Media Release
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Phase 2a study results in binge eating disorder

Allschwil, Switzerland – May 10, 2022
Idorsia Ltd (SIX: IDIA) today announced that ACT-539313, a selective orexin-1 receptor antagonist, did not show an improvement over placebo in reducing the number of binge eating days per week in adult patients with moderate to severe binge eating disorder – the primary endpoint was therefore not met. ACT-539313 was very well tolerated over the treatment period of 12 weeks.

Alberto Gimona, Head of Global Clinical Development of Idorsia, commented:
"Assessing pharmaceutical intervention in disorders such as binge eating, when we target modification of the behaviors underpinning the disorder is very challenging. The result is obviously disappointing for the team and investigators who flawlessly executed the study, and of course for the patients affected by this disorder. The study confirmed the encouraging safety profile seen in the pharmacology studies, but it is clear that we will not pursue the binge eating disorder indication."

The company will now fully analyze the data and publish the results of the study in scientific literature in due course.

Notes to the editor

About the Phase 2 study
In the study, 136 patients were randomized to receive either ACT-539313 at a dose of 100 mg twice daily, or placebo in a 1:1 ratio over a 12-week treatment period. The primary efficacy endpoint was the change from baseline to Week 12 in the number of binge eating days per week. A binge eating day was defined as a day with at least one confirmed binge eating episode. The study also assessed the effect of ACT-539313 in modulating behavioral features that contribute to the psychopathology in BED, in addition to reducing the frequency of binge eating.

About ACT-539313
ACT-539313 is a potent, brain-penetrating, selective orexin 1 receptor antagonist. Preclinical studies have shown that orexins play a role in driving compulsive binge-like consumption, and ACT-539313 reduced binge-like eating behavior in animal models.

In the Phase 1 studies, ACT-539313 was well tolerated at single oral doses of up to and including 400 mg and at multiple oral doses of up to and including 200 mg twice daily for 10 days in healthy volunteers.

About Idorsia
Idorsia Ltd is reaching out for more – We have more ideas, we see more opportunities and we want to help more patients. In order to achieve this, we will develop Idorsia into a leading biopharmaceutical company, with a strong scientific core.

Headquartered near Basel, Switzerland – a European biotech-hub – Idorsia is specialized in the discovery, development and commercialization of small molecules to transform the horizon of therapeutic options. Idorsia has a broad portfolio of innovative drugs in the pipeline, an experienced team of professionals covering all disciplines from bench to bedside, state-of-the-art facilities, and a strong balance sheet – the ideal constellation to translate R&D efforts into business success.

Idorsia was listed on the SIX Swiss Exchange (ticker symbol: IDIA) in June 2017 and has over 1,200 highly qualified specialists dedicated to realizing our ambitious targets.

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