WHO Causality Assessment

Evaluation and Assessment of Factors-

1. Is this event known to be related to the vaccine? (Consistency of findings, strength of association.)

Yes. Both flares of rheumatoid arthritis (RA) and new onset RA reported by others.

2. What is the frequency of occurrence of this adverse event? Very common (>1/10); common (>1/100); uncommon (>1/1,000); rare (>1/10,000); very rare (<1/10,000), or not previously reported.

Considering flare: >1% (Common); reported in multiple studies.

Considering new onset: Rare (Frequency unclear)

3. Are similar events known to occur with other diseases? (Specificity of association.)

Yes.

4. Is this event explainable by the biological properties of the vaccine? (Biological plausibility.)

Yes.

5. Is the vaccination-to-event interval compatible with the event? (Temporal relation.)

Yes. Similar to previous reports.

6. Has the patient had similar symptoms in the past?

No.

7. Is there a history of concomitant or preceding drug therapy?

Yes. Anti-hypertensives (telmisartan, amlodipine, hydrochlorothiazide taken irregularly in the past).

8. Is there a history of concomitant or preceding condition?

Yes. Hypertension.

9. Are there other factors that could affect the occurrence of the event?

Unlikely.

Causality Category Determination

1. Is this an unknown event in relation to this vaccine?

No. Multiple reports present.

2. Is this a new event?

No.

3. Is there lack of sufficient data to reach a more definite conclusion?

Yes. Pathogenetic link needs to be established from preclinical and clinical studies.

4. Would the case benefit from a second review if more data became available?

Yes.

5. Based upon answers the questions above (in Section C), in which WHO category does the case fit best? N.B. not a numerical score.

Probable. (Reasonable temporal relation; unlikely to be explained by other factors)