Bimekizumab

Instructions for use

Table 1: Instructions for use (Bimekizumab)

Pre-treatment

- Physicians are encouraged to enrol their patients in a registry (if available)
- Objective assessment of disease (such as PASI/BSA/PGA; arthritis)
- HRQoL (such as DLQI/Skindex-29 or -17)
- Medical history and physical examination including prior exposure to treatments, malignancies, infections, inflammatory bowel disease
- Recommended measures include:
    - Check for skin cancer
    - Check for lymphadenopathy
    - Laboratory parameters (see **Fehler! Verweisquelle konnte nicht gefunden werden.**)
    - Exclusion of tuberculosis (see chapter: “tuberculosis”)
    - Check for evidence of active infection
    - Check need for vaccines
- Reliable contraception

During treatment

- Objective assessment of the disease (such as PASI/BSA/PGA; arthritis)
- HRQoL (such as DLQI, Skindex-29 or 17)
- Laboratory controls (see **Table 2**)
- Medical history and physical examination focusing on infections (in particular upper respiratory tract infections, candida, tuberculosis), contraception and signs or symptoms of inflammatory bowel disease

Post-treatment

- After discontinuation of bimekizumab, patients should be followed up with medical history and physical examination
- For information regarding the ongoing need for contraception immediately following biologic treatment cessation, please see chapter: "Wish for child / pregnancy"

Recommendations for lab controls

Table 2: Recommended laboratory controls (Bimekizumab)

Parameter	Pre-treatment	After 3-6 months
Full blood count	X	X
Liver enzymes	X	X
Serum creatinine	X	
Urine status	X	
Pregnancy test (urine or blood)	X	
CRP	X	
HBV/HCV	X	
HIV	X	
Interferon gamma release assay (TB exclusion)	x	
Not all tests may be necessary for all patients. Patient history, risk exposure and patient characteristics have to be taken into account. Further specific testing may be required according to clinical signs, risk, and exposure.		
The recommendations are based on clinical experience. No evidence is available.		

Adverse drug reactions

Please see SmPC and other sources for complete listing. The guideline subcommittee decided to comment on the following aspects:

Current evidence suggests a similar safety profile for bimekizumab compared to other IL-17 antagonists ixekizumab and secukinumab and IL-17R antagonist brodalumab. (In all phase III trials (BE READY, BE VIVID, BE SURE and BE RADIANT), bimekizumab was well tolerated. In a 56 weeks follow-up

phase III trial (BE READY) with 435 patients receiving bimekizumab or placebo, and in a 52 weeks follow-up phase III trial (BE VIVID) with 567 patients receiving bimekizumab or ustekinumab or placebo, the most common treatment-emergent adverse events (TEAE) [1-3] were candidiasis, nasopharyngitis and upper respiratory tract infections. In BE VIVID, the occurrence of TEAEs was similar between bimekizumab and ustekinumab, except for oral candidiasis that was more frequent in the bimekizumab group [1]. In BE SURE [4], the occurrence of diarrhoea and oral candidiasis were more common in the bimekizumab than adalimumab group, and in BE RADIANT [5] study, there was a higher frequency of oral candidiasis with bimekizumab compared to secukinumab (i.e. 79 Candida infection events in 373 patients (21.2%) versus 17 in 370 patients (4.6%), respectively).

Five major adverse cardiovascular events in patients with cardiovascular risk factors were reported in the BE VIVID study, one of which was fatal cardiac arrest.

Inflammatory Bowel Disease

There is limited data in patients with IBD. Patients with a known history of Crohn's disease were excluded from phase III clinical trials. One case of ulcerative colitis was reported in a patient who received bimekizumab. Caution is advised in prescribing bimekizumab in patients with a history of IBD.

Candidiasis

In all phase III clinical trials [6-9], the majority of oral candidiasis cases were mild or moderate and no cases led to discontinuation. The incidence of bimekizumab oral candidiasis infections seems to be higher than observed with other IL-17 inhibitors. The dual inhibition of IL-17A and IL-17F could impair more profoundly the normal mucocutaneous defense and, consequently, put at a greater risk of oral candidiasis. Early treatment of candida infections, either with topical or systemic treatment (see table below) is recommended. Cases are usually described as mild-to-moderate, respond to standard treatment and do not require bimekizumab treatment discontinuation. Note that clinically significant, severe infections are always a contraindication for all biologics.

Fluconazole treatment recommendations [10-12]

Candidiasis	Fluconazole dose (mg)	Duration
Oropharyngeal	100–200 daily	7–14 days
Oesophageal		

- Acute	200–400 daily	14–21 days
- Recurrent	100–200	Three times weekly
- **Balanoposthitis**	200mg	For 14 days
Vulvovaginal		
- Acute	150	Single dose
- Severe acute	150	Every 72 hours for a total of 2–3 doses
- Recurring	150	Induction therapy by a topical agent or oral fluconazole, thereafter weekly for 6 months

Special consideration during treatment

Please see SmPC and other sources for complete listing. The guideline subcommittee decided to comment on the following aspects:

Surgery

There is no data on the management of surgery in patients treated with bimekizumab. The decision to discontinue of bimekizumab prior to surgery must be based on individual factors, such as type and risk of surgical procedure, patient characteristics, severity of psoriasis in case of treatment discontinuation etc. Counselling with the surgeon is advised.

Important contraindications

Please see SmPC and other sources for complete listing. The guideline subcommittee decided to comment on the following aspects:

Absolute contraindications:

- Clinically important active infections

Relative contraindications:

- Pregnancy or breastfeeding
- Inflammatory bowel disease

Drug interactions

Please see SmPC and other sources for complete listing. The guideline subcommittee decided to comment on the following aspects:

No drug interactions expected. Combination therapy with other immunosuppressant agents has not been studied.

Overdose/ measures in case of overdose

No cases of overdose have been reported. Doses of up to 320 mg have been administered in clinical studies. In case of overdose, the patient should be monitored and appropriate symptomatic treatment should be instituted immediately.

References

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