UNION therapeutics announces regulatory approval of Treatment Extension for the ongoing OSIRIS Phase 2a open label study with orismilast MR tablet for patients with Hidradenitis Suppurativa (HS)

- OSIRIS is an investigator-initiated Phase 2a open label study, studying orismilast modified release (MR) tablet as a potential treatment for HS
- Treatment Extension gives the possibility to allow patients to continue their study medication after their study participation has been completed
- HS is a scarring inflammatory skin disease with unmet medical need with few or no good treatment options
- Orismilast MR is a potent next-generation PDE4 inhibitor with broad anti-inflammatory properties also in development for the treatment of psoriasis and atopic dermatitis (AD)

Hellerup, Denmark, 1 September 2022 – UNION therapeutics A/S (UNION), a privately-held, multi-asset, clinical stage, pharmaceutical development company focused on immunology and infectious diseases, today announced the implementation of Treatment Extension to the ongoing OSIRIS Phase 2a study with orismilast MR tablet for the treatment of patients with mild to severe HS following approval granted by the Danish Medicines Agency and Ethics Committee. With the Treatment Extension, patients who have completed the OSIRIS study may continue treatment with orismilast MR tablets for a period of 52 weeks.

Professor Gregor B. Jemec, PhD, MD, Founding Chairman of the Department of Dermatology, Zealand University Hospital Roskilde, Denmark 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. There is a significant and urgent unmet need for an effective therapy, and we are therefore pleased to be able to offer patients with a favorable response to orismilast MR tablet an extended treatment period."

About the OSIRIS Phase 2 study
OSIRIS is a phase 2a, open-label, single-center, prospective, single arm, investigator-initiated proof of concept study investigating the efficacy and safety of orismilast MR tablet taken 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 HS and treatment of HS
HS is a chronic, inflammatory skin disease which results in painful inflammation of the hair follicles, most notably in the armpit and genital 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.[1)]

Currently, there is only one drug approved for treatment of moderate to severe HS, which is an injectable drug. For mild HS there are no treatments approved. The general standard of care for HS patients, although off-label, includes topical, oral or intravenous antibiotic treatment which often provides only temporary symptomatic relief. Antibiotics do not target the underlying inflammation and they are associated with resistance development. [2)]

About orismilast
UNION is developing orismilast, which is a next-generation phosphodiesterase type-4 ("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 the potential to become a safe and efficacious treatment option in these diseases.

UNION is developing orismilast MR tablet for the treatment of psoriasis, AD and HS; and topical orismilast with clinical proof of concept established in AD. UNION is progressing orismilast as a modified release 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 collaboration and license agreement for the development and commercialization of orismilast in Mainland China, Hong Kong, Macau and Taiwan.

Sources

1) https://www.ncbi.nlm.nih.gov/books/NBK534867/ and https://pubmed.ncbi.nlm.nih.gov/28942360/
2) https://pubmed.ncbi.nlm.nih.gov/29183082/

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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 www.uniontherapeutics.com