

# UNION therapeutics announces two peer-reviewed publications of preclinical and clinical Phase 2a data on orismilast

- New insights into the pharmacological properties of orismilast and Phase 2a data published in peer-reviewed journal JEADV
- Data supports orismilast's potential as a first-in-class or best-in-class treatment for a range of immunological diseases
- UNION is currently developing orismilast modified release (MR) tablet as a safe oral treatment of psoriasis, atopic dermatitis (AD) and hidradenitis suppurativa (HS)

**Hellerup, Denmark, 22 December 2022** – UNION therapeutics A/S (UNION), a privately-held, multi-asset, clinical stage, pharmaceutical development company focused on immunology and infectious diseases, today announced publication of two articles on the pharmacological properties of orismilast from its preclinical studies with orismilast and clinical Phase 2a data on the safety and efficacy of orismilast immediate release (IR) formulation in the peer-reviewed Journal of European Academy of Dermatology and Venerology (JEADV).

Described in the paper on the pharmacological properties of orismilast, the preclinical results demonstrated that orismilast is a potent and selective inhibitor of PDE4 subtypes involved in the inflammatory signaling cascades associated with chronic inflammatory diseases. Orismilast more selectively inhibited PDE4-B and PDE4-D subtypes, which are believed to be most relevant for inflammation, compared to apremilast. Furthermore, orismilast inhibited the release of cytokines related to type 1, 2 and 17 pathways and general inflammation (e.g., TNF $\alpha$ , IFN $\gamma$ , IL-1 $\alpha$ , IL-13, IL-17A, IL-22 and IL-23) in human immune cells (PBMCs), thus showing significant potential across a range of immunologic conditions, including psoriasis, AD and HS. Specifically, orismilast inhibited TNF $\alpha$  release more potently than apremilast, the only approved oral PDE4 inhibitor in dermatology, in human whole-blood. Finally, orismilast demonstrated a comparable anti-inflammatory effect to dexamethasone in the oxazolone-induced ear inflammation mouse model.<sup>1)</sup>

The paper on the clinical Phase 2a data on the safety and efficacy of orismilast IR formulation describes the potential for differentiated efficacy profile of orismilast IR in patients with moderate to severe psoriasis. This supports the potential of orismilast as a first-in-class or best-in-class treatment of psoriasis, AD and HS. <sup>2)</sup>

# Kim Kjøller, Chief Executive Officer of UNION therapeutics said:

"These important preclinical and Phase 2a data on orismilast published in the peer-reviewed journal JEADV, underscores the unique potential for orismilast as first-in-class or best-in-class treatment for psoriasis, atopic dermatitis, and hidradenitis suppurativa."

## **About orismilast**

UNION is developing orismilast, which is a next-generation PDE4 inhibitor with high potency for the PDE4 subtypes linked to inflammation. It operates early in the inflammation cascade to induce a broad range of anti-inflammatory effects. Orismilast has the potential to inhibit many inflammatory pathways involved in dermatological and immunological diseases and holds

potential to become a safe and efficacious treatment option in various dermatological and immunological diseases.

UNION is currently developing orismilast MR tablet for the treatment of psoriasis, AD and HS. UNION is progressing orismilast as a MR tablet to minimize the occurrence of gastrointestinal side effects typically associated with PDE4 inhibition.

In November 2020, the FDA cleared UNION's Investigational New Drug (IND) application for orismilast MR tablet, and, in November 2021, the FDA granted Fast Track designation to orismilast MR tablet for the treatment of moderate to severe AD. Moreover, in September 2021, UNION entered into a strategic partnership and licensing agreement with Innovent Biologic for orismilast in Mainland China, Hong Kong, Macau and Taiwan.

### **Sources**

- 1) Silverberg J.I. et al., Pharmacology of orismilast, a potent and selective PDE4 inhibitor, JEADV 2022: http://onlinelibrary.wiley.com/doi/10.1111/jdv.18818
- 2) Warren R.B. et al., Efficacy and safety in moderate-severe psoriasis and development of modified release tablets, JEADV 2022: http://onlinelibrary.wiley.com/doi/10.1111/jdv.18812

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# **About UNION therapeutics**

UNION therapeutics is a privately held, multi-asset, clinical stage, pharmaceutical development company focused on immunology and infectious diseases. The company is currently working with two complementary chemistry classes, spanning immunology and microbiology with multiple candidates in clinical development. UNION is headquartered in Hellerup, Denmark, and led by an international team combining biotech entrepreneurs and seasoned pharma executives, with a track record of developing and launching more than fifteen marketed drugs. Read more at <a href="https://www.uniontherapeutics.com">www.uniontherapeutics.com</a>