UNION therapeutics A/S receives FDA approval for IND of oral next generation PDE4-inhibitor (orismilast) for investigation in plaque psoriasis

Thursday, January 7th 2021

- Orismilast is a next generation oral PDE4-inhibitor with an improved therapeutic window compared to other PDE4-inhibitors
- Oral orismilast (UNI50001) has demonstrated proof of concept in patients living with plaque psoriasis and indicated "best-in-class" potential
- PDE4-inhibition is a validated pharmacological target published for a broad range of inflammatory indications[1]
- The improved therapeutic window of orismilast suggests potential for use in a number of inflammatory conditions, which have so far been limited by the typical narrow therapeutic window of PDE4-inhibitors

Hellerup, Denmark, January 7th, 2021 – UNION therapeutics A/S (UNION) today announces that the US Food and Drug Administration (FDA) has approved an Investigational New Drug program (IND) for oral orismilast; a next generation PDE4-inhibitor for the treatment of plaque psoriasis in adults.

A potential game-changer for people living with severe skin conditions
With the IND approval, UNION is granted permission to advance oral orismilast into Phase 2b trials in humans with moderate to severe plaque psoriasis to evaluate the safety and efficacy of orismilast.

"Orismilast is a next generation PDE4-inhibitor with an improved therapeutic window compared to earlier oral PDE4 inhibitors, supporting the opportunity to achieve improved efficacy while maintaining good tolerability. It holds the potential to become a best-in-class treatment and a game-changer for psoriasis patients. Currently, oral treatment options for plaque psoriasis are limited, and many patients with moderate-to-severe psoriasis are receiving systemic injectable therapies. Oral orismilast would therefore offer an efficacious and patient-friendly treatment," says UNION co-founder Professor Morten Sommer.

"Further, PDE4-inhibition is a well-documented pharmacological target for a number of other inflammatory indications, and we look forward to advancing our clinical research to realize the full potential of orismilast for the benefit of the millions of patients living with inflammatory conditions globally," adds Professor Sommer.

One step closer to a novel treatment
Psoriasis is a common inflammatory skin condition involving 2–4% of the global population. It is clinically characterized by erythematous and scaly plaques that persist throughout life in variable severity.

"Plaque psoriasis is associated with an increased risk of developing severe comorbidities such as psoriatic arthritis, cardiovascular disease, metabolic syndrome, overweight/obesity, inflammatory bowel disease, and depression - all resulting in a substantial impact on the quality of life[2]", says Dr. Kim Domela Kjoeller, CEO of UNION. He continues:

"With the green light granted by the FDA to continue our clinical research, we are one step closer to offering psoriasis patients a novel, improved oral treatment option and thereby enhancing their quality of life. We confidently believe in the benefits of oral orismilast, and the IND approval marks a significant milestone in our clinical development."

The trial design of the planned Phase 2b study will be a parallel-group, randomized, dose-ranging, double-blinded, four-armed study to evaluate the safety and efficacy of orismilast tablets compared with placebo in adults with moderate-to-severe plaque psoriasis.

UNION therapeutics expects to commence the Phase 2b trial in second half of 2021.

About orismilast
Orismilast is an investigational drug candidate that is a selective inhibitor of phosphodiesterase type 4, commonly referred to as PDE4. PDE4-inhibition is a validated pharmacological target for inflammatory indications. Orismilast is a next-generation PDE4-inhibitor with an improved therapeutic window, and attractive physicochemical properties allowing it to be formulated for multiple routes of administration, including oral (UNI50001) and topical (UNI50002).

About UNION therapeutics A/S
UNION therapeutics A/S is a privately held, clinical stage, pharmaceutical company dedicated to the development of novel treatments for inflammatory and infectious diseases. The Company is working on two complementary chemistry classes spanning immunology and microbiology and has five candidates in clinical development. UNION is headquartered in Hellerup (Denmark) and is managed by an experienced international team. For more information please visit: www.uniontherapeutics.com.

Sources
1: Li et al. (2018)
2: Menter MA, Armstrong AW, Gordon KB, Wu JJ. Common and Not-So-Common Comorbidities of Psoriasis. Semin Cutan Med Surg. 2018 Feb;37(2S):S48-S51. doi: 10.12788/j.sder.2018.011.

Contacts

UNION therapeutics
Morten Boesen
Chief Financial Officer
Tel: +45 2381 5487
Email: morten.boesen@uniontherapeutics.com

Szpirt & Company
Marie-Louise Jersin
Senior PR Manager
Tel: +45 3049 4967
Email: mlj@szpirt.com