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Bispecific anti-17 A/F nanoantibody – The first nanoantibody in treatment of psoriasis.

Nanoantibodies are a new class of antibody -derived biologics. Nanotechnology was originally developed following the discovery and identification that Camelidae possess fully functional antibody that consists of heavy chain only and lack light chain. They form the basis of a new generation of therapeutic molecules “nanoantibodies”. The anti-IL-17 A/F nanoantibody neutralizes the pro-inflammatory cytokines IL-17A and IL-17 F, which have been implicated in the pathogenesis of psoriasis. This multicentric, phase I and II, randomized, double -blind, placebo-controlled study investigated multiple ascending doses of anti-IL-17 A/F nanoantibody in patients with moderate-to-severe psoriasis vulgaris. The 33 patients were evaluated; mean age 44,8 year, male/female ratio 29/4. Body surface area (BSA) $\geq 10\%$, Psoriasis Area and Severity Index (PASI) ≥ 12 , and static Physician’s Global Assessment (sPGA) ≥ 3 were evaluated. Patients received 30, 60, 120 or 240 mg anti-IL-17 A/F nanoantibody or placebo every two weeks subcutaneously for 6 weeks. Primary endpoints were safety, tolerability, immunogenicity, and pharmacokinetics (demonstrated on 2017 Annual Meeting of American Academy of Dermatology). Secondary endpoints were pharmacodynamics, efficacy and histologic analysis. On day 85, 6 weeks after the last dose of the drug, PASI 75 was achieved in 7/8 patients (88%) receiving 30 or 60 mg, 8/8 (100%) receiving 120 mg, and 9/9 (100%) receiving 240 mg of drug. PASI 90 was achieved in 4/8 (50%), 7/8 (88%) and 9/9 (100%) patients receiving 30 mg, 60 mg, 120 mg or 240 mg, respectively. PASI 100 was achieved in 1/8 (13%), 2/8 (25%), 4/8 (50%) and 5/9 (56%) patients receiving 30 mg, 60 mg, 120 mg or 240 mg, respectively. No placebo-treated patient achieved PASI 75, 90 or 100 on Day 85. Improved PASI scores were seen 7 days post-first dose in all 4 cohorts. Biopsy assessment of skin lesion showed complete reversal of disease pathology in majority of patients in high dose groups.

Conclusion: Anti-IL-17 A/F bispecific nanoantibody is well tolerated and effective in patients with moderate-to severe psoriasis and was associated with clear skin improvement in all indices of psoriasis studied. The trial was supported by Merck/EMD Serano.

Biography

Danka Svecova, Medicine Doctor (PhD. – dermatology), now is a professor of Dermatovenerology, Head of Bullous Disorders Unit at Dept. of Dermatovenerology, University Hospital and Faculty of Medicine, Comenius University in Bratislava, Slovakia. She is a board member of Division Committee for Dermatovenerology and Immunology Dissertation for Ph.D. at Comenius University in Bratislava. She is a member of committee for Probation of Specialization for Dermatovenerology at Comenius University in Bratislava and University of J.P. Safarik in Kosice. At Hokkaido University in Sapporo, Japan, she participated in research on Skin Allergology and Immunology under the supervision of Professor Akira Ohkawara. She attended Good Clinical Practice Guideline Course of the International Conference on Harmonization at Royal Holloway University of London, UK. She held several grant projects on fungal infection, therapy of psoriasis, borreliosis (the cooperation with University of Oxford, UK, under supervision of Professor Michael Donaghy), immunomodulatory and anti-inflammatory efficacy of normal polyphenols, immunogenetic determination to psoriasis vulgaris and pemphigus vulgaris, clinical trial of anti-IL17A/F bispecific nanoantibody in psoriasis vulgaris (multicentric European study), GWAS (Genome wide association study) on pemphigus vulgaris (the cooperation with Anhui Medical University in China and Harvard Medical School in USA under supervision of Professor Liangdan Sun). She wrote 4 monographs, about blistering disorders and allergy, 3 textbooks of dermatology, 75 scientific articles.

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