



## **Supplemental Material to:**

**Himal Lal, Toufik Zahaf and Thomas Heineman**

**Safety and immunogenicity of an AS01-adjuvanted  
varicella zoster virus subunit candidate vaccine (HZ/su): a  
phase-I, open-label study in Japanese adults**

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## Online supplement

### Safety and immunogenicity of an AS01-adjuvanted varicella zoster virus subunit candidate vaccine (HZ/su): a phase-I, open-label study in Japanese adults.

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#### ***AEs of specific interest***

*Adverse events of specific interest for safety monitoring include the NOADs and other immune mediated disorders such as those listed below.*

*Occurrences of adverse events of specific interest will be reported throughout the entire study whether or not they are considered to be possibly related to the treatment administration. Medical documentation of the events will be reported in appropriate targeted follow-up forms included in the eCRF. These events have also to be reported as AE or SAE as appropriate in the eCRF*

*AEs of interest to be reported and documented are the following:*

- *Neuroinflammatory disorders: cranial nerve disorders, multiple sclerosis, demyelinating disease, transverse myelitis, Guillain-Barré syndrome, myasthenia gravis, encephalitis, neuritis*
- *Musculoskeletal disorders: systemic lupus erythematosus, cutaneous lupus, Sjogren's syndrome, scleroderma, dermatomyositis, polymyositis, rheumatoid arthritis, polymyalgia rheumatica, reactive arthritis, psoriatic arthropathy, ankylosing spondylitis, undifferentiated spondyloarthropathy.*
- *Gastrointestinal disorders: Crohn's disease, ulcerative colitis, ulcerative proctitis, celiac disease.*