

Philippine FDA approves Novartis medicine Inclisiran for effective cholesterol management

Nov 15, 2023

- *The Philippine Food and Drug Administration (FDA) has approved inclisiran for the treatment of hypercholesterolemia or mixed dyslipidemia.*
- *Inclisiran is a first-in-class small interfering RNA (siRNA) providing effective and sustained LDL-C reduction for patients with atherosclerotic cardiovascular disease (ASCVD), ASCVD risk equivalent and heterozygous familial hypercholesterolemia (HeFH), which are major drivers of heart attacks, strokes and may ultimately lead to death.*

The Philippine Food and Drug Administration (FDA) has approved inclisiran for the treatment of adults with hypercholesterolemia or mixed dyslipidemia. This approval is based on the results of the robust ORION clinical development program, where inclisiran provided an effective and sustained low-density lipoprotein cholesterol (LDL-C) reduction of up to 52% in patients with elevated LDL-C, despite maximally tolerated statin therapy. With two doses a year, after an initial dose and one at 3 months, inclisiran is expected to support long-term adherence.¹

Inclisiran is a first-in-class small interfering RNA (siRNA) providing effective and sustained LDL-C reduction for patients with atherosclerotic cardiovascular disease (ASCVD), ASCVD risk equivalent and heterozygous familial hypercholesterolemia (HeFH), which are major drivers of heart attacks, strokes and may ultimately lead to death.

Elevated levels of LDL-C can lead to atherosclerosis, a disease in which plaque builds up in the arteries and over time can trigger a heart attack and stroke. The most common type of medicine currently used to lower cholesterol is statins; however, statins are not very effective among patients with low compliance or tolerance and therefore need long-term and more tolerable alternatives.

"In the Philippines, 2 in 3 patients with stable coronary heart disease and 3 in 4 patients with acute coronary syndrome do not reach target LDL-C, with little to no use of non-statin therapies. Such patients are at very high risk for heart attack and stroke, and represent missed opportunities for better monitoring and treatment,"² said Dr. Jude Erric Cinco, cardiac intensivist.

"Sustained lowering of LDL-C is essential to reducing ASCVD risk. It can slow the progression of artery-clogging plaque formation or decrease plaque volume and reduce the risk of heart attack,"³⁻⁵ said Dr. Lourdes Ella Santos, President, Philippine Lipid and Atherosclerosis Society (PLAS).

ORION-8, the largest trial with inclisiran to date involving 3274 patients, provides additional evidence to support the long-term efficacy, safety and tolerability of inclisiran in patients with high cardiovascular risk and elevated LDL-C.⁶

"Seventy-eight percent of patients achieved pre-specified lipid goals with an LDL-C reduction of 49.4% at the end of the trial. Inclisiran demonstrated LDL-C lowering effects consistent with the Phase III trials in patients with ASCVD and ASCVD risk equivalent. The safety profile of inclisiran remained favorable and similar to previous reports,"⁶ said Dr. Richard Henry Tiongco II, interventional cardiologist.

"Current statin-based lipid-lowering therapies may not be enough to attain optimal LDL targets and clinical goals for patients with heightened cardiovascular risk. The existing statin-centric paradigm of treatment, though reliable and time-tested, is still hampered by real-world issues such as de-escalation, diversion and discontinuation, all of which contribute not just to non-adherence to but more importantly non-persistence on evidence-based treatments. The timely addition of non-statin agents such as Inclisiran to intensify lipid lowering strategies represents a bold yet logical step in addressing gaps in clinical care, minimizing inertia, non-adherence, and non-persistence while ultimately providing prompt and pervasive cardioprotection." said Dr. Jose Donato Magno, Executive Director of the Cardiovascular Institute, Angeles University Foundation Medical Center.

"Cardiovascular disease remains the leading cause of mortality in the Philippines, accounting for a third of deaths in the country.⁷ As such, there is an urgent need for innovative treatments for patients struggling to reach their LDL-C goals. With inclisiran, we're proud to bring a first-in-class treatment delivering effective and sustained LDL-C reduction that has the potential to improve outcomes for people living with ASCVD. Innovation isn't just about making things more effective, it's also making things more convenient, and a twice a year medication helps patients adhere to their treatment," said Mr. Joel Chong, Country President, Novartis Healthcare Philippines.

Inclisiran is indicated in adults with primary hypercholesterolemia (heterozygous familial and non-familial) or mixed dyslipidemia, as an adjunct to diet:

- In combination with a statin or statin with other lipid-lowering therapies in patients unable to reach LDL-C goals with a maximally tolerated dose of a statin or,
- Alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.

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References:

1. <https://www.novartis.com/news/media-releases/novartis-receives-eu-approval-levio-inclisiran-first-class-sirna-lower-cholesterol-two-doses-year>
2. Rody G. Sy, et al. Low-density Lipoprotein Cholesterol Target Attainment in Patients with Stable or Acute Coronary Heart Disease in the Philippines: Results from the Dyslipidemia International Study II. ACTA MEDICA PHILIPPINA. VOL. 52 NO. 6 2018
3. Ference BA, et al. J Am Coll Cardiol. 2018;72(10):1141-1156.
4. Ference BA, et al. Eur Heart J. 2017;38(32):2459-2472. 3. Nicholls SJ, et al. JAMA. 2016;316(22):2373-2384.

5. Nicholls SJ, et al. JAMA. 2007;297(5):499-508. 5. Nissen SE, et al. JAMA. 2006;295(13):1556-1565.
6. Ray KK, et.al. Lancet Diabetes Endocrinol. 2023; 11(2):109-119; 2. Wright RS, et.al. J Am Coll Cardiol. 2021; 77(9):1182-1193.
7. [https://www.who.int/philippines/news/detail/30-09-2022-doh-who-rtsl-whf-commit-strengthen-collaboration-cardiovascular-diseases-prevention#:~:text=Cardiovascular%20diseases%20\(CVDs\)%20%25E2%2580%2593%20or,in%20the%20country%20in%202021](https://www.who.int/philippines/news/detail/30-09-2022-doh-who-rtsl-whf-commit-strengthen-collaboration-cardiovascular-diseases-prevention#:~:text=Cardiovascular%20diseases%20(CVDs)%20%25E2%2580%2593%20or,in%20the%20country%20in%202021)

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