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Response to: 'Correspondence on 'EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2019 update' by Fallon et al

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We thank Fallon and Jones¹ for their correspondence on the European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis (PsA) and their comments on the clarity of the specific recommendation regarding the use of Janus kinase inhibitors (JAKi) in the management of PsA,² which was based on the associated systematic literature research (SLR).³

We appreciate the support of the authors to provide as much clarification to the wording of our recommendations as possible, since these are the currently most up-to-date literature for the current and future treatment of patients with PsA.

In their remarks, Fallon and Jones refer to recommendation 7 and especially the wording on the safety signals of tofacitinib related to events of venous thromboembolism (VTE, including pulmonary embolism (PE) and deep vein thrombosis (DVT)). Indeed, the conclusions of the available literature, so far, are as they describe: in an interim analysis of a study in patients with rheumatoid arthritis (RA) aged ≥ 50 years and with ≥ 1 cardiovascular risk factor, the incidence of PE events has been found to be statistically significantly increased in the group treated with tofacitinib 10 mg two times per day (a dose not approved in PsA or RA), when compared with tumour necrosis factor inhibitors (TNFi); however, while not statistically significantly different from the control arm, the data of the 5 mg arm still show a numerical increase in thromboembolic events and thus are right in between control and 10 mg arms. Similarly, the HR for DVT was 1.7 and 3-fold increased for PE compared with control, as Fallon and Jones show in their table. While no data on patients with PsA with cardiovascular risk factors exist, the task force felt that it was important to make the readers aware of these risks, even if primarily coming from RA. Indeed, the warning by the regulators also does not exempt PsA from the risks. Importantly, recommendation 7 is not only referring to the comparison of JAKi with TNFi but also to the use of JAKi in PsA in general.

Fallon and Jones also comment on the sentence comparing the efficacy of tofacitinib and adalimumab on skin psoriasis in the text accompanying recommendation 7. As they mention, the OPAL Broaden data were fully presented in the SLR.² However, EULAR recommendations are not solely based on evidence but include experts' opinion and the discussions among the experts are reflected in the text accompanying the recommendations, as is the case here. Of note, the text clearly said that tofacitinib 'may' have 'numerically lower efficacy in skin psoriasis' and not 'has lower efficacy', reflecting the various positions within the expert committee.

Finally, we fully agree with the remark that it is important for the readers to remember that the Summary of Product Characteristics updates related to VTE are relevant for the treatment of patients with any condition for which tofacitinib is indicated, including patients with RA or PsA.

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REFERENCES

- Fallon L, Jones TV. Correspondence on 'EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2019 update'. *Ann Rheum Dis* 2022;**81**:e173.
- Gossec L, Baraliakos X, Kerschbaumer A, *et al.* EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2019 update. *Ann Rheum Dis* 2020;**79**:700–12.
- Kerschbaumer A, Smolen JS, Dougados M, *et al.* Pharmacological treatment of psoriatic arthritis: a systematic literature research for the 2019 update of the EULAR recommendations for the management of psoriatic arthritis. *Ann Rheum Dis* 2020;**79**:778–86.