ANAVEON From Cytokines to Therapies

Anaveon receives CTA approval to start a Phase I/II study to evaluate the safety, dosing and clinical activity of ANV419 in patients with solid tumors

- ANV419 is a powerful and selective interleukin-2 (IL-2) agonist targeting cancer -

Basel, 25 March 2021 – Anaveon, a clinical stage, immuno-oncology company, today announced that its Clinical Trial Application (CTA) has been accepted by the Spanish Agency of Medicines and Medical Devices (AEMPS) to conduct a Phase I/II study evaluating the safety and clinical activity of its lead product, ANV419, as a monotherapy in advanced solid tumors. The Company will initiate the first two arms of a multi part, first-in-human dose finding study, with the expectation of enrolling the first patient in Q2 2021.

"Approval to start our first clinical study represents an important validation of our approach and is a significant milestone for Anaveon," **said Dr Christoph Bucher, Chief Medical Officer of Anaveon.** "Our lead program is a powerful and selective interleukin-2 (IL-2) agonist that is designed to overcome known challenges with tolerability and selectivity of human IL-2, which, if approved, could have wide applicability in a range of cancer indications, as well as in combination with other therapeutics."

ANV419 is a novel IL-2/anti-IL-2 fusion protein with preferential signaling through the IL-2 beta/gamma receptor. It has antibody-like pharmacology, behaviour and stability and selectively stimulates the proliferation of CD8 T cells and NK cells without promoting the expansion of Regulatory T cells (Tregs). In non-human primate studies, ANV419 demonstrated excellent tolerability, a highly favorable safety profile and pharmacokinetics with strong in-vivo expansion of NK and CD8 T cells but not Tregs. No significant changes in body weight or blood pressure were seen at any dose during the entire study period and no signs of capillary leak syndrome were observed.

Anaveon was founded in December 2017 by Andreas Katopodis, previously Director at the Autoimmunity, Transplantation & Inflammation Group at the Novartis Institutes for BioMedical Research and Onur Boyman, Professor and Chair in the Department of Immunology at the University of Zurich. The Company is developing selective IL-2 Receptor Agonists, which have the potential to therapeutically enhance a patient's immune system to respond to tumors. In the body, human IL-2 stimulates a type of immune cell, called a T-cell, to multiply and become activated. Activated T-cells are able to attack tumors and, consistent with this approach, human IL-2 is already approved as a therapeutic for the treatment of metastatic melanoma and renal cancer; however, due to lack of specificity, human IL-2 has severe, dose-limiting side effects and a short half-life that requires frequent infusions. The lead compound, ANV419, is designed to preferentially signal through the IL-2 beta/gamma receptor and therefore overcome known challenges of human IL-2. This novel type of therapeutic, if approved, could potentially have a wide utility in oncology, including in combination with cell therapies, vaccines, checkpoint inhibitors and radiotherapy.

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About Anaveon:

Anaveon is a clinical stage, biopharmaceutical company, based in Switzerland, that develops biologics to modulate the function of cytokines and provide substantial therapeutic benefit to cancer patients. Our vision is to develop novel immune therapies benefiting patients suffering from a wide variety of diseases with immune pathology.