US FDA approves expanded indication for Novartis Leqvio® (inclisiran) to include treatment of adults with high LDL-C and who are at increased risk of heart disease

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- Expanded indication now enables broader use of Leqvio for LDL-C reduction in patients with primary hyperlipidemia (high LDL-C) [1]
- Leqvio can now be used earlier in LDL-C treatment as an adjunct to diet and statin therapy for patients who have not had a cardiovascular event but are at an increased risk of heart disease[1]
- Label update reinforces robust safety and effectiveness data for Leqvio

EAST HANOVER, N.J., July 10, 2023 /PRNewswire/ -- Novartis announced today that the US Food and Drug Administration (FDA) has approved a label update for Leqvio® (inclisiran) to enable earlier use in patients with elevated LDL-C who have an increased risk of heart disease, as an adjunct to diet and statin therapy[1]. This patient population includes those who have comorbidities such as hypertension and diabetes and have not yet had a first cardiovascular event[2].

"Novartis is committed to addressing the rising burden of cardiovascular disease, a substantial public health burden affecting 30 million Americans," said Victor Bulto, President of Novartis Innovative Medicines US. "High LDL-C is one of the most readily modifiable risk factors for heart disease and this label update for Leqvio will help us reach a greater number of patients who struggle with lowering their LDL-C."

Initially approved by the FDA in December 2021, Leqvio is the first and only small interfering RNA (siRNA) therapy to lower LDL-C. The updated indication for primary hyperlipidemia allows for the expanded use of Leqvio as an adjunct to diet and statin therapy beyond the previously approved atherosclerotic cardiovascular disease (ASCVD) and heterozygous familial hypercholesterolemia (HeFH) patient populations[1].

With two doses a year, after two initial doses, Leqvio was proven to provide powerful and consistent LDL-C lowering of up to 52% vs. placebo for patients with heart disease or at increased risk of heart disease, who were unable to reach their LDL-C target despite statin therapy[1,3,4]. After administration of Leqvio by a health care provider (HCP), HCPs can be confident that a dose won't be missed for 6 months[1].

Other updates to the label include the removal of the Limitations of Use statement and the safety section was streamlined to remove four adverse events since the frequency of these events were the same as the placebo arm[1]. Effective immediately in the US, this label update reinforces the robust safety and effectiveness data for Leqvio that are being generated by the VictORION clinical trial program. VictORION is one of the largest cardiovascular clinical trial programs with more than 20 trials and is designed for consistent and comprehensive data generation.

About Leqvio
Leqvio is an injectable prescription medicine indicated as an adjunct to diet and statin therapy for the treatment of adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce low-density lipoprotein cholesterol (LDL-C).

Novartis has obtained global rights to develop, manufacture and commercialize Leqvio under a license and collaboration agreement with Alnylam Pharmaceuticals, a leader in RNAi therapeutics.

Important Safety Information:
The most common side effects of Leqvio were: injection site reaction (including pain, redness, and rash), arthralgia (joint pain), bronchitis (chest cold).

These are not all the possible side effects of Leqvio. Ask your health care provider for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please click here for Leqvio full Prescribing Information.

About VictORION
VictORION is an innovative and robust clinical program for Leqvio, comprising 27 trials and enrolling more than 60,000 patients in more than 50 countries worldwide. The program is designed to expand on the foundational evidence of LDL-C reduction with Leqvio in diverse patient populations to include implementation research, real-world evidence, and trials that establish its benefits on cardiovascular outcomes. A growing number of studies are planned to generate a vast array of data with major trials such as ORION-4 (secondary prevention), V (VictORION)-2-PREVENT (secondary prevention), V-1-PREVENT (high-risk primary prevention), V-INITIATE, V-INCEPTION, V-REAL, V-DIFFERENCE, and V-PLAQUE. The VictORION program reinforces our commitment to stopping premature death from cardiovascular disease and to leading a generational decline in cardiovascular morbidity and mortality.

About atherosclerotic cardiovascular disease (ASCVD), also known as heart disease
Atherosclerosis corresponds to the accumulation of lipids over time, mainly low-density lipoprotein cholesterol (LDL-C) in the inner lining of the arteries[5]. Unexpected rupture of the atherosclerotic plaque can cause an atherosclerotic cardiovascular event such as a heart attack or stroke[6]. Events due to ASCVD, including heart attacks and strokes, account for 85% of all cardiovascular disease deaths[7]. ASCVD is the primary cause of death in the United States and its burden is greater than that from any other chronic diseases[8]. Many patients with elevated LDL-C are living with other conditions like hypertension, obesity or diabetes, that significantly increase their risk of developing ASCVD and having a cardiovascular event[2].

About Novartis in Cardiovascular
Cardiovascular disease (CVD) is the leading cause of death in the United States, surpassing all types of cancer, unintentional injury and stroke, combined[9]. Of the many CV events, 80% can be prevented[10]. Patients and their families deserve better, and our society deserves more.

Thanks to a combination of our legacy, global footprint and leading science, Novartis is uniquely positioned to help change this landscape. We are transforming the way we think about how CV disease is managed throughout life. Our efforts include the use of early interventions and the development of pioneering treatments that address the spectrum of CV disease, from prevention to management, as well as the creation of innovative access models. By re-writing the way we work with society, we will lead a worldwide effort to improve health outcomes and roll back the crisis of CV death. Our goal is to bend the curve of life by reducing and stopping premature death from CV disease.

This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as "potential," "can," "will," "plan," "may," "could," "would," "expect," "anticipate," "look forward," "believe," "committed," "investigational," "pipeline," "launch," or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the investigational or approved products described in this press release, or regarding potential future revenues from such products. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations regarding such products could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures and requirements for increased pricing transparency; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; general political, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases such as COVID-19; safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Novartis
Novartis is reimagining medicine to improve and extend people's lives. We deliver high-value medicines that alleviate society's greatest disease burdens through technology leadership in R&D and novel access approaches. In our quest to find new medicines, we consistently rank among the world's top companies investing in research and development. Novartis employs about 14,000 people in the United States. For more information, please visit https://www.novartis.us

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List of links present in page

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