Model of information letter for an office-based rheumatologist

....., on .....

Dear Colleague,

Thank you for referring your patient, Mr./Ms ..... born on .....

For this patient, we have decided to start abatacept therapy as part of the management of his/her rheumatoid arthritis.

This patient ❒ has never taken biological agents
❒ has taken one or more biological agents, of which the last was stopped
in (month/year) for ❒ lack of effectiveness ❒ or intolerance: .....

The following criteria were used to evaluate disease activity, and the results led us to recommend abatacept therapy:

- Number of swollen joints: .../.../... ❒ not evaluated
- Number of tender joints: .../.../... ❒ not evaluated
- HAQ (Health Assessment Questionnaire): .../.../... ❒ not evaluated
- Progression of joint radiograph abnormalities ❒ yes ❒ no ❒ not evaluated
- Overall disease activity assessment by the patient: .../.../... 100 ❒ not evaluated
- ESR: .../.../...mm ❒ not evaluated
- CRP: .../.../... /.../ mg/l ❒ not evaluated
- DAS 28 (Disease Activity Score): .../.../..., /.../ ❒ not evaluated

Other criteria used: _____

The patient does not present any contraindication to abatacept : allergy, active infection, premalignant or malignant lesion (of less than 5 years).

- **Before prescribing abatacept, we checked the absence of contraindications to this drug by collecting the following information:**

❒ Absence of a major risk of infection, as assessed based on conventional risk factors (e.g., age, diabetes, glucocorticoid use, and co-morbidities) and absence of iatrogenic factors related to prior biological therapy. If the patient had a history of rituximab therapy, the circulating immunoglobulin and B-cell levels were included in the infection risk assessment.

❒ Risk of infection requiring special attention: .....

We have checked the immunization status of the patient (including tetanus, polio, influenza, and pneumococcal vaccines). Non-live vaccines, particularly those administered seasonally, can be given safely after the abatacept infusion, although their effectiveness may be decreased in this situation, and administration of the influenza vaccine once a year is recommended. Live viral vaccines (yellow fever, varicella, oral polio, and MMR) are contraindicated.

❒ All immunizations were up-to-date or ❒ the following vaccines were prescribed:_____

We evaluated the patient for latent tuberculosis
❒ yes
❒ no, because this evaluation had been performed previously.

These measures are recommended although the risk of tuberculosis during abatacept therapy has not been documented. The risk of tuberculosis cannot be evaluated accurately because the patients included in the initial studies of abatacept had been screened for latent tuberculosis and either excluded from the study or given prophylactic antibiotics.

If the patient was evaluated for latent tuberculosis, the results showed
❒ no history of tuberculosis according to the patient interview
Or
❒ a history of tuberculosis that was appropriately treated
Or
❒ a history of tuberculosis that was either not treated or inadequately treated
❒ Intradermal tuberculin test showing an induration of /__/__/ mm
Or
❒ Intradermal tuberculin test not done

❒ Blood test for tuberculosis detection (QuantiFERON® or T.SpotTB®), which was
❒ negative ❒ postive ❒ indeterminate ❒ or not done

❒ Chest radiograph, which was ❒ normal ❒ abnormal ❒ not done

Contact with a tuberculosis patient ❒ no ❒ yes

Based on these date, we

❒ Considered that the patient was not at risk for tuberculosis

❒ Initiated prophylactic tuberculosis treatment

Treatment with: .....Date on day 1: .....recommended duration: .....

The first abatacept dose can be given 3 weeks after starting the prophylactic antibiotic treatment, which must be continued for a total of 3 months (if isoniazid + rifampin is used).

- We evaluated the risk of malignancy, based on the presence of a known malignant or premalignant lesion and on the presence of risk factors in the patient or in family members.

The following findings are important in your patient:

- Risk factors for malignancy ❒ yes ❒ no
  If yes, which ones?

- Need for a gynecological screen in women ❒ yes ❒ no
  No specific precautions are needed ❒ yes ❒ no

Conduct of abatacept therapy

- Abatacept was started with a dose of ..... mg with no premedication on (date: .....).

Abatacept was given in combination with

❒ Methotrexate in a dose of ……..mg/week

❒ The following medication(s)……

- **The administration of abatacept**

  ❒ Was uneventful. There was no infusion-related reaction

  ❒ The patient experienced the following event: . . . . . .

  Intolerance (reaction to the molecule) can develop during or after the abatacept infusion. Such infusion-related reactions are rare (about 5% to 10% of patients) and, more importantly, they are very rarely severe (fewer than 1%).

- **The second injection** is scheduled 14 days after the first infusion, with the same dosage. The third injection will be given 14 days after the second injection. Thereafter, the patient will receive one injection per month, in the same dosage, in the absence of contraindications (e.g., severe infection, tuberculosis, or surgery).

How to evaluate the clinical and biological response to abatacept?

Your objective is to evaluate the treatment response and to provide monitoring, jointly with the patient's primary-care physician.

The treatment objective is to obtain a response

- at week 16, with an at least 0.6-point decrease in the DAS28
- at week 24, with an at least 1.2-point decrease in the DAS28 and, if possible, a DAS28 $\leq$ 3.2.

To monitor the response to abatacept, the following should be determined at least once every 3 months: clinical disease activity (DAS 28 or SDAI), quality of life, and laboratory markers for inflammation (erythrocyte sedimentation rate [ESR] and/or C-reactive protein [CRP]). Structural effects should be assessed by obtaining radiographs of the hands and feet 1 to 2 years after the first abatacept infusion.

How to evaluate the safety of abatacept?

As you know, infections can develop during treatment with biologic agents. The most common infections are pneumonia and bronchitis, although cellulitis, pyelonephritis, and diverticulitis may develop. Prompt treatment with appropriate antimicrobial agents may be necessary.
Other adverse events have been reported, such as blood pressure changes (hypertension, hypotension), hepatic cytolysis (without severe hepatitis), and headaches.

There is no risk of induced systemic or localized autoimmune diseases, except perhaps an increased rate of cutaneous psoriasis. Other rare adverse events may occur. Additional information is available in the CRI fact sheets (downloadable at www.cri-net.com).

To date, there is no evidence that abatacept therapy increases the risk of malignant disease in patients with rheumatoid arthritis, but close monitoring is necessary

The only laboratory tests required to monitor the safety of abatacept are a blood cell count (risk of leukopenia and thrombocytopenia, which are rare) and liver function tests (transaminases), which should be obtained at 3-month intervals. When selecting follow-up tests, concomitant drugs (most notably methotrexate) should be considered. No widely used immunological tests are available for monitoring and measuring the response to abatacept.

How to go on abatacept therapy?

- If the patient has no response at week 16 (DAS28 decrease by less than 0.6 point) the treatment can be stopped.
- If there is a partial response at week 16 (DAS 28 decrease by more than 0.6 but less than 1.2 points), the treatment can be continued until week 24.
- If there is no response at week 24 (DAS 28 decrease by less than 1.2 points), the treatment strategy should be reappraised.

In patients who respond to abatacept (DAS 28 decrease greater than 1.2 at week 24) but who exhibit residual disease activity (DAS 28 greater than 3.2), the treatment strategy should be reappraised in the light of other treatment options.

How to follow-up your patient in everyday practice?

Recommendations regarding vaccinations, surgery, travelling, pregnancy, and breast-feeding are available as information sheets that you can obtain from us or from the CRI website (www.cri.net.com). We have given the patient a written document that describes abatacept and the treatment modalities

How to improve the follow-up of abatacept-treated patients and obtain useful information?

The SFR and CRI have established a prospective registry called ORA, whose objective was to collect data on patients with RA who are treated with abatacept. The inclusion period has ended.

We will be happy to provide you with any additional information you may need.

cachet du médecin

Sincerely,

Physician in charge:
Dr. .....
Telephone: .....
Physician's stamp