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Novartis announces exclusive option, collaboration and license agreement with Conatus to develop new oral treatments for chronic liver diseases

- *Novartis to broaden liver portfolio to deliver best-in-class single and combination therapies for non-alcoholic steatohepatitis (NASH) with advanced fibrosis and cirrhosis through an option, collaboration and license agreement with Conatus*
- *There are currently no approved treatments for NASH patients in all stages of the disease, which is expected to be the leading cause of liver transplants in the US by 2020¹*
- *Novartis has FXR agonists in clinical development for NASH, the most advanced of which is in a Phase 2 clinical trial and has been granted Fast Track designation from the US FDA*

Basel, December 19, 2016 – Novartis announced today the signing of an exclusive option, collaboration and license agreement with Conatus Pharmaceuticals Inc., a biotechnology company focused on the development of novel medicines to treat liver disease. This agreement will enable Novartis and Conatus to jointly develop emricasan. Emricasan is an investigational, first-in-class, oral, pan-caspase inhibitor for the treatment of non-alcoholic steatohepatitis (NASH) with advanced fibrosis (scarring) and cirrhosis. This collaboration has the potential to expand treatment options for people in various stages of fatty liver disease, where no approved medicines currently exist.

Under the terms of this agreement, Novartis will make an upfront payment to Conatus of USD 50 million. Any additional exercise fee will be paid to Conatus following achievement of certain criteria as defined in the option, collaboration and license agreement, including required anti-trust approvals.

“Our collaboration with Conatus is a major step forward to delivering innovative oral treatments for NASH patients, who are in urgent need of new approved options,” said Vasant Narasimhan, Global Head, Drug Development and Chief Medical Officer, Novartis. “Emricasan shows great promise as a single agent and in potential combination with our internal FXR agonists as a treatment for NASH patients”.

Novartis is developing Farnesoid X receptor (FXR) agonists for the treatment of chronic liver diseases. As part of this collaboration, Conatus will conduct multiple Phase 2b clinical trials with emricasan in NASH. If concluded positively, Novartis would then conduct Phase 3 studies of emricasan as a single treatment and start development of combination therapies with an FXR agonist.

FXR agonists have been shown to address three of the most important aspects of NASH progression by reducing fat, inflammation and fibrosis in the liver. The most advanced Novartis investigational compound, a potent, non-bile acid FXR agonist, has recently received

Fast Track designation from the US Food and Drug Administration (FDA) for NASH with liver fibrosis and is in a Phase 2 clinical trial.

NASH is a common, often silent liver disease; the major feature of which is fat in the liver, along with inflammation and scarring. Around 3-5% of the US population is affected with NASH², which is set to become the leading cause of liver transplants in the US by 2020¹.

About emricasan

Emricasan is a first-in-class, oral, pan-caspase inhibitor for the treatment of NASH fibrosis and cirrhosis. To date, emricasan has been studied in over 650 patients in sixteen clinical trials across a broad range of liver diseases. In multiple clinical Phase 2 trials conducted by Conatus, emricasan has demonstrated significant, rapid and sustained reductions in elevated levels of key biomarkers of inflammation and cell death, which play a role in the severity and progression of liver disease. The FDA has granted Fast Track designation for the development of emricasan in patients with NASH cirrhosis.

About Novartis FXR agonists

Novartis scientists began to develop leads for the FXR agonism program in 2007. Through this effort, several non-bile acid FXR agonists have been identified and pre-clinical data demonstrates that these compounds are very selective with differentiated biological profiles. First-in-human studies have continued to support their differentiated profiles and their potential for further development. Two Novartis FXR agonists are now in worldwide clinical studies in NASH patients.

About Non-Alcoholic Steatohepatitis (NASH)

NASH is a chronic, progressive form of non-alcoholic fatty liver disease and it is estimated to affect 3% to 5% of the US population alone². As fat builds up in the liver, it triggers a vicious cycle of chronic inflammation and liver scarring called fibrosis. Over time, liver inflammation and fibrosis may progress to cirrhosis, which can lead to liver failure and, barring a transplant, death. NASH is expected to be the principal cause of liver transplantation in the US by 2020¹. Currently, there are no approved treatment options for people living with the varying stages of NASH.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as "option," "to broaden," "to develop," "expected," "by 2020," "Fast Track designation," "investigational," "potential," "will," "option," "step forward," "promise," "would," "set to become," or similar terms, or by express or implied discussions regarding potential marketing approvals for emricasan and the FXR agonists being developed internally by Novartis, either as single agents or in combination, or regarding potential future revenues from emricasan and the FXR agonists being developed internally by Novartis, either as single agents or in combination, or regarding the possible exercise of the option for the collaboration with Conatus and license for emricasan, or regarding the intended goals and objectives of the collaboration with Conatus and license for emricasan. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management 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 necessary government approvals for the transaction or option exercise will be obtained in any particular time frame, or at all. Neither can there be any guarantee that any other closing conditions for the transaction or option exercise will be met in any particular time frame, or at all. Nor can there be any guarantee that the option for the collaboration with Conatus and license for emricasan will be exercised within the expected time frame, or at all. Neither can there be any guarantee that the collaboration with Conatus and license for emricasan will achieve any of their intended goals and objectives, or in any particular time frame. Nor can there be any guarantee that emricasan or the FXR agonists being developed

internally by Novartis, either as single agents or in combination, will be submitted or approved for sale in any market, or at any particular time. Neither can there be any guarantee that emricasan or the FXR agonists being developed internally by Novartis, either as single agents or in combination, will be commercially successful in the future. In particular, management's expectations regarding emricasan and the FXR agonists being developed internally by Novartis, either as single agents or in combination, and the option for the collaboration with Conatus and license for emricasan, could be affected by, among other things, the potential that the intended goals and objectives of the collaboration with Conatus and license for emricasan may not be achieved or may take longer to achieve than expected; the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally, including an unexpected failure to obtain necessary government approvals for the transaction or option exercise, or unexpected delays in obtaining such approvals; the potential that any other closing conditions for the transaction or option exercise may not be met; the company's ability to obtain or maintain proprietary intellectual property protection; general economic and industry conditions; global trends toward health care cost containment, including ongoing pricing pressures; unexpected safety, quality or manufacturing issues, 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 provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care and cost-saving generic pharmaceuticals. Novartis is the only global company with leading positions in these areas. In 2015, the Group achieved net sales of USD 49.4 billion, while R&D throughout the Group amounted to approximately USD 8.9 billion (USD 8.7 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 118,000 full-time-equivalent associates. Novartis products are available in more than 180 countries around the world. For more information, please visit <http://www.novartis.com>.

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