BIOBUSINESS BRIEFS

DEAL WATCH

Galderma pursues 'itchy cytokine' by licensing antibody from Roche's Chugai

Galderma Pharma has agreed to license nemolizumab from Chugai Pharmaceutical Co. for an undisclosed amount (FIG. 1). Nemolizumab is a humanized monoclonal antibody that targets the interleukin-31 (IL-31) receptor-α (IL-31RA) and is being developed for atopic dermatitis (eczema) and pruritus (itching). Galderma will have the rights to develop and market this drug — which, if approved, would be the company's first biologic — in all countries other than Japan and Taiwan.

Several potential therapeutics for atopic dermatitis, including antibodies targeting the IL-13, IL-4 and IL-13, IL-17 or thymic stromal lymphopoietin (TSLP) pathways, are being developed to address the inflammatory component, but drugs targeting the IL-31 pathway specifically target itchiness. "IL-31 has been coined the 'itchy cytokine'," explains Gil Yosipovitch, a professor of dermatology at the University of Miami, Florida, USA, who has also consulted for Chugai. IL-31 is released by T helper 2 (Th2) cells in areas of inflammation and activates IL-31 receptors in local sensory neurons, which transmit the itching sensation. "IL-31 is the missing link between the T cell and peripheral sensory neurons", says Bernhard Homey, a professor in dermatology at the University Hospital Düsseldorf, Germany.

The IL-31 field began in earnest after researchers at ZymoGenetics found that mice overexpressing IL-31 in lymphocytes developed pruritus and dermatitis that resembled atopic dermatitis (*Nat. Immunol.* **5**, 752–760; 2004). ZymoGenetics was acquired by Bristol-Myers Squibb in 2010, and a Phase I trial of its IL-31-targeting antibody, BMS-981164, was completed in patients with atopic dermatitis in 2015.

In Chugai's 12-week Phase II trial of nemolizumab in patients with moderate to severe atopic dermatitis, patients treated with the highest dose of the drug every 4 weeks had a 60% decrease in pruritus from baseline, whereas patients assigned to placebo had a 20% decrease (see Further information). A Phase II trial of nemolizumab to treat pruritus in patients receiving haemodialysis is ongoing.

Targeting the communication between immune cells and nerves rather than inflammation itself might offer advantages over other approaches in dermatitis. "I would expect that the IL-31 receptor neutralizing antibody would be even more targeted than the IL-4/IL-13-targeting antibody, but we will need to see from a clinical perspective," says Homey. Nemolizumab could also be useful in combination with anti-inflammatory therapies.

There could be opportunities to develop nemolizumab in other diseases too. "This drug seems to target the itch, which is a cardinal part of eczema, but it's not only eczema that's associated with itch," says Yosipovitch. According to results from Yosipovitch, Homey and others, IL-31 and/or its receptor are also overexpressed in cutaneous T cell lymphoma, prurigo nodularis and lichen amyloidosis, all of which are associated with severe pruritus.

Megan Cully

FURTHER INFORMATION

Phase II nemolizumab results: http://www.businesswire.com/news/home/20160305005005/en/Chugai-Announces-Phase-II-Global-Study-Results

ALL LINKS ARE ACTIVE IN THE ONLINE PDF

Galderma Pharma to license nemolizumab from Chugai Pharmaceutical Co.	Date announced: 21 July 2016
Deal type: licensing agreement • Licensee: Chugai Pharmaceutical Co. • Licensor: Galderma Pharma	**Value: undisclosed** • Upfront, milestone and royalty payments
Asset characteristics • Nemolizumab, an anti-IL-31 receptor-α humanized monoclonal antibody, in Phase II development for atopic dermatitis and pruritus in patients receiving haemodialysis	
Focus • Galderma gains an exclusive licence to develop and market nemolizumab in all countries except Japan and Taiwan • Chugai will continue to manufacture nemolizumab	

Figure 1 | **Deal snapshot.** IL-31, interleukin-31.