

New study shows early combination treatment with metformin plus vildagliptin better than standard of care in newly diagnosed type 2 diabetes patients

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- *VERIFY study shows early combination therapy of vildagliptin plus metformin provides greater and durable long-term benefits compared with the current standard-of-care initial metformin monotherapy for patients with newly diagnosed type 2 diabetes.*
- *VERIFY's major strength is the selection of a geographically distributed diverse, multi-ethnic population and long-term duration of 5 years for all participants.*

Early intervention with a combination therapy of vildagliptin plus metformin provides greater and durable long-term benefits compared with the current standard-of-care initial metformin monotherapy for patients with newly diagnosed type 2 diabetes.

This was the initial key finding of VERIFY, a unique study designed to determine durability, over a pre-specified five-year follow-up of early use of combination therapy strategy with vildagliptin-metformin. The study was conducted across 254 centers in 34 countries and involved 2001 diverse individuals recently diagnosed with type 2 diabetes whose HbA1c ranged between 7.5 and 6.5 and who had not yet been prescribed treatment.

"We all know that early treatment intensification to achieve good blood glucose control is crucial to delaying diabetic complications. What we're not yet certain was whether early combination therapy would be more beneficial than an ad hoc sequential process starting with metformin monotherapy, knowing that the majority of type 2 diabetes patients over a period of three years are going to experience treatment failure. Not anymore. VERIFY clearly shows that investing in early combination therapy pays big dividends in terms of less treatment failures over the long term," said Professor Merlin Thomas, endocrinologist and kidney specialist, Department of Diabetes, Monash University in Melbourne, Australia.

"Previous studies on type 2 diabetes have been repeating the same pattern, and not really focusing on the clinically relevant questions and clinical situations that doctors face. With VERIFY, we are finally asking the right questions and getting marvelous answers," said Dr. Päivi Paldánus, Novartis Worldwide Brand Medical Director for Diabetes and one of the VERIFY study investigators.

VERIFY showed that early combination therapy of vildagliptin (50 mg, twice daily) and metformin (individually, 1000–2000 mg, daily) resulted in a statistically significant 49% reduction in the relative risk for time to initial treatment failure, versus metformin alone. Treatment failure is defined as HbA1c of 7.0% or higher, twice consecutively, 13 weeks apart. The combination treatment strategy also showed a lower frequency of secondary failure when all patients were receiving combination therapy. Furthermore, patients treated with early combination had consecutively lower HbA1c levels (below 6.0%, 6.5% or 7.0%) for 5 years versus those receiving combination therapy only after metformin monotherapy failure.

The major strength of the VERIFY study is the selection of a geographically distributed diverse, multi-ethnic population and long-term duration of 5 years for all the participants. This study design ensures the

generalizability of the trial results and provides guidance in clinical decision making for the increasing number of people with newly diagnosed type 2 diabetes.

“In designing the study, we thought about what was actually needed to make a difference in the management of type 2 diabetes. Diabetes is a worldwide epidemic, so we decided to go to every continent and ethnic group, as well as countries with different kinds of health care systems, from the most advanced to the very basic,” explained Dr. Paldánus.

Professor Thomas and Dr. Paldánus were in Manila recently in connection with the Philippine launch of the VERIFY study. The initial VERIFY findings were first presented at the European Association for the Study of Diabetes (EASD) Annual Meeting held in Barcelona, Spain on September 16-20, 2019. The findings were published simultaneously in *The Lancet*. Additional pre-defined secondary analyses of the VERIFY study results are ongoing and data will be disclosed over the coming months at international and local medical congresses and in scientific journals.

“There are an estimated 3.8 million Filipinos with type 2 diabetes. We hope that the promising results of the VERIFY study can help improve patient outcomes and type 2 diabetes treatment,” said Mr. Jugo Tsumura, Country President & Managing Director, Novartis Healthcare Philippines.



The VERIFY study showed that early combination therapy of vildagliptin plus metformin provides greater and durable long-term benefits compared with the current standard-of-care initial metformin monotherapy for patients with newly diagnosed type 2 diabetes. Two respected diabetes experts were in Manila recently where they shared their insights on the VERIFY results. Photo shows (from left: Dr. Sjoberg Kho, past president, Philippine Society of Metabolism Endocrinology and Metabolism; Dr. Päivi Paldánus, Novartis Worldwide Brand Medical Director for Diabetes; and Professor Merlin Thomas, endocrinologist and kidney specialist, Department of Diabetes, Monash University in Melbourne, Australia.



The VERIFY study showed that early combination therapy of vildagliptin plus metformin provides greater and durable long-term benefits compared with the current standard-of-care initial metformin monotherapy for patients with newly diagnosed type 2 diabetes. Photo shows during the launch of VERIFY (from left): Mr. Jugo Tsumura, Country President & Managing Director, Novartis Healthcare Philippines; Dr. Sjoberg Kho, past president, Philippine Society of Metabolism Endocrinology and Metabolism; Dr. Päivi Paldánius, Novartis Worldwide Brand Medical Director for Diabetes; and Professor Merlin Thomas, endocrinologist and kidney specialist, Department of Diabetes, Monash University in Melbourne, Australia; Mr. Sonny Cuenco, Franchise Head, Novartis Healthcare Philippines, and Ms. Vanessa Ang, Sales and Marketing Head Metabolic and Established Medicines, Novartis Healthcare Philippines.

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2. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6594102/>

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