Rituximab biosimilars open new horizons in immunotherapy

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The anti-CD20 antibody rituximab has remarkably improved outcome in patients with malignant B cell lymphomas and autoimmune diseases, thereby improving progression-free survival and in many cases overall survival with many lives saved. Rituximab has established itself as one of the drugs with the best therapeutic ratio in haematoto-oncology since its introduction around the turn of the century. Likewise, it is one of the well established agents against B cells in rheumatology. In the last few years, a subcutaneous application for the original product has proven to be very helpful for outpatient treatment and the next generation of anti-bodies against CD20 has been introduced. While rituximab remains one of our most used agents it also represents one of our main cost factors in the therapy of B cell-mediated diseases. It was therefore expected and necessary that, with the advent of patent expiration, biosimilars would be produced. In December 2016, the European Medicines Agency (EMA) published the approval of Truxima (rituximab; CT-P10) followed by ‘duplicate applications’ for the treatment of non-Hodgkin’s lymphoma, chronic lymphocytic leukaemia, granulomatosis with polyangiitis and microscopic polyangiitis. Rituximab CT-P10 has gone through comparative analytical and in vitro studies, non-clinical in vivo studies, comparative PK-studies and PD-studies and comparative clinical efficacy and safety studies. The approval process is based on EMA’s activities to make biosimilars available for the European public and the studies have been found sound enough to allow for an indication extrapolation compared with the originator. In May 2017, the EMA recommended approval for another rituximab biosimilar, Rixathon (and its ‘duplicate application’ Riximyo), intended for the treatment of non-Hodgkin’s lymphoma, rheumatoid arthritis, granulomatosis with polyangiitis and microscopic polyangiitis, and additionally for Rixathon for chronic lymphocytic leukaemia. A biosimilar medicine is a biological medicine that is highly similar to another biological medicine already authorised for use and therefore there will always be discussions on similar clinical activity and safety as well as on interchangeability of these medicines. While EMA has approved this biosimilar rituximab it is now up to haematologists and rheumatologists in their clinical practice to use these biosimilars in the best possible way. In our view, there is no doubt that patients who receive rituximab for the first time can be treated with the biosimilar, but it will have to be seen in practice to what extent biosimilars will be used in patients who have already been pretreated with the originator rituximab.

Lastly, we have to acknowledge that costs of expensive drugs like rituximab will be positively influenced by the introduction of biosimilars. This ‘financial toxicity’ will be considerably reduced and will affect the biosimilars and the originator’s price. In reality, in many hospitals in Europe the decision about which anti-CD20 antibody is available will not be made by the physician but by administration and pharmacy. Therefore, it is important for us to have a solid scientific background covering all aspects of similarities between the originator and the biosimilar. This evidence will be based on the clinical studies conducted so far and on the practical experience with these antibodies. We should also consider the fact that the availability of more options for patients with cancer and rheumatology is important and that price reductions for already well established medicines will increase our capacity to make novel and again expensive drugs available for the European patient community.

Rituximab is only the beginning and more monoclonal antibody biosimilars, some of them even produced in Europe, will follow. This is a chance for doctors and patients and health authorities to increase the access of good treatments without inequalities all over Europe and to explore novel possibilities.
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