UNION therapeutics announces enrollment of first patient in the IASOS Phase 2b study of oral orismilast in psoriasis patients

- IASOS is a Phase 2b dose-ranging study of oral orismilast in psoriasis patients with the purpose of identifying the appropriate dose-regimen for Phase 3 studies
- Orismilast is a next generation PDE4 inhibitor with broad anti-inflammatory properties also in development for the treatment of hidradenitis suppurativa (HS) and atop dermatitis (AD)

Hellerup, Denmark, 4 January 2022 – UNION therapeutics A/S, a privately-held, multi-asset, clinical stage, biotechnology company focused on immunology and infectious diseases, today announced that the first patient has been enrolled in IASOS, a Phase 2b dose-ranging study evaluating the safety and efficacy of oral orismilast in patients with moderate to severe psoriasis.

In November 2020, the US Food and Drug Administration (FDA) approved UNION’s Investigational New Drug Program (IND) for advancing oral orismilast into a Phase 2b trial in patients with moderate to severe psoriasis. UNION has now launched the IASOS Phase 2b study with the purpose of identifying the appropriate dose-regimen for Phase 3 studies.

Prof. Richard Warren, MD, PhD, The University of Manchester and Consultant Dermatologist, Salford Royal NHS Foundation Trust, Senior Investigator of the Phase 2b study said:

“Psoriasis is one of the most common chronic inflammatory skin diseases in the world. Even though there are many biologics approved for the treatment of psoriasis, there are still limited oral treatments that are efficacious, can be used long term and do not require screening before initiation and during use. Oral orismilast has the potential to become an efficacious and patient-friendly treatment option for patients with psoriasis and we are pleased to have enrolled the first patient in this Phase 2b study.”

Kim Kjøller, Chief Executive Officer of UNION therapeutics said:

“Orismilast holds the potential to be a best-in-class treatment and game-changer for psoriasis patients. With the first patient enrolled in the Phase 2b study in psoriasis, we are one step closer to offering psoriasis patients a novel oral treatment option.”
About the IASOS Phase 2b study
The Phase 2b study is a randomized, double-blind, placebo-controlled, parallel-group, dose-ranging study to evaluate the efficacy and safety of orismilast in patients with moderate to severe plaque psoriasis. The primary objective is to evaluate the efficacy and safety of a modified release orismilast tablet versus placebo. The study targets to include 200 patients who will be randomized to three active doses and placebo administered twice daily. The study will be conducted in approximately 40 centers in Europe and North America. The overall aim of the study is to identify the appropriate dose-regimen for Phase 3 studies with oral orismilast in psoriasis.

About orismilast
UNION is developing orismilast, which is a next generation phosphodiesterase type-4 (PDE4) inhibitor with high selectivity for the PDE4 subtypes which operates early in the inflammation cascade to induce a broad spectrum of downstream anti-inflammatory effects, and therefore has the potential to inhibit many inflammatory pathways involved in dermatologic diseases. UNION has developed oral orismilast as a modified release (MR) tablet to minimize the occurrence of gastrointestinal side effects.

The safety and tolerability of PDE4 inhibitors is well established with several PDE4 inhibitors already available in oral and topical form for the treatment of psoriasis, atopic dermatitis, and chronic obstructive pulmonary disease (COPD). UNION has two product candidates with orismilast in its clinical stage pipeline: UNI50001, oral orimilast currently investigated for the treatment of psoriasis, AD and HS; and UNI50002, topical orismilast in AD. In November 2021, the US Food and Drug Administration (FDA) granted Fast Track designation to oral orismilast for the treatment of moderate to severe AD.

About psoriasis and treatment of psoriasis
Psoriasis is an autoimmune disease that is diagnosed in an estimated 13 million patients in 2021 in the Seven Major Markets (US, EU5 and Japan)\(^1\). Plaque psoriasis can appear on any area of the body, but most often appear on the scalp, knees, elbows, trunk, and limbs, and the plaques are often itchy and sometimes painful.

Most psoriasis patients are treated with topical therapies. Patients with more moderate-severe psoriasis often require treatment with systemic therapies which can be either oral tablets or injectable biologics. There are limited number of oral treatments available, and
they generally have a less favorable effect relative to their safety and tolerability profile. The biologic treatments can be very effective, but their use is limited by their high cost, patient preference against injections, and requirements for the treating physician to screen patients and monitor for infections.

Sources
EU5 and Japan: Decision Resources Group Psoriasis Report 2020

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About UNION therapeutics
UNION therapeutics is a privately-held, multi-asset, clinical stage, biotechnology company focused on immunology and infectious diseases. The company is currently working with two complementary chemistry classes, spanning immunology and microbiology with six programs in clinical development. UNION is headquartered in Hellerup, Denmark, and led by an international team combining biotech entrepreneurs and senior pharma executives, with a track record of developing and launching more than fifteen marketed drugs. Read more at www.uniontherapeutics.com