

PRESS RELEASE

ProtAffin AG granted Orphan Drug Designation in the US for lead anti-inflammatory product

5th September, 2008, Graz, Austria: ProtAffin AG, a biotechnology company developing anti-inflammatory therapeutics that act by targeting cell-surface glycan structures, today announced that it has received Orphan Drug Designation in the US from the Food and Drug Administration (FDA) for ProtAffin's lead product PA401 (also designated as Recombinant human CXCL8 mutant). PA401 has been granted Orphan Drug designation in the US for the "prevention of delayed graft function after solid organ transplantation". PA401 is ProtAffin's lead anti-inflammatory product and is a modified form of the human chemokine IL-8 which acts as a potent, targeted anti-inflammatory protein preventing the infiltration of neutrophils which is often seen in the first days following solid organ transplantation.

Dr. Jason Slingsby, CEO of ProtAffin commented: "I am encouraged that the FDA has approved the Orphan Drug designation for PA401 for the prevention of delayed graft function after solid organ transplantation. This encouraging step builds on the announcement by the EMEA in July this year of granting of Orphan Medicinal Product Designation for PA401 in the EU for the same condition. There remains a real unmet medical need for an innovative anti-inflammatory product that works to prevent the delay in graft function that is so often experienced following solid organ transplants. There are no products currently authorized in the US to prevent this condition and we hope to make an important contribution to the field of clinical medicine and to improve patient outcomes in transplantation and other inflammatory diseases."

– ENDS –

Notes to Editors:

About ProtAffin AG

ProtAffin is a European pre-clinical stage biotechnology company based in Austria, developing protein-based products targeting inflammation. Its novel class of biologics target heparin-like glycan structures that drive inflammatory processes. ProtAffin has used its proprietary CellJammer[®] discovery technology to develop a pipeline of pre-clinical development candidates based on engineered human chemokine proteins. The discovery technology is also applicable to many targets in the field of oncology.

Since its foundation, the Company has raised €4.3m in equity financing. A €4m Series A financing in 2007 was led by Aescap Venture Management BV in Amsterdam, The Netherlands with participation from The Entrepreneurs Fund in London, UK and Z-Cube Srl, the venture arm of the Zambon Company, Milan, Italy. The Company has also raised €2m in non-dilutive financing in Austria in the form of seed finance and product development grants. The Company currently has 17 employees in its offices and labs in Graz, Austria. The Company also has a Corporate Office in Vienna, Austria.

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About Delayed Graft Function (DGF)

Delayed graft function (DGF) represents a reduced function of the transplanted organ that occurs in the first days after transplantation. Following organ donation, the organ must be transported to a specialist centre where the transplant operation will be carried out. Following transplantation, the reintroduction of the blood supply to the organ causes a well recognised inflammatory process called ischemia/reperfusion (I/R) injury, with many white blood cells such as neutrophils infiltrating into the organ. This can prevent the organ from adequately functioning in the first week after transplantation.

There were over 16,600 kidney transplants in the U.S. in 2006, with nearly 70,000 patients on the waiting list for a kidney transplant in the US. It is estimated that 25% of patients experience DGF, which is defined by the requirement for dialysis within the first 7 days following transplantation. The incidence of DGF can rise to up to 63% depending on various clinical factors. DGF can contribute to organ loss in the short term and the 10-year graft survival for kidneys which experience DGF is 33% versus 53% of those kidneys that do not experience DGF. Therefore, there is a clear need within transplantation medicine for an authorized product for the prevention of delayed graft function. The high incidence of DGF incurs significant additional costs to the healthcare provider and makes the dosing of standard immunosuppressive regimes more complex in the first week. None of the authorized immunosuppressive products traditionally used in organ transplantation area able to significantly reduce the ischemia/reperfusion injury which leads to delayed graft function.

About PA401

ProtAffin's lead anti-inflammatory product is PA401, a modified form of the human chemokine IL-8. PA401 acts as a potent, targeted anti-inflammatory protein preventing the infiltration of neutrophils which is often seen in the first days following solid organ transplantation. By binding to glycans that drive the infiltration of neutrophils in inflammation with a higher affinity than wild-type IL-8, PA401 can prevent wild-type IL-8 from activating neutrophils and inhibit the events that would normally lead to inflammation. PA401 is in pre-clinical development at ProtAffin for the prevention of delayed graft function after solid organ transplantation.

About Orphan Product Designation in the US

Medicines for rare diseases, so called "orphan drug products" in the US are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions that affect no more than 200,000 people annually in the US. The legislative framework for orphan drugs aims to stimulate research and development of medicines for rare diseases by providing incentives to the pharmaceutical and biotechnology industry. These incentives include fee reductions or exemptions for regulatory services, and 7 years marketing exclusivity.

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