

> PROJECT FACTSHEET: Dersalazine sodium

Ulcerative colitis is a chronic relapsing inflammatory disease of the large bowel. Current therapies for mild and moderate cases of the disease rely mainly on aminosalicylates, but often efficacy is limited. Resistant or more severe cases can be treated with corticosteroids, immunosuppressants or anti-TNF α agents; however, adverse effects, an inconvenient dosing schedule and prohibitive price limit their long-term use.

Dersalazine sodium is a new chemical entity that will provide a new therapeutic alternative to corticosteroids, immunosuppressants and anti-TNF α treatments, helping patients to avoid the adverse effects commonly associated with the use of these therapies with worse tolerability profiles.

> A Company Founded On Solid Market And Patients Needs

Palau Pharma, S.A. ("Palau") is a product-driven biopharmaceutical company focused on the discovery and development of revolutionary and differentiated new medicines that are designed to address the unmet needs of patients suffering from inflammatory and autoimmune diseases. Our core business model is to develop novel drugs through Phase IIa clinical trials. At that point, we decide whether to keep the development in-house or partner the compound for further development and commercialization. We have a broad portfolio of projects at different stages of development from early discovery to the late clinical stages, and have forged partnerships with leading pharmaceutical companies such as GlaxoSmithKline.

Our R&D strategy is focused on developing "best-in-class" or "first-in-class" drugs that modulate the activity of validated targets with established preclinical or clinical proof-of-concept. Based on a unique and high-quality cost-effective structure, our final objective is to achieve early positive differentiation from our competitor's molecules by addressing their limitations and designing a clear, focused and fast path to commercial success.

> The Target: Platelet Activating Factor (PAF)

PAF is a proinflammatory lipid mediator involved in hypersensitivity and inflammatory reactions. In addition, it stimulates the release of eicosanoids as well as several cytokines such as IL-1 and tumour necrosis factor (TNF). All these actions contribute to the genesis and amplification of inflammatory processes, including ulcerative colitis.

> The Opportunity: A New Oral Treatment For Ulcerative Colitis

Dersalazine sodium is an anti-inflammatory agent for the oral treatment of ulcerative colitis. The compound has recently completed a Phase IIa clinical trial.

> Solid Results

Dersalazine sodium is a new chemical entity resulting from the link of a potent Platelet-activating Factor (PAF) antagonist with anti-TNF α properties (UR-12715) and 5-aminosalicylic acid (5-ASA) by an azo bond. Dersalazine sodium is carried unaltered through the upper gastrointestinal tract until azo-reduction by the colonic bacteria splits dersalazine sodium into the two metabolites. Unlike other azo-based compounds, the key anti-inflammatory action is driven by the anti-PAF metabolite, and not by 5-ASA. As a matter of fact, the total amount of 5-ASA released in the colon at the clinically tested doses of dersalazine sodium is unlikely to produce a significant effect. Nevertheless a synergy on the anti-inflammatory actions of UR-12715 and 5-ASA has been shown at the preclinical stage.

At a glance

- Founded: November 2006
- Spin-out from Grupo Uriach
- Employees: 85
- €40M raised at inception

Management

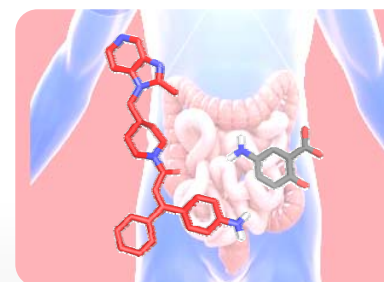
- **Ignacio Faus**
Chief Executive Officer
- **Manel Barallat**
Chief Financial Officer
- **Xavi Bartrolí**
Director of Innovation & Drug Discovery
- **Manuel Merlos**
Director of Drug Development & Clinical Research
- **Heidi Sisniega**
Head of Business Development & Licensing
- **Neus Virgili**
Head of Patents & Legal Affairs
- **Caridad Pontes**
Head of Clinical Research & Regulatory Affairs

Shareholders

- Grupo Uriach
- Caixa Catalunya
- Caja Duero
- Andosins Capital
- Najeti Capital
- Senior Management

Scientific Advisory Board

- Dr. Roderick Flower
- Dr. Desmond Fitzgerald
- Dr. Alberto Grignolo
- Dr. Trevor Hansel
- Dr. Thomas Luger

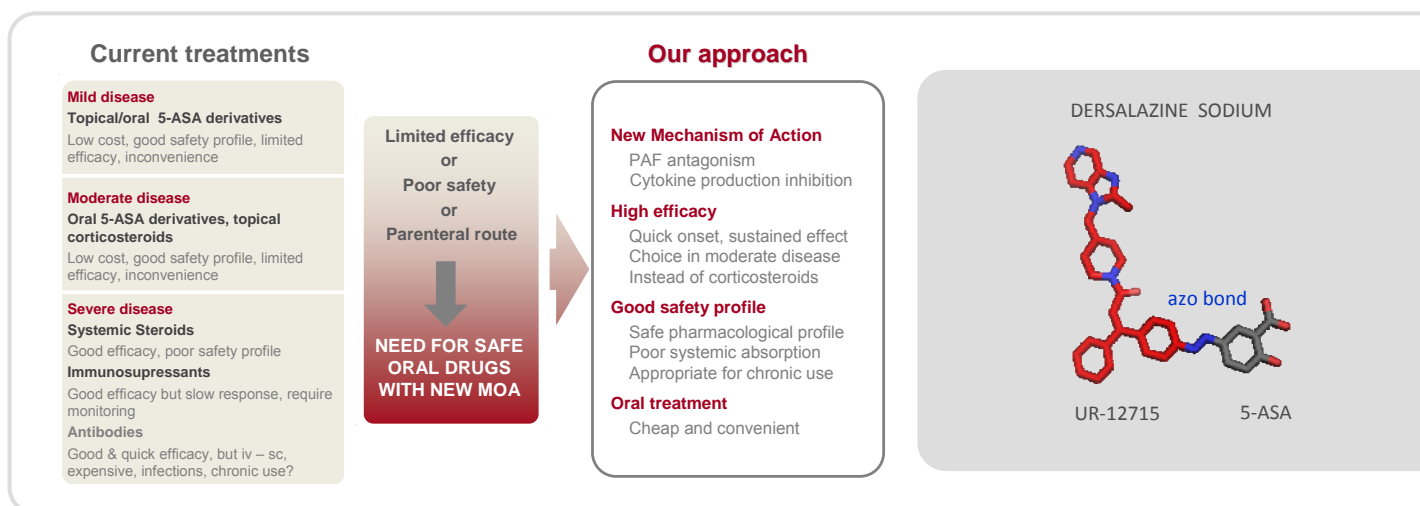
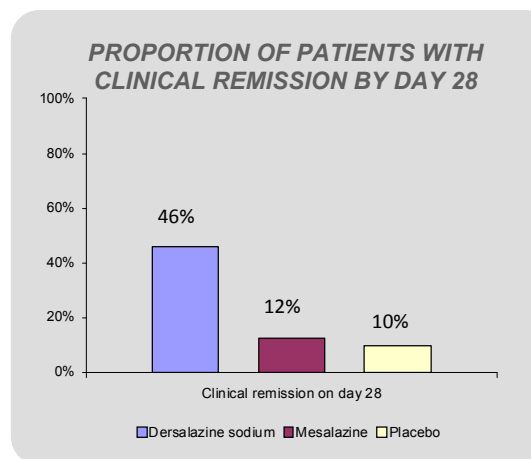


Dersalazine sodium has demonstrated its efficacy and safety in a thorough program of preclinical studies, and has completed a regulatory preclinical package to support clinical development.

In Phase I clinical development, dersalazine sodium has been tested for safety and pharmacokinetics in single and multiple escalating dose placebo-controlled studies in healthy volunteers, and has been shown to be safe and well tolerated. The pharmacokinetics in humans has been assessed using both cold and radiolabelled compound, confirming minimal dersalazine sodium disposition and an extensive azo-reduction by colon bacteria.

A Phase IIa double-blind randomized mesalazine and placebo controlled multicenter trial in patients with mild to moderate UC has been recently completed. A significant and clinically relevant reduction of disease activity was observed only with dersalazine sodium as soon as 14 days, and clinical remission by day 28 was achieved by 46% of dersalazine sodium treated patients, as compared to 12% and 10% in mesalazine and placebo groups respectively.

Preliminary results of the study suggest that dersalazine sodium induces an early clinical response in active UC patients, and provide the first proof of concept on PAF antagonism as a new therapeutic alternative for this indication.



> **Intellectual Property**

The product is protected by patents in most the major markets, with an expiry date which can be extended up to 2026 where extensions are available.

> **Every Partnership Is a Solid Commitment**

Palau is seeking a licensing partner for the worldwide development and commercialization of dersalazine sodium.

Contacts

For further information on Palau Pharma and its products, please visit

www.palaupharma.com

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