well as a number of well defined niche indications. Biovitrum develops and produces protein-based drugs on a contractual basis and markets a range of specialist pharmaceuticals primarily in the Nordic countries. Biovitrum has approximately revenues of USD 119 million and 550 employees. Biovitrum is listed on the Stockholm Stock Exchange since September 15, 2006. For more information see www.biovitrum.com/.

Resistentia

Resistentia Pharmaceuticals AB is a Swedish privately held biotech company developing innovative immunotherapies that target allergy and asthma as well as inflammatory disorders. Founded in 1998, the company has developed an industrial organization with experiences ranging from molecular immunology, pre-clinical and clinical drug development to industrial biopharmaceutical production. In addition to its lead anti-IgE immunotherapeutic, Resistentia has initiated pre-clinical development of an immunotherapeutic against complement factor C5a for the treatment of rheumatoid arthritis and other autoimmune diseases.

Clinical phase III development

The manufacturing of protein pharmaceuticals for later clinical phases (phase III) imposes higher demands on both process and manufacturer than production of clinical materials for earlier phases (phase I/II). When phase III processes are developed, focus is directed toward manufacturing costs, process robustness and industrial scalability. After development and characterization, these processes are finalized for validation and can subsequently be utilized when a product is registered with the medical products agency. Process characterization involves identification of critical parameters of a manufacturing process in a laboratory environment in order to assess and adjust the process so that manufacturing meets the high demands for reproducibility and consistency during validation. Process validation involves investigating through a number of consecutive manufacturing batches whether the product meets the pre-specified requirements.