UNION therapeutics receives FDA Fast Track designation for oral orismilast for the treatment of moderate to severe atopic dermatitis

- FDA’s Fast Track designation for oral orismilast underscores the urgent need for new treatment option with potential to fulfil the unmet medical needs for people affected by atopic dermatitis (AD)
- AD is the most common chronic inflammatory skin disease in the developed world
- Orismilast is a next generation PDE4 inhibitor with broad anti-inflammatory properties also in development for the treatment of psoriasis and hidradenitis suppurativa (HS)

Hellerup, Denmark, 4 November 2021 – UNION therapeutics A/S, a privately-held, multi-asset, clinical stage, pharmaceutical company focused on immunology and infectious diseases, today announced that the US Food and Drug Administration (FDA) has granted Fast Track designation to oral orismilast for the treatment of moderate to severe AD. The FDA’s Fast Track designation is intended to facilitate the development and review of drug candidates that treat serious conditions and address an unmet medical need. A drug candidate that receives Fast Track designation is eligible for more frequent interaction with the FDA to discuss the drug candidate’s development plan as well as eligibility for rolling review and priority review.

Kim Kjøller, Chief Executive Officer of UNION therapeutics said:
“We are very pleased to receive this Fast Track designation for oral orismilast and look forward to working closely with the FDA. We believe that oral orismilast holds great promise and has the potential to become an efficacious treatment option for patients who need systemic therapy for atopic dermatitis without the safety issues associated with oral corticosteroids.”

Jonathan Silverberg, MD, PhD, MPH and well recognized KOL adds:
“Atopic dermatitis is one of the most common chronic skin diseases worldwide. Despite the recent advancements in the treatment of atopic dermatitis, there is still a high unmet need in terms of safe and efficacious oral treatments that can be used before biologics. It is
encouraging to see that FDA recognizes the potential of orismilast in atopic dermatitis and grants it fast track designation, which would bring orismilast one step closer to patients.”

About orismilast
Orismilast is a potent and selective next generation PDE4 inhibitor. PDE4 inhibition works high in the inflammation cascade and as such has the potential to inhibit many autoimmune pathways involved in dermatologic diseases. The safety and tolerability of PDE4 inhibitors is well understood, with two oral treatments and one topical approved and marketed.

Two challenges exist for the currently commercialized oral PDE4 inhibitors: their overall efficacy within existing indications tends to be moderate and they are limited by gastrointestinal side effects which worsens with dose increase. This represents challenges for an effective PDE4 therapy. Orismilast was selected to improve anti-inflammatory potency whilst minimizing gastrointestinal side effects. Additionally, orismilast has demonstrated clinical proof-of-concept in both psoriasis and AD patients.

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, AD and HS; and UNI50002, a non-steroidal topical PDE4 inhibitor currently investigated for the treatment of AD.

About atopic dermatitis
Atopic dermatitis is a chronic inflammatory skin disease affecting approximately 3% of the adult population worldwide and is the most common skin disease among children, with the disease commonly occurring by five years of age. There was approximately 26 million diagnosed cases of AD in 2021 in the Seven Major Markets (US, France, Germany, Italy, Spain, UK, and Japan). Disease symptoms are characterized by recurrent eczematosus skin lesions and intense itch. AD has a substantial psychosocial impact on patients and relatives. During disease flares, approximately 80% of patients may experience disturbed sleep, which may also disrupt the sleep of family members. The disease impacts the mood and affected individuals may experience depression.
Sources

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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