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PRESS RELEASE

Consequences of the serious accident which occurred in Rennes: Marisol Touraine is increasing the safety of volunteers who take part in clinical trials

Today, Marisol Touraine, Minister for Social Affairs and Health, presented an action plan to increase the safety of volunteers who take part in clinical trials in France. This initiative follows on from the serious accident which occurred on 10 January within the framework of a clinical trial in Rennes, an accident without precedent in our country which resulted in the death of one man and the hospitalisation of five other volunteers. The action plan presented today is based on the conclusions of the team entrusted with the assignment by Marisol Touraine at the Inspectorate General of Social Affairs (IGAS).

The IGAS report concludes that the conditions under which the trial was authorised by the health authorities were compliant with the legislation in effect. It also indicates that the laboratory BIAL's and BIOTRIAL's liability is incurred in several respects.

The IGAS report provides 19 recommendations that the minister has decided to adopt in full. Marisol Touraine has, on this basis, presented an action plan with four themes to increase the safety of volunteers who take part in clinical trials:

With respect to the accident which occurred in Rennes:

- **The minister requests that BIOTRIAL provide an action plan without delay guaranteeing that the major failings observed cannot happen again.** If BIOTRIAL has not handed over its action plan within 1 month, its research site authorisation for phase 1 trials will be suspended. The implementation of this plan will be overseen by a joint inspection by IGAS, the national agency of medicine and health product safety (ANSM) and the regional health agency (ARS).

- **The 90 clinical files of the healthy volunteers concerned by the Rennes trial will undergo an independent expert health review.** These files, which will be made anonymous, will also be sent to the group of European experts that the Minister requested from the European Commission and which is already at work.

With respect to clinical trials more generally:

- **The conditions for authorisation of clinical trials, in particular for initial administration in humans, will be strengthened**. The minister asks each ARS, in connection with ANSM, to this year inspect all the centres which are today authorised to conduct clinical trials in their region. The rules which apply to the assessment by ANSM of early phase trials will be made more strict. The law will also reinforce the obligations to inform the health authorities which are incumbent on the sponsor when it submits its project.
- **France will continue its action at European level to develop regulations in terms of research on healthy volunteers:** the minister will also propose to the HMA (*Head of medicine agencies* - the European committee of national medicine

agencies) that harmonised conditions for assessment and management of a serious accident like the one at Rennes be put in place at European level.

Four months after the serious accident in Rennes, the IGAS report establishes the responsibility and identifies the failings which contributed to this exceptionally serious event. **The measures already put in place and the action plan presented today by Marisol Touraine draw all the consequences, to protect the participants in clinical trails, which are essential for medical progress.**

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