

# Novartis' TRANSFORM study confirms strong efficacy and significantly reduced infection rate of Everolimus-based regimen in transplant patients

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- *Developed by Novartis, everolimus is approved in more than 100 countries to prevent organ rejection in adult heart and kidney transplant patients. It is also approved for liver transplant patients in over 80 countries, in both Europe and the US*
- *TRANSFORM demonstrated strong efficacy and reduced viral infection rate of everolimus-based regimen in kidney transplant patients with lower exposure to nephrotoxic calcineurin inhibitor (CNI)<sup>1</sup> leading to better long-term outcomes for kidney transplant patients<sup>2</sup>*
- *TRANSFORM is the largest de novo interventional study in kidney transplantation, including more than 2,000 kidney transplant patients in 42 different countries including the Philippines*

Advancing renal **TRANS**plant **e**fficacy and safety **O**utcomes with an eve**R**olimus-based regi**M**en (TRANSFORM study) is Novartis' new Phase IV data that confirms the strong efficacy and significantly reduced infection rate of everolimus-based regimen in kidney transplant patients. Developed by Novartis, everolimus is approved in more than 100 countries to prevent organ rejection in adult heart and kidney transplant patients. It is also approved for liver transplant patients in over 80 countries, in both Europe and the US.

TRANSFORM studied the evolution of kidney function over time and demonstrated that everolimus-based regimen, combined with reduced CNI dose, not only preserved kidney function but also significantly reduced viral infections. It is the largest de novo interventional study ever conducted in renal transplantation with over 2,000 kidney transplant patients recruited across 195 sites in 42 countries, including the Philippines. It compares concentration-controlled everolimus-based regimen with reduced calcineurin inhibitor exposure, to mycophenolic acid (MPA) with standard exposure CNI. CNI is a class of immunosuppressant medicines linked to kidney injury and an increased risk for viral infections and malignant tumors. Data show that only 50% of kidney transplant patients survive more than 10 years after transplantation due to CNI complications<sup>3</sup>.

"Transplant patients continue to seek alternate treatment regimens that support long-term function of the transplanted kidney, while minimizing side effects including viral infections as seen with current standard-of-care treatment," said Dr. Sheeram Aradhya, Global Head Medical Affairs and Chief Medical Officer, Novartis Pharmaceuticals. "The TRANSFORM study results demonstrate that an everolimus-based regimen significantly lowers exposure to kidney-damaging CNIs, delivers strong efficacy and reduces viral infections. We now have a viable alternative to current standard of care with the potential to improve long-term patient outcomes."

"As the largest clinical trial undertaken to date in kidney transplantation, and with an extended follow-up of 5 years, TRANSFORM will provide critical data required to help maximize long-term outcomes. Everolimus-based regimen with reduced-CNI exposure may also lower the cost of patients' maintenance medications," said Dr. Romina A. Danguilan, Deputy Director for Medical Education, and Dr Concesa B. Cabanayan-Casasola, Clinical Trial and Research Unit, of the National Kidney and Transplant Institute (NKTI).

“TRANSFORM provides data for us to optimize immunosuppression by the use of low dose CNI in combination with everolimus which will help improve long-term graft and patient survival. Patient survival can significantly improve because the use of everolimus offers several benefits such as its effect in reducing risk of malignancy, viral infections and of course, cardiovascular diseases, as well. A total of 29 Filipino patients were enrolled in the TRANSFORM study, giving local transplant physicians the opportunity to experience this new regimen firsthand.” said Dr. Angel Joaquin M. Amante, Head, Organ Transplant Service, St. Luke’s Medical Center-Global City.

“With the positive results of the TRANSFORM study, Novartis continues to demonstrate a commitment to research and development in the field of transplant medicine, always with the aim to save lives,” said Cheryl Maley, President and Managing Director, Novartis Healthcare Philippines.

## About Novartis

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1. Pascual J, et al. Oral presentation (Abstract ID # 3805491) at the European Society for Organ Transplantation Congress; Barcelona, Spain; September 24-27, 2017.
2. Campistol JM et al Transplantation • Volume 92, Number 3S, August 15, 2011
3. OPTN, Organ Procurement and Transplantation Network, <https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#>; Accessed on August 17, 2017

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