NEW DRUGS

New drugs

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Bimekizumab

Approved indication: plaque psoriasis
Bimzelx (UCB Australia)
pre-filled syringes or pens containing 160 mg/mL solution for injection

High concentrations of interleukin (IL)-17A, IL-17F and IL-17AF are involved in inflammation and the development of plaque psoriasis. Cytokine modulators, such as ixekizumab and secukinumab, have therefore been used as systemic treatments for psoriasis. These do not always result in rapid and sustained skin clearance, so a treatment is needed to achieve complete skin clearance quickly. Bimekizumab is a humanised monoclonal (IgG1) antibody designed to inhibit both IL-17A and IL-17F on the outer layer of the skin. The drug is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

Bimekizumab is given as two subcutaneous injections of 160 mg each, once every four weeks to week 16 and once every eight weeks thereafter. In patients with a body weight of 120 kg or more, continuing with a four-weekly dose may need to be considered. Suitable injection sites include the thighs, abdomen and upper arms. The sites should be rotated. Injections must not be given into psoriasis plaques or skin that is tender, bruised, erythematous or indurated.

Steady state is reached at approximately 16 weeks with four-weekly dosing. Bimekizumab is likely to be metabolised into small peptides and amino acids via catabolic pathways like other immunoglobulins, so adverse interactions with drugs metabolised by the CYP450 system are not expected. The mean terminal elimination half-life is 23 days.

The safety and efficacy of bimekizumab have been studied in four multicentre, double-blind, phase III trials (Table):

- BE-VIVID: placebo and ustekinumab, an IL-12/23 inhibitor[1]
- BE-READY: placebo[2]
- BE-SURE: adalimumab, a tumour necrosis factor inhibitor[3]
- BE-RADIANT: secukinumab, an IL-17A inhibitor.[4]

These trials all included patients with moderate to severe psoriasis, defined by a Psoriasis Area and Severity Index (PASI) score of at least 12 (range 0–72, with higher scores indicating worse disease), at least 10% body surface area affected by psoriasis, and an Investigator's Global Assessment score of at least 3 on a 5-point scale (with 0 representing complete clearance and 4 representing severe

Table **Efficacy of bimekizumab in patients with moderate to severe plaque psoriasis**

Trial (duration)	Treatment arm	Number of patients	Proportion of patients achieving efficacy endpoints at week 16 (n)	
			PASI 90 response *	PASI 100 response †
BE-VIVID[1] (52 weeks)	Bimekizumab	321	85% (273)	59% (188)
	Ustekinumab	163	50% (81)	21% (34)
	Placebo	83	5% (4)	0% (0)
BE-READY[2] (56 weeks)	Bimekizumab	349	91% (317)	68% (238)
	Placebo	86	1% (1)	1% (1)
BE-SURE[3] (56 weeks)	Bimekizumab	319	86% (275)	61% (194)
	Adalimumab	159	47% (75)	24% (38)
BE-RADIANT[4] (48 weeks)	Bimekizumab	373	86% (319)	62% (230)
	Secukinumab	370	74% (275)	49% (181)

* PASI 90 response: 90% or greater improvement from baseline in the PASI score
† PASI 100 response: 100% improvement from baseline in the PASI score (i.e. complete skin clearance)

The new drug commentaries in *Australian Prescriber* are prepared by the Editorial Executive Committee. Some of the views expressed on newly approved products should be regarded as preliminary, as there may be limited published data at the time of publication, and little experience in Australia of their safety or efficacy. However, the Editorial Executive Committee believes that comments made in good faith at an early stage may still be of value. Before new drugs are prescribed, the Committee believes it is important that more detailed information is obtained from the manufacturer's approved product information, a drug information centre or some other appropriate source.

psoriasis). Although the patients were followed up for 48–56 weeks, the efficacy end points were assessed at week 16 in these trials. Bimekizumab led to significant improvements in disease activity in all the trials. The improvements in the PASI score compared to baseline were sustained to the end of each study period.[1–4] The efficacy of bimekizumab in patients with renal or hepatic impairment is unknown, as these populations were absent from the trials.

The rates of treatment-related discontinuation and death were low and similar across the different treatment and placebo arms.[1–4] The most common treatment-emergent adverse events were oral candidiasis, upper respiratory tract infections, urinary tract infections, hypertension and diarrhoea.[1–4] Cardiovascular events were reported in a small number of patients with pre-existing cardiovascular risk factors receiving bimekizumab in the BE-VIVID and BE-READY trials.[1,2] Bimekizumab can increase the risk of infections such as respiratory tract infections and oral candidiasis. Treatment must not be continued in patients with an active infection until the infection resolves. Bimekizumab should be given with caution in patients with a history of recurrent infection or tuberculosis. New onset of ulcerative colitis was observed in the BE-VIVID and BE-RADIANT trials.[1,4] Injection-site reactions were also reported. As with all therapeutic proteins, immunogenicity may occur. However, there has been no evidence of changes in efficacy or safety associated with the development of anti-bimekizumab or neutralising antibodies.

The effect of bimekizumab on fertility is unknown. The treatment is not recommended in pregnant and breastfeeding women due to a lack of safety and efficacy data.

The dual-action mechanism of inhibiting both IL-17A and IL-17F with bimekizumab is effective and well tolerated in adult patients with plaque psoriasis. Further studies are needed to determine the sustainability of skin clearance achieved with bimekizumab beyond 56 weeks of treatment.

T manufacturer provided relevant information

REFERENCES

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The Transparency Score is explained in New drugs: transparency, Vol 37 No 1, Aust Prescr 2014;37:27.

At the time the comment was prepared, information about this drug was available on the websites of the European Medicines Agency.