Seek and Find

MoonLake turns a key for nanobody development

MoonLake Immunotherapeutics AG is a clinical stage biotechnology company, founded in 2021, with a focus on treating inflammatory diseases. Unlike other young enterprises, the Switzerland-based company gained traction early. This is on the basis of a single asset that is in clinical development and could have multiple indications. This single-asset strategy will be tested in the coming months as the molecule, sonelokimab, approaches a regulatory review for hidradenitis suppurativa, a leading dermatology indication. If a marketing approval is won, it could set sonelokimab up to challenge Cosentyx from Novartis.

Sonelokimab was developed by Ablynx, now part of Sanofi SA, and outlicensed to Merck KGaA in 2013. Merck out-licensed the asset to MoonLake in 2021 which is now investigating the molecule in multiple studies. The most advanced studies are Phase 3 trials in hidradenitis suppurativa (HS) and the rheumatology indication psoriatic arthritis. The primary endpoint of the hidradenitis suppurativa programme, which consists of two trials, is the percentage of participants achieving a significant reduction in total abscess and inflammatory nodule count. If achieved, MoonLake will proceed with a biologics licence application to the US Food and Drug Administration soon thereafter. "We expect to send the BLA to the FDA in the second half of 2026, and so we expect to be on the market in the second half of 2027," Jorge Santos da Silva, the chief executive, told *MedNous* in an interview.

Thus far, some major indicators are positive. MoonLake ended 2025 with cash, cash equivalents and marketable securities of $448 million. At its founding in 2021, it was financially supported by venture capital and an equity investment from Merck. Early on, the MoonLake executive team decided to list the company on the US Nasdaq market by way of a special purpose acquisition company. The transaction resulted in a share listing with an initial valuation of $192.24 million on 8 April 2022, according to the newswire Startupticker.ch. As of 24 March, the market capitalisation of the company had risen to $2.58 billion which is partially due to the promise of its potentially large portfolio. Dr Santos da Silva is upbeat about the financial position of the company. "As you know, the more you go forward and the closer you get to commercial, the more you can start tapping other forms of cash, not just equity," he commented. The bottom line is that MoonLake won't have difficulty financing the upcoming trials for the lead inflammatory disease indications.

Fundamentally, the executive believes it is the science behind sonelokimab as a tri-specific nanobody that is driving the investment forward. Dr Santos da Silva holds a PhD in neurobiology and did post-doctoral studies at the Cold Spring Harbor Laboratory in the US. Prior to joining MoonLake he was a senior partner at McKinsey & Co. "The mechanism of action is what really matters here because it is the next generation beyond Cosentyx. There are only two molecules that are able to do this. It is our molecule and bimekizumab from UCB, a traditional antibody," he said. UCB SA's Bimzelx (bimekizumab) has received four approvals from the FDA and has a strong market position.

Both sonelokimab and Bimzelx target interleukin-17A (IL-17A) and interleukin-17F (IL-17F), two key cytokines that drive the inflammation process. The difference between the two is their structure and the way they interact with the target. Bimzelx is a monoclonal antibody that simultaneously neutralises IL-17A and IL-17F in order to treat inflammatory disorders. It is described in the scientific literature as a bispecific or a dual specific agent. Sonelokimab, on the other hand, is a tri-specific agent that inhibits IL-17A and IL-17F by inhibiting the IL-17A/A, IL-17A/F and IL-17F/F dimers that drive inflammation. In addition, sonelokimab binds to human albumin, enabling further activity at the site of inflammatory swelling.

Bimzelx received its first FDA approval in 2023 for severe plaque psoriasis and subsequently for three other indications including, in 2024, for severe hidradenitis suppurativa. The monoclonal antibody is one of UCB's top selling drugs. By contrast sonelokimab is a nanobody, which is an antibody fragment derived from heavy-chain only IgG antibodies found in the *Camelidae* family of camels and llamas. Unlike conventional antibodies, the nanobody is missing light protein chains. Supporters of nanobodies say they have comparative advantages over monoclonal antibodies including their small size and ability to penetrate tissue and bind to cavities efficiently.

Cablivi (caplacizumab), the first nanobody drug to reach the market, was approved in the EU in 2018 and in the US in 2019 for acquired thrombotic thrombocytopenic purpura, a rare blood clotting disorder. Since that time, several other nanobody constructs have been approved including a nanobody based chimeric antigen receptor (CAR) T cell therapy for multiple myeloma, authorised by the FDA in 2022.

Merck's licensing deal with Ablynx in 2013 covered sonelokimab plus two other nanobody drugs and atacicept, a fusion protein. Vera Therapeutics Inc acquired rights to atacicept and Novartis got rights to the other nanobody products. This left Merck to develop sonelokimab internally. The German company, together with Avillion LLC, took sonelokimab through a Phase 2b study in 303 patients with moderate to severe psoriasis which achieved statistical significance. In the study, the drug also numerically outperformed the active control which was secukinumab (Cosentyx). Before the trial completed, Merck engaged Kristian Reich, a specialist in dermatology, to study sonelokimab. Both Drs Reich and Santos da Silva agreed there was unexploited value in sonelokimab which led to MoonLake's founding.

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