



NIMBUS
THERAPEUTICS

Nimbus Therapeutics Granted Fast Track Designation for Its Allosteric ACC Inhibitor, Ndi-010976, for the Treatment of Nash

CAMBRIDGE, Mass. – February 2, 2016 – Nimbus Therapeutics, a biotechnology company focused on harnessing the power of computational chemistry to design breakthrough drugs for serious, underserved human diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for NDI-010976, Nimbus' liver-targeted allosteric inhibitor of acetyl-CoA carboxylase (ACC), for the treatment of NASH (non-alcoholic steatohepatitis).

In addition, the company announced that it is on track to start Phase II clinical testing in the first half of this year, and that the results of the Phase I program to support entry into Phase II will be presented at the upcoming European Association for the Study of Liver Diseases (EASL) meeting in April.

“Inhibitors of ACC have the potential to become important therapeutics in the treatment of NASH, as well as other important diseases.” said Don Nicholson, Ph.D., Chief Executive Officer (CEO) at Nimbus. “We are very pleased that the FDA provided us the opportunity to engage them more directly to help expedite our clinical development program so that we can bring NDI-010976 to patients sooner.”

The FDA's Fast Track program is designed to facilitate and expedite development and review of new drugs to treat serious or life-threatening conditions and address unmet medical needs. Companies receiving Fast Track designation benefit from more frequent meetings and communications with the FDA regarding development plans to support product registration. In addition, companies with Fast Track designation may be eligible for rolling review, such that sections of a New Drug Application (NDA) are reviewed once available and prior to submission of the complete application. Fast Track development programs may also be eligible for priority review, which carries an abbreviated review timeline of six months.

About NASH

Non-alcoholic steatohepatitis (NASH) is a serious chronic liver disease caused by excessive fat accumulation in the liver. It affects between 5-10% of the adult population in the United States and represents a growing and underserved medical need. A substantial fraction of those affected by NASH will progress to advanced fibrosis (liver scarring) and cirrhosis (over a million Americans), which frequently leads to liver failure and death. End-stage liver disease secondary to NASH is predicted to become the leading cause of liver transplants within the next decade, surpassing chronic hepatitis C and alcoholic liver disease. Currently, there are no approved therapeutics for the treatment of NASH or related fatty-liver diseases, underscoring the need for effective treatments.

About ACC and NDI-010976

Acetyl-CoA carboxylase (ACC) is a pair of enzymes that catalyze a very early biochemical step in the synthesis of endogenous fatty acids (*de novo* lipogenesis). In addition, the product of the ACC reaction regulates the ability of cellular mitochondria to 'burn' pre-existing fat through beta-oxidation. Inhibitors of ACC therefore prevent both new fat synthesis and stimulate mitochondrial beta-oxidation in certain tissues. In animal models of fatty liver diseases like NASH, the effects of ACC inhibition extend to reducing liver inflammation and limiting fibrosis (scarring), which are important hallmarks of NASH progression. NDI-010976 is a high-potency allosteric inhibitor of both ACC enzymes. By design, it is hepatotropic (liver 'homing'), which directs it to the target organ for NASH and related diseases that Nimbus is pursuing. Nimbus is also developing allosteric ACC inhibitors with broad distribution in the body to treat immune-inflammatory disorders and cancer.

About Nimbus

Nimbus Therapeutics is a biotechnology company headquartered in Cambridge, Massachusetts (USA). It is pioneering the application of computational chemistry to design breakthroughs for the treatment of substantial and underserved human diseases. The company's focus on metabolic diseases, cancer and immune-inflammatory disorders reflects the mechanistic relationship between these disorders, and Nimbus' ability to rapidly tackle well validated targets as well as those that have proven intractable to the approaches taken by others in the pharmaceutical and biotechnology industry. To learn more, please visit www.nimbustx.com.

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