Ten years of omalizumab

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Tags
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- Omalizumab was authorised in 2007 for the treatment of severe allergic asthma in adults and children aged 12 years and over. Its authorisation has meanwhile been extended to include the treatment of severe allergic asthma in children aged 6 to 12 years and that of chronic idiopathic urticaria (chronic spontaneous urticaria) in adults and children aged 12 years and over.
- In 2007, only one placebo-controlled authorisation study was carried out among the appropriate target group (patients with severe allergic asthma). After post-hoc adjustment for the baseline history of exacerbations, the reduction in the number of exacerbations proved to be merely statistically significant, not clinically relevant.
- Post-registration studies using the average number of exacerbations as a hard outcome measure have shown that this number is statistically significantly reduced when using omalizumab compared to placebo. However, these studies also included patients with moderately severe asthma.
- The extension of the authorisation to include children was approved by the registration authorities on the basis of a study among children with severe allergic asthma. This study found a statistically significant and clinically relevant reduction of the number of exacerbations.
- The authorisation of omalizumab for the treatment of urticaria is based on two studies. These studies found a statistically significant improvement of itchiness but no, or hardly any, clinically relevant improvement.
- Post-marketing studies of omalizumab have not revealed any noticeable additional side-effects.
- Omalizumab is mentioned in guidelines for pulmonologists, though not as the drug of first choice. The guideline on ‘Urticaria’ of the Dutch society for dermatology and venereology (NVDV) recommends adding omalizumab as a third step to the existing treatment.
- The 2007 Ge-Bu drug rating for the use of omalizumab to treat severe allergic asthma was ‘+/-’ (product of doubtful value or whose value can as yet not be adequately evaluated). Since the lack of clarity about its efficacy for its originally registered indication has now persisted for 10 years, its rating should be reduced to ‘-‘ (‘product offering no added value’).
- Some preliminary evidence has emerged for the clinically relevant efficacy of omalizumab for children who get insufficient relief from high-dosage alternative treatments. This calls for a Ge-Bu drug rating of ‘+/-’ (‘product of doubtful value or whose value can as yet not be adequately evaluated’), partly because its long-term efficacy and safety cannot yet be evaluated.
- Omalizumab appears to be a possible addition to the current treatment options for patients with severe itch due to chronic idiopathic urticaria, if antihistamines have insufficient effect. However, in view of the lack of clear evidence for its clinically relevant efficacy, a Ge-Bu drug rating of ‘-‘ (‘product offering no added value’) for this newly registered application appears justified for now.

Literature references