



Statement of Retraction

Treatment of Recent-Onset Type 1 Diabetic Patients With DiaPep277: Results of a Double-Blind, Placebo-Controlled, Randomized Phase 3 Trial. *Diabetes Care* 2014;37:1392–1400. DOI: 10.2337/dc13-1391

DOI: 10.2337/dc15-rt01

On behalf of the authors identified below, the corresponding author has formally requested to retract the above-cited article. An accompanying article (1) has also been retracted.

The article reports on the DIA-AID 1 trial, which examined the safety and efficacy of DiaPep277 to treat type 1 diabetes. The DIA-AID 1 trial, as noted in the Duality of Interest section, was funded by Andromeda Biotech, Ltd.

On 8 September 2014, Hyperion Therapeutics, Inc., which acquired Andromeda Biotech in June 2014, announced that it had chosen to terminate the DiaPep277 program. As stated in the press release issued by Hyperion Therapeutics, “The company has uncovered evidence that certain employees of Andromeda Biotech, Ltd. . . . engaged in serious misconduct, including collusion with a third-party biostatistics firm in Israel to improperly receive un-blinded DIA-AID 1 trial data and to use such data in order to manipulate the analyses to obtain a favorable result” (2).

The corresponding author notified the journal about these issues and subsequently submitted the following statement, which was reviewed by the American Diabetes Association’s Panel on Ethical Scientific Programs and approved for publication by the editors of *Diabetes Care*:

In view of the public statements by Hyperion Therapeutics [2] regarding alleged scientific misconduct, we, the authors of this statement, are retracting the above-cited article. This alleged misconduct included collusion with a third-party biostatistics firm to improperly receive unblinded trial data and to use such data in order to manipulate the analyses to achieve favorable results. We wish to emphasize that we were not involved in the assembly of the raw data or the alleged misconduct. Despite our request, we have not been provided with the evidence upon which the allegations were made. On 7 October 2014, Hyperion Therapeutics and Clal Biotechnology announced that they had agreed to suspend legal proceedings and to engage an independent third party to analyze data from both the recent clinical trial, upon which this article was based, and the current phase 3 clinical trial, which will be completed at the end of this year. We further expect the participation of an independent third party approved by the authors. Following disclosure of the results of such independent analysis of both completed studies, we will issue a follow-up statement.

The following authors support the decision to retract the article: Itamar Raz, Anette G. Ziegler, Thomas Linn, Guntram Schernthaner, Francois Bonnici, Larry A. Distiller, Carla Giordano, Francesco Giorgino, Liat de Vries, Didac Mauricio, Vlastimil Procházka, Julio Wainstein, Irun R. Cohen, and Paolo Pozzilli.

The coauthors who are/were Andromeda Biotech employees—Dana Elias, Ann Avron, Merana Tamir, Rachel Eren, Dana Peled, and Shlomo Dagan—were unavailable for comment and therefore are not part of this retraction process.

This issue was reviewed by my institution. The funding agency, Andromeda Biotech, did not respond to our requests to review this matter.

Respectfully submitted,
Itamar Raz, MD

References

1. Pozzilli P, Raz I, Peled D, et al. Evaluation of long-term treatment effect in a type 1 diabetes intervention trial: differences after stimulation with glucagon or a mixed meal. *Diabetes Care* 2014;37:1384–1391
2. Hyperion Therapeutics terminates DiaPep277(R) program [press release]. Brisbane, CA, 8 September 2014. Available from <http://investors.hyperiontx.com/releasedetail.cfm?ReleaseID=869508>. Accessed 16 October 2014

Itamar Raz, Anette G. Ziegler, Thomas Linn, Guntram Schernthaner, Francois Bonnici, Larry A. Distiller, Carla Giordano, Francesco Giorgino, Liat de Vries, Didac Mauricio, Vlastimil Procházka, Julio Wainstein, Dana Elias, Ann Avron, Merana Tamir, Rachel Eren, Dana Peled, Shlomo Dagan, Irun R. Cohen, Paolo Pozzilli, and the DIA-AID 1 Writing Group