UNION therapeutics announces enrollment of first patient in the OSIRIS Phase 2a study of oral orismilast for the treatment of mild to severe hidradenitis suppurativa

- OSIRIS is an investigator-led, proof-of-concept Phase 2 study of orismilast for the treatment of mild to severe hidradenitis suppurativa (HS)
- HS is a scarring inflammatory skin disease with significant unmet treatment need
- Orismilast is a next generation PDE4 inhibitor with broad anti-inflammatory properties also in development for the treatment of psoriasis and atopic dermatitis

Hellerup, Denmark, 14 October 2021 – UNION therapeutics A/S, a privately-held, multi-asset, clinical stage, pharmaceutical company focused on immunology and infectious diseases, today announced the enrollment of the first patient in OSIRIS, a Phase 2, open-label, proof of concept study of an oral tablet formulation of orismilast in adult patients with mild, moderate and severe HS. The primary objective of OSIRIS is to explore evidence of efficacy of oral orismilast in the treatment of patients with HS for up to 16 weeks. Orismilast is currently in Phase 2 of clinical development for various inflammatory skin diseases, including psoriasis and atopic dermatitis.

The investigator-initiated, single-site OSIRIS study is led by Professor Gregor B. Jemec, Founding Chairman of the Department of Dermatology, Zealand University Hospital Roskilde, Denmark. Dr. Jemec is at the global forefront of HS research, contributing significantly to the definition and management of the disease with more than 200 publications so far.

Professor Gregor B. Jemec said:
“Hidradenitis suppurativa is an autoimmune systemic skin disease. It causes wide-spread inflammation and scarring causing serious detrimental effects on the quality of life of patients. Yet it has only limited treatment options, that often provide only temporary symptomatic relief. There is a significant and urgent unmet need for an effective therapy. We are therefore very pleased to be able to enroll the first of 24 patients in the study and hope that orismilast as an innovative oral approach will demonstrate benefit in the management of this devastating illness.”

Kim Kjøller, Chief Executive Officer of UNION therapeutics said:
“While HS may be a niche indication, it has serious consequences for the patient. Due to chronic pain, drainage, and malodor associated with lesions, the condition imposes a significant burden on patients’ quality of life. With limited treatment options today, we are eager to support Gregor B. Jemec and his team at Zealand University Hospital investigating the potential of orismilast for becoming a safe and efficient, first in class, oral treatment for HS.”

About the OSIRIS Phase 2 study
OSIRIS is a phase 2, open-label, single-centre, prospective, single arm, investigator-initiated proof of concept study investigating the efficacy and safety of an oral tablet formulation of

orismilast applied twice daily for up to 16 weeks in adult patients with mild, moderate, and severe HS. The clinically relevant primary endpoint is percent change from baseline in abscesses and nodules count at week 16 of treatment. The study will enroll 24 adult patients (men and women); 8 with mild, 8 with moderate, and 8 with severe HS.

About orismilast
Orismilast is a potent and selective PDE4 inhibitor. PDE4 inhibition works high in the inflammation cascade and as such have the potential to inhibit many autoimmune pathways involved in dermatologic diseases such as HS. The safety and tolerability of PDE4 inhibitors is well understood, with two oral treatments and one topical approved and marketed. The selectivity of orismilast for PDE4 subtypes B and D has preclinically resulted in improved anti-inflammatory potency. Orismilast has generated positive proof of concept data orally in psoriasis and topically in atopic dermatitis.

UNION therapeutics has two product candidates with orismilast in its clinical stage pipeline: UNI50001, an oral PDE4 inhibitor currently investigated for the treatment of psoriasis, atopic dermatitis and HS; and UNI50002, a non-steroidal topical PDE4 inhibitor currently investigated for the treatment of atopic dermatitis.

About HS
HS is a chronic, inflammatory skin disease which results in painful inflammation of the hair follicles, most notably in the armpit and genitalia regions. The clinical hallmarks of the disease include very painful inflammatory nodules, boils or abscesses that typically open and release odorous inflammatory fluids. HS patients suffer primarily from pain and significant discomfort resulting from the constant formation of pus, often requiring the use of bandages and diapers, resulting in social isolation. Patients are often stigmatized by these symptoms. Not surprisingly, HS severely and adversely affects patients' quality of life and is associated with an increased overall mortality rate due to cardiovascular disease and completed suicides.

HS is an immune-mediated disorder with an unknown etiology, with many immune pathways activated - expectedly requiring a broad anti-inflammatory approach to achieve good efficacy. Treatment for HS patients typically includes topical, oral or intravenous antibiotic treatment, which often provide only temporary symptomatic relief. In some cases, patients also undergo different types of surgery.

Contacts

UNION therapeutics A/S
Morten Boesen, Chief Financial Officer
+45 2381 5487
morten.boesen@uniontherapeutics.com

Media enquiries

UNION therapeutics A/S
Sarah Toft-Jørgensen, Director of Communications and IR
+45 5385 3044
stj@uniontherapeutics.com

About UNION therapeutics
UNION therapeutics is a privately-held, multi-asset, clinical stage, pharmaceutical company focused on immunology and infectious diseases. The company is currently working with two complementary chemistry classes, spanning immunology and microbiology with seven 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