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The authors were assisted by a professional medical writer or editor in the preparation of this manuscript. (**Note:** Any involvement of medical writers in the writing of this article, particularly those writers employed or supported by the pharmaceutical industry, must be clearly defined and disclosed here and in the Authorship section of the manuscript.)

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Yes

Not applicable

If the manuscript deals with recombinant DNA research, a description has been included of the procedures practiced, which follows the National Institutes of Health guidelines.

Yes

Not applicable

Reports on human experimentation have been reviewed in accordance with the precepts established by the Helsinki Declaration. A statement has also been included showing that the human investigations were performed with informed consent, as well as verifying that the human investigations were preceded by local institutional review board approval and, if appropriate, in accordance with an assurance filed with and approved by the U.S. Department of Health and Human Services.

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All clinical trials are registered in a public trials registry approved by the ICMJE website (<http://www.icmje.org>) as fully compliant with World Health Organization's minimal data set.

Yes

Not applicable

If yes, provide name of registry: _____

Authors have complied with published CONSORT guidelines (<http://www.consort-statement.org/>). The checklist is being submitted to AlphaMed Press along with the manuscript; the recommended trial flow diagram is presented as a figure.

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