

cascade compared with TNF- $\alpha$  antagonists, but nevertheless the TNF- $\alpha$  antagonists elicit more rapid suppression of inflammation in psoriasis and generally have a more profound effect on the disease. This suggests existence of an alternative pathway in psoriasis, which can be activated after blockage of interaction between antigen-presenting cells and T-cells. On the other hand, Raptiva® seems to be relatively effective in the treatment of chronic psoriasis of the hands and feet, whereas Remicade® and Enbrel® generally need more time.

During 2006 we hope to be able to present national guidelines for use

of biological drugs in dermatology in Norway. This is a very important project, because at present the six university departments in Norway use different treatments protocols with regards to selection of patients, history of previous malignancies, use and interpretation of Mantoux reaction, treatment regimes and follow-up. On a Nordic level it will be important to have a registry to monitor outcome data in a day-to-day population, not just those selected for clinical trials. The registry will enable us to compare the safety data for a particular biological drug against other therapies and to record

variable co-morbidities and concurrent medical treatments.

Since the biological drugs as a group exhibit rapid onset of action, control of inflammation, significant improvement in symptoms and improvement in quality of life, in the future the patient population and organizations will demand that therapy with biological drugs commences in the early stage of the disease. The medico-economic issues of the cost to society need to be clarified and will be an important challenge.

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## Biological Drugs for Psoriasis in Iceland

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A number of dermatologists have stated that we have entered a new era with the use of biological drugs. However, we are not entirely without experience when it comes to using potent drugs. To name a few potent and potentially dangerous "old" drugs: azathioprine, cyclosporine, dapsone, methotrexate, isotretinoin, etretinate and steroids. Generally speaking, the biologicals are not necessarily more effective than the old drugs, but they seem to work in

many cases where other treatments fail. I guess I am a little defensive here, as some dermatologists, myself included, have been conservative and late to start using these potent drugs for our patients.

### Rules and regulations

In Iceland, rheumatologists have been using biological drugs from the start, but we have only recently entered the arena. In order to reduce the use of expensive drugs, the Icelandic authorities limited the use of most of the very expensive drugs to the Landspítali University Hospital. This means that even if the drug is registered in the country, and thus available, the doctor has to apply to the hospital drug committee to have the drug paid for in full by the hospital. Otherwise



the patient has to pay the full price. Most drugs in Iceland are paid for by state insurance, except for a small amount paid by the patient. In the case of the biologicals the hospital then continues to pay for the drug after the patient has received the first treatment and has been discharged home. The system for the biologicals

described above was probably implemented to limit their use, i.e. to save money. Psoriasis patients have to fulfil certain criteria to be accepted for treatment with biological drugs. Treatments such as methotrexate, ultraviolet-B (UVB), psoralen ultraviolet treatment (PUVA), bathing in the Blue Lagoon, etc., must have been tried before treatment with a biological drug is initiated. Yes, even the Blue Lagoon is in this list. The psoriasis has to be extensive, with a high Psoriasis Area and Severity Index (PASI) score. After 12 weeks a reduction of 75% in the PASI score has to be obtained to be able to continue the treatment. This is roughly similar to the rules in the UK, except for the Blue Lagoon and some other rules that we are not yet subject to; for example, the gate-keeping system. If the indication for a biological drug is a skin disease such as psoriasis, then a dermatologist must be responsible for the treatment, and this is sensible. Of course, if the doctor and the patient are of the opinion that a certain treatment, which should normally be tried first, is not suitable, this is

taken into consideration and most often accepted.

Iceland has a population of 300,000. There are currently approximately 15 patients with skin disease without joint involvement who are being treated with biological drugs. If patients with psoriasis arthritis are included that figure doubles or triples. This is probably comparable to many European countries, but exact figures are not easy to obtain. We estimate that within a few months there will be between 30 and 50 psoriasis patients without arthritis being treated with biologicals.

The necessity for treatment with biologicals is probably greatest for arthritis, but we all have experience of patients with a skin disease for which everything has been tried, and we and the patient are getting desperate. For those patients, treatment with biologicals can be invaluable, provided they work well. Most dermatologists have seen patients who have had a new and a better life with these

drugs. When things are difficult, this can be a good recollection for the responsible dermatologist. If they do not work, and we have tried more than one drug, we have to wait for yet another treatment choice, which will certainly come.

Responsible use of biologicals for patients with serious skin diseases is, in most instances, cost-effective. On the other hand, it is likely that unlimited use of the most expensive drugs would have a dramatic impact on the health system. We can hope that these treatments will eventually become less expensive, but that will probably not happen in the near future. Thus we have to continue to use these drugs in a responsible way.

Our psoriasis patients treated with biological drugs have fared well, though most of them also require additional treatments such as methotrexate. There is no magic occurring here: the new drugs help some patients but not all, as is the case for most other potent treatments.