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Geneva, 11 December 2014

## Vaccinations with VSV-ZEBOV have been suspended and will resume in early 2015

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Since 10 November 2014, a total of 59 volunteers have been included in the clinical trial of the experimental VSV-ZEBOV Ebola vaccine at the University Hospitals of Geneva (HUG). All of these volunteers are in good health and are being monitored regularly by the team in charge of the study.

Initial results show that the vaccination is very well tolerated. In the hours and days following the injection, some volunteers had some fever or muscle pain; these reactions were expected and participants were informed about them during the medical consultation which took place before their inclusion in the study.

Close monitoring of the volunteers by the VSV-ZEBOV Geneva study team has allowed the identification of four cases of mild joint pain (in the hands and feet), 10 to 15 days after receiving the injection. These symptoms were not part of the expected side effects and were not included in the prior information given to volunteers, since this vaccine is being tested on humans for the first time.

As a precautionary measure, the study team has declared a pause in the injections. No injections will take place next week. This pause is beginning one week earlier than an already scheduled pause in the vaccination series. The available time will serve to gather more information and exchange it with the other teams that are testing the same experimental vaccine. Several investigations have been launched to ensure that the symptoms which have been identified are benign and transient. In the context of clinical trials the safety of volunteers is always a priority.

The onset of joint pain after infection or vaccination is very common. This happens, for instance, in one out of five vaccinations against rubella. This is a well-documented phenomenon which does not worry specialists. However, it deserves to be carefully studied in order to update the information which is provided to the volunteers. The temporary interruption of a clinical trial is a standard precautionary measure in such cases.

The VSV-ZEBOV Geneva study team is constantly exchanging information with teams conducting similar studies in the United States, Canada, Germany and Gabon. Up to now, these teams have not observed inflammatory symptoms among their volunteers. In Geneva, vaccinations will resume on 5 January 2015, with maximum 15 volunteers per week in order to ensure optimal monitoring conditions.