ISTITUTO AUXOLOGICO ITALIANO
Istituto di ricovero e cura a carattere scientifico

Milan, Italy, 14-09-2022

To the European Medicines Agency
Domenico Scarlattilaan 6,
1083 HS Amsterdam,
The Netherlands

| | |
|---|---|
| **EudraCT n°** | 2007-00947-88 |
| **Sponsor** | Istituto Auxologico Italiano IRCCS, Milan, Italy |
| **Sponsor Code** | 09A502 |
| **Study title** | Therapeutic Strategies of Prevention of Diabetes and Hypertension in Subjects with Metabolic Syndrome and High-Normal Blood Pressure. |
| **Study acronym** | PHIDIAS |
| **Principal Investigator** | Prof. Alberto Zanchetti |
| **Study start** | 2008-02-18 |
| **Study premature end** | 2009-11-20 |
| **Study population - planned** | 6000 |
| **Study population - enrolled** | 5 |

Dear Sirs,

The abovementioned trial is recorded in the EudraCT database as "**prematurely ended**".

This letter wishes to summarizes the reasons for the premature end of the study and consequently for the missing results in the EudraCT database.

This non-profit Italian multicentre study was programmed to involve 20 local health centres on the Italian territory. Study drugs were freely provided by the pharmaceutical company Merck & Co.

Only some of the 20 selected local health centres approved the study and the process of approval proved to be much longer and difficult than foreseen. The National Competent Authority (AIFA) was informed of this delay.

As a consequence of this delay, in October 2009 Merck & Co decided to withdraw from the study and to stop the supply of study drugs, thus causing the premature end of the study. This can be read in the attached letter of intent (*Att. 1 - AIFA-Letter of transmission study end),* that was sent together with the official declaration of study end (*Att. 2 - AIFA-Declaration of study end*) to the National Competent Authority (AIFA).

At the moment of study end, as can be read in Att. 2, section C3.2.8.2., only 5 patients had been enrolled out of the 6000 that were planned according to the Study Protocol. For this reason, it can be concluded that the study has never really taken off and for this reason no study results are available.

List of documents attached to this letter:

- *Att. 1 - AIFA-Letter of transmission study end*
- *Att. 2 - AIFA-Declaration of study end*

Best regards,

ISTITUTO AUXOLOGICO ITALIANO
ISTITUTO DI RICOVERO E CURA A CARATTERE SCIENTIFICO
20145 MILANO - Via L. Ariosto, 13
Codice Fiscale e Partita IVA 02703120150

Dr. Mario Colombo
General Manager
Istituto Auxologico Italiano, IRCCS
Via L. Ariosto 13
20145 Milano
Italy