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# Novartis to acquire The Medicines Company for USD 9.7 bn, adding inclisiran, a potentially transformational investigational cholesterollowering therapy to address leading global cause of death

← Back to News Archive

#### Nov 24 2019

- Over 50 million secondary prevention patients worldwide with atherosclerotic cardiovascular disease (ASCVD) or familial hypercholesterolemia (FH) on current standard of care do not achieve LDL cholesterol (LDL-C) goal and remain at increased risk of cardiovascular events<sup>1</sup>
- First-in-class siRNA biological mechanism enables unique twice-yearly, subcutaneous dosing regimen and seamless integration into routine healthcare professional visits, potentially improving adherence and patient outcomes<sup>2,3,4</sup>
- Comprehensive Phase III inclisiran program showed potent and durable reduction of >50% in LDL-C on top of standard of care, with excellent safety profile<sup>2,3,4</sup>
- Transaction expected to create significant value with soon-to-launch, potentially first-in-class product that could become one of the largest products by sales in Novartis portfolio, leveraging significant synergies with existing global cardiovascular commercial capabilities
- Highly efficacious, safe and convenient profile of inclisiran combined with flexible market access strategies and value-based pricing can enable broad access
- Offer price of USD 85.00 per share in cash represents a premium of approximately 41% over The Medicines Company's 30-day volume weighted average price of USD 60.33; valuing the company at approximately USD 9.7 billion on a fully diluted basis
- Novartis updates Innovative Medicines (IM) Division core margin outlook; now expects to achieve mid-thirties in the near term and mid-to-high thirties in the medium term

Basel, November 24, 2019 — Novartis CEO Vas Narasimhan said:

"We are excited about entering into an agreement to acquire The Medicines Company as inclisiran is a potentially transformational medicine that reimagines the treatment of atherosclerotic heart disease and familial hypercholesterolemia. With tens of millions of patients at higher risk of cardiovascular events from high LDL-C, we believe that inclisiran could contribute significantly to improved patient outcomes and help healthcare systems address the leading global cause of death. The prospect of bringing inclisiran to patients also fits with our overall strategy to transform Novartis into a focused medicines company and adds an investigational therapy with the potential to be a significant driver of Novartis' growth in the medium to long term."

Novartis announced today that it has entered into an agreement and plan of merger with The Medicines Company (NASDAQ: MDCO) to acquire the US-based biopharmaceutical company for USD 85.00 per share in cash, valuing the company at approximately USD 9.7 billion on a fully diluted equity basis. The offer price represents a premium of approximately 41% over The Medicines Company's 30-day (to November 22, 2019) volume weighted average price of USD 60.33 and approximately 24% premium over The Medicines Company's closing share price of USD 68.55 on November 22, 2019 which represented a fully diluted equity value of approximately USD 7.7 billion when including the impact of outstanding stock options and convertible debt. The transaction has been unanimously approved by the Boards of Directors of both companies.

The Medicines Company recently announced data from its comprehensive clinical program consisting of three Phase III trials (ORION-9, 10 and 11) for inclisiran involving over 3,600 high-risk patients with ASCVD and FH. In all trials, inclisiran demonstrated potent and durable LDL-C reduction with an excellent safety and tolerability profile<sup>2,3,4</sup>. Furthermore, inclisiran's potentially first-in-class, twice-yearly dosing schedule allows administration during patients' routine visits to their healthcare professionals and will likely contribute to improved patient adherence and sustained, lower LDL-C levels<sup>2,3,4</sup>. The Medicines Company expects to file regulatory submissions in the U.S. in the fourth quarter of 2019 and in Europe in the first quarter of 2020. An ongoing clinical trial (ORION-4) will evaluate the cardiovascular morbidity and mortality benefits of inclisiran<sup>5</sup>.

"Novartis has a longstanding history of delivering breakthrough cardiovascular treatments for patients, and I am very excited about the opportunity to add inclisiran to our cardiovascular portfolio," said Marie-France Tschudin, President, Novartis Pharmaceuticals. "This transformational, new investigational medicine has the potential to

meaningfully address one of the largest areas of underserved patient need. We believe our strong capabilities and global footprint can help drive broad worldwide access to this much needed treatment."

# Transaction fits long-term strategic goals

The planned acquisition of The Medicines Company would allow Novartis to continue building pipeline depth in a key therapeutic area a central pillar of its M&A strategy - and is aligned with the Novartis strategic priority of delivering truly transformational medicines for patients. It would add a potentially first-in-class siRNA inhibitor targeting PCSK9 with the potential to fundamentally change the treatment of elevated LDL-C in high risk patients<sup>2,3,4</sup>. Additionally, with The Medicines Company expecting to file regulatory submissions in the U.S. in the fourth quarter of 2019 and in Europe in the first quarter of 2020, inclisiran represents a near-term product launch opportunity and is expected to contribute to Group sales from 2021. Furthermore, broadening the cardiovascular portfolio would enable Novartis to leverage its core commercial capabilities including its strong cardiovascular field force both in the US and globally. Finally, the transaction is consistent with Novartis' capital allocation priorities to invest in transformative innovation and long term value creation for shareholders.

# Financial highlights and updated IM Division margin outlook guidance

The offer price represents a premium of approximately 41% over The Medicines Company's 30-day volume weighted average price of USD 60.33 and approximately 24% premium over The Medicines Company's closing share price of USD 68.55 on November 22, 2019 which represented a fully diluted equity value of approximately USD 7.7 billion when including the impact of outstanding stock options and convertible debt.

The transaction is expected to create significant value for patients, payers and Novartis shareholders. Assuming completion in the first quarter of 2020, Novartis expects inclisiran to start to contribute to Group and IM Division sales from 2021. It is also expected to further drive growth of the Cardiovascular-Renal-Metabolism franchise with the potential to become one of the largest products by sales in the Novartis portfolio, leveraging Novartis' global cardiovascular commercial capabilities.

The acquisition is expected to modestly dilute core EPS versus a no deal scenario during the next few years as the company invests for a successful launch of inclisiran. Novartis expects the transaction to be significantly accretive to Group core operating income and core EPS in the medium term, driven by sales growth and operational synergies, leveraging the worldwide footprint of the cardiovascular business.

Novartis expects to continue to expand IM Division core margins to reach mid-thirties in the near term, and mid to high-thirties in the medium term, while investing in launches, including inclisiran. This guidance assumes that no Gilenya® generics will enter the US market in 2020.

The core margin expansion for IM Division is driven by the continued sales momentum of key growth drivers, expected new launches as well as previously announced productivity programs. Novartis believes these factors will offset investments in new launches including inclisiran as well as the impact of generic erosion.

#### Transaction details

The transaction is expected to close in the first quarter of 2020, subject to the satisfaction or waiver of all closing conditions. Until closing, Novartis and The Medicines Company will continue to operate as separate and independent companies.

Under the terms of the agreement and plan of merger, Novartis will, through a subsidiary, commence a tender offer to purchase all outstanding shares of The Medicines Company for USD 85.00 per share in cash. Following completion of the tender offer, Novartis expects to merge the acquiring subsidiary with The Medicines Company, resulting in The Medicines Company becoming an indirect wholly-owned subsidiary of Novartis. The transaction is subject to customary closing conditions, including antitrust clearance.

Novartis plans to finance the transaction through available cash and short- and long-term borrowings.

#### Investor call

A conference call for investors will take place on November 25, 2019 at 7:00 CET. Details can be found at

https://www.novartis.com/investors/event-calendar.

#### Additional information

This press release is neither an offer to purchase nor a solicitation of an offer to sell securities. The tender offer for the outstanding shares of common stock, par value USD 0.001, of The Medicines Company (the "Company") described in this press release has not commenced. At the time the tender offer is commenced, Novartis and its indirect wholly-owned subsidiary,

Medusa Merger Corporation ("*Purchaser*"), will file, or will cause to be filed, a Schedule TO Tender Offer Statement with the U.S. Securities and Exchange Commission (the "*SEC*") and the Company will file a Schedule 14D-9 Solicitation/Recommendation Statement with the SEC, in each case with respect to the tender offer. The Schedule TO Tender Offer Statement (including an offer to purchase, a related letter

of transmittal and other offer documents) and the Schedule 14D-9 Solicitation/Recommendation Statement will contain important information that should be read carefully when they become available and considered before any decision is made with respect to the tender offer. Those materials and all other documents filed by, or caused to be filed by, Novartis and Purchaser and the Company with the SEC will be available at no charge on the SEC's website at <a href="www.sec.gov.org">www.sec.gov.org</a> The Schedule TO Tender Offer Statement and related materials also may be obtained for free under the "Investors – Financial Data" section of Novartis website at <a href="https://www.novartis.com/investors/financial-data/sec-filings">https://www.novartis.com/investors/financial-data/sec-filings</a>. The Schedule 14D-9 Solicitation/Recommendation Statement and such other documents also may be obtained for free from the Company under the "Investors & Media" section of the Company's website at

https://www.themedicinescompany.com/investor/financial/ ☑.

#### About Novartis in Cardiovascular-Renal-Metabolism

Bending the curve of life requires addressing some of society's biggest public health concerns. Novartis has an established and expanding presence in diseases covering the heart, kidney and metabolic system. In addition to essential treatment Entresto® (sacubitril/valsartan), Novartis has a growing pipeline of potentially first-in-class molecules addressing genetic cardiovascular risk factors, rare renal diseases and metabolic disorders.

#### About atherosclerotic cardiovascular disease

Atherosclerotic cardiovascular disease is the leading cause of death worldwide<sup>6</sup>. ASCVD results from a thickening and loss of elasticity in the arterial wall. It is a severe disorder and the leading cause of morbidity (sickness) and mortality (death) in most developed countries<sup>7</sup>. High levels of LDL-C build up on the walls of blood vessels. This buildup is called "plaque." As blood vessels build up plaque over time, the insides of the vessels narrow. This narrowing blocks blood flow to and from the heart and other organs and eventually causes heart disease or stroke<sup>8</sup>.

#### About familial hypercholesterolemia

Familial hypercholesterolemia (FH) is a genetic condition that leads to high cholesterol. People with FH have high levels of LDL-C as a result of a mutation in one gene that controls the way cholesterol is cleared by the body. High levels of LDL-C build up on the walls of the blood vessels and over time, the vessels narrow. This can lead to increased risk of heart attack or stroke. While lifestyle factors are important, for people with FH this isn't sufficient to control LDL-C<sup>9</sup>.

#### About inclisiran

Inclisiran, potentially the first and only cholesterol-lowering therapy in the siRNA (small-interfering RNA) class. is The Medicines Company's investigational twice-yearly therapy in Phase III clinical development to evaluate its ability to reduce low-density lipoprotein cholesterol (also known as LDL-C). As a siRNA, inclisiran harnesses the body's natural process of RNA interference to specifically prevent production of the PCSK9 protein in the liver, which enhances the liver's ability to remove LDL-C from the bloodstream, thereby lowering LDL-C levels<sup>2,3,4</sup>. Inclisiran is not yet approved by the FDA or any other regulatory authority. The Medicines Company obtained global rights to develop, manufacture and commercialize inclisiran under a license and collaboration agreement with Alnylam Pharmaceuticals, Inc. On January 23, 2018, the FDA granted orphan drug designation to inclisiran for the treatment of homozygous familial hypercholesterolemia (HoFH)<sup>10</sup>.

# About ORION clinical development program

Durable and potent LDL-C reduction with twice-yearly administration was demonstrated in three pivotal Phase III trials. <u>ORION-11</u>: showed a 54% LDL-C lowering with time-adjusted reductions of 50% sustained over 18 months of treatment<sup>2</sup>. <u>ORION-10</u>: showed a 58% (observed) LDL cholesterol lowering with time-adjusted reductions of 56% sustained over 18 months. ORION-10 met all primary and secondary endpoints, with profound, durable efficacy and excellent safety of inclisiran that were at least as favorable as observed in ORION-11<sup>3,4</sup>. <u>ORION-9</u>: met all primary and secondary efficacy endpoints, including durable and potent efficacy and excellent safety in a patient population where cardiovascular disease is most severe<sup>4</sup>.

In addition, inclisiran has a highly attractive dosing regimen. After an initial 3-month lead in, twice-yearly subcutaneous dosing thereafter applicable to all tested patients and subgroups. A clean long-term safety profile across a broad range of patient groups was observed. The benefit of inclisiran on cardiovascular outcomes is being assessed in an on-going 15 000 patient 5-year clinical trial (ORION-4)<sup>5</sup>.

## Disclaimer

This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995, that can generally be identified by words such as "to be commenced," "to purchase," "to acquire," "to transform," "potential," "expected," "offers," "future," "ongoing," "would," "potentially," "believe," "can," "hopefully," "excited," "ambition," "priorities," "confidence," "to strengthen," "opportunity," "pending," "will," "expects," "subject to," "planned," "soon to launch," "transformational" or similar expressions, or by express or implied discussions regarding the potential outcome of the tender offer for the shares of The Medicines Company to be commenced by Novartis, and the potential impact on Novartis of the proposed acquisition, including express or implied discussions

regarding potential tuture sales or earnings of inovartis, and any potential strategic benefits, synergies or opportunities expected as a result of the proposed acquisition; and regarding potential marketing or regulatory approvals for inclisiran, or regarding potential future revenues from such product. 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 proposed tender offer or the acquisition described in this press release will be completed, or that it will be completed as currently proposed, or at any particular time. Neither can there be any guarantee that Novartis or The Medicines Company's product, inclisiran, will achieve any particular future financial results, or that Novartis will be able to realize any of potential strategic benefits, synergies or opportunities as a result of the proposed acquisition. Nor can there be any guarantee that inclisiran will be submitted or approved for sale in any market, or at any particular time. Neither can there be any guarantee that such product will be successfully commercialized even if regulatory approvals are obtained. In particular, our expectations could be affected by, among other things: regulatory actions or delays or government regulation generally, including potential regulatory actions or delays relating to the completion of the potential acquisition described in this release, as well as potential regulatory actions or delays with respect to the development of inclisiran; the potential that the strategic benefits, synergies or opportunities expected from the proposed acquisition may not be realized or may take longer to realize than expected; the successful integration of The Medicines Company into the Novartis Group subsequent to the closing of the transaction and the timing of such integration; potential adverse reactions to the proposed transaction by customers, suppliers or strategic partners; dependence on key personnel of The Medicines Company; dependence on third parties to fulfill manufacturing and supply obligations; the uncertainties inherent in the research and development of new healthcare products, including clinical trial results and additional analysis of existing clinical data; our ability to obtain or maintain proprietary intellectual property protection; safety, quality, data integrity or manufacturing issues; global trends toward health care cost containment, including government, payer and general public pricing and reimbursement pressures and requirements for increased pricing transparency; the particular prescribing preferences of physicians and patients; uncertainties regarding actual or potential legal proceedings, including, among others, potential legal proceedings with respect to the proposed acquisition; and other risks and factors referred to in Novartis' current

Form 20-F on file with the SEC. 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 as a result of new information, future events or otherwise.

#### **About Novartis**

Novartis is reimagining medicine to improve and extend people's lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world's top companies investing in research and development. Novartis products reach more than 750 million people globally and we are finding innovative ways to expand access to our latest treatments. About 109,000 people of more than 140 nationalities work at Novartis around the world. Find out more at www.novartis.com.

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