EUROCALIN

EUROCALIN: EUROpean consortium for antiCALINs as next generation high-affinity protein therapeutics

The EUROCALIN Project consortium

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Medizinische Universitaet Innsbruck (AT)
Stichting Katholieke Universiteit (NL)
Covance Laboratories LTD (UK)
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Fujifilm Diosynth Biotechnologies UK Limited (UK)
Coriolis Pharma Research GmbH (DE)
FGK Clinical research GmbH (DE)
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COVANCE

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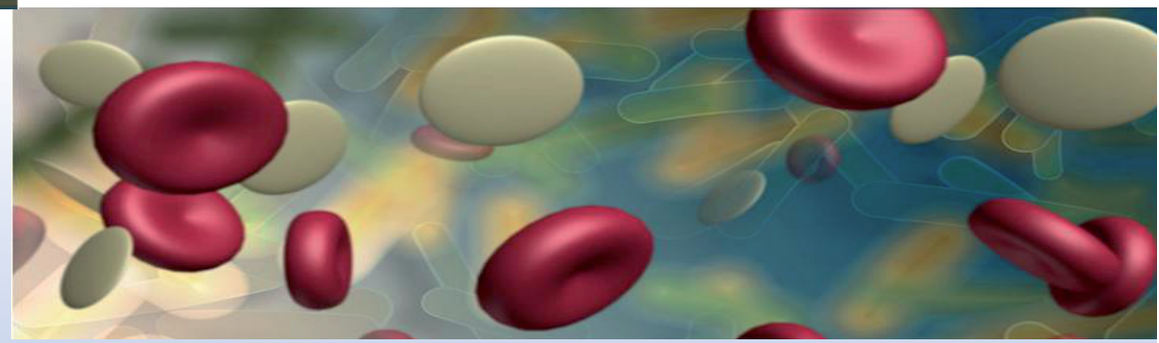
EUROCALIN

COOPERATION



EUROpean consortium for antiCALINs as next generation high-affinity protein therapeutics (EUROCALIN)

SME-targeted Collaborative Project
Programme: FP7-COOPERATION-HEALTH

Start date of project: August 1st, 2011
Duration: 48 months

Project coordinator organization: PIERIS AG
Project coordinator: Andreas Hohlbaum, PhD

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Summary

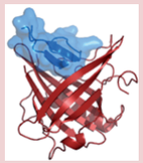
The EUROCALIN consortium aims to develop and produce an Anticalin, a member of a **novel high-affinity scaffold** derived from the lipocalin protein family. The Anticalin is **specific for hepcidin** which is a central regulator of iron homeostasis, and will be used to antagonize hepcidin for the treatment of "anemia of chronic disease" (ACD).

The consortium has already generated proof-of-concept data in an animal model with early candidates.

The project aims at **identifying, validating, and developing** a specific, high affinity drug candidate based on the lipocalin scaffold as promising alternatives to immunoglobulins and a therapeutic approach based on the neutralization of hepcidin. **Animal models** will be developed and utilized to **characterize pharmacokinetic and pharmacodynamic relationships, to optimize dosing, to determine safety, biomarker responses** and potential synergy with ESA's. Furthermore, **production processes** will be optimized leading to a scalable GMP process which provides material for **preclinical** and **clinical studies** to establish the **safety, tolerability, and PK/PD** of an Anticalin hepcidin blocker (Phase Ia/b).

Anticalins

Anticalins (red) are genetically modified lipocalins that can target almost any desired molecule (blue).



Anticalin bound to the peptide hepcidin

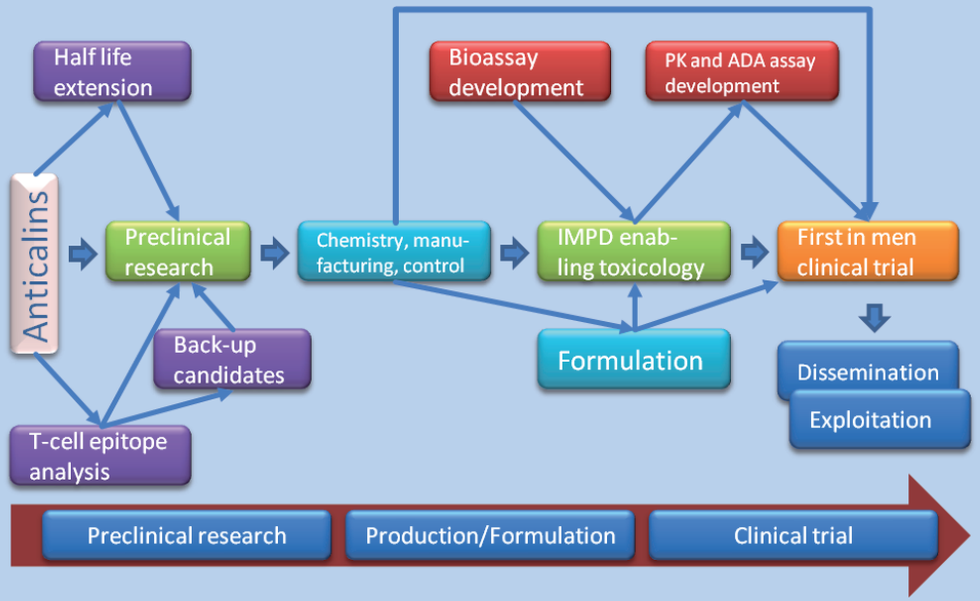
Unlike immunoglobulins, they can be produced at low cost in microbial expression systems, are expected to be non immunogenic and offer therapeutic advantages where antibody effector functions are not desired.

Hohlbaum, A. M. et al. (2012): PK/PD-Guided Development of a Novel Hepcidin Antagonist for the Treatment of Functional Iron Deficiency in CKD

Anemia of chronic disease

Anemia of chronic disease (ACD), the most frequent anemia in hospitalized patients, develops in subjects suffering from infections, inflammatory and auto-immune disease, cancer and chronic kidney disease. It is often successfully treated by administering Erythropoiesis-Stimulating Agents (ESA). However, a significant number of patients are hypo- or non-responsive to ESA. Anti-hepcidin therapies, alone or together with ESAs, may improve anemia and the patients' erythropoietic response and enable the use of no or even much lower ESA doses, avoiding the potential detrimental effects of high doses of ESA.

EUROCALIN project overview



EUROCALIN is a **drug development collaboration** between 10 distinct companies and academic institutions across Europe and is funded in large part by the European Commission under its FP7 HEALTH program (2011.1.4.3; Grant Agreement number 278408).

EUROCALIN stands for "EUROpean Consortium for AntiCALINS as next generation high-affinity protein therapeutics". The goal of the collaboration is to develop an exciting potential treatment for anemia into and through the first stage of clinical evaluation. The project started in August 2011 and will continue for four years.

www.eurocalin-fp7.eu