

Innorna Announces ODD Granted by the US FDA to IN016 for the Treatment of Progressive Familial Intrahepatic Cholestasis

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/EINPresswire.com/ -- Innorna
Announces Orphan Drug Designation
Granted by the US FDA to IN016 for the
Treatment of Progressive Familial
Intrahepatic Cholestasis



Innorna, a clinical-stage biotech company pioneering its proprietary lipid nanoparticle (LNP) technology to develop novel RNA therapeutics, today announced that the U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation (ODD) to its investigational therapy IN016, for the treatment of progressive familial intrahepatic cholestasis (PFIC). IN016 was also granted a Rare Pediatric Disease Designation (RPDD) on July 10, 2024. The RPDD and ODD granted by the US FDA will significantly facilitate the clinical development and approval of IN016, quickly bringing this potential therapy to PFIC patients.



The RPDD and ODD granted by the US FDA will significantly facilitate the clinical development and approval of IN016. We are excited to bring this potential therapy to PFIC patients quickly."

*Linxian Li, Ph.D., CEO and
Founder of Innorna*

About PFIC and IN016

Progressive familial intrahepatic cholestasis (PFIC) is a heterogeneous group of rare genetic disorders associated with defects in bile acid secretion or transport, resulting in unwanted bile accumulation within the liver. Typical symptoms include jaundice, hepatomegaly, pruritus,

splenomegaly, and diarrhea. Over time, this disease can evolve into severe liver damage, fibrosis, and cirrhosis and is associated with high mortality rates. While symptoms can be managed to some extent, more effective treatment is greatly needed for PFIC. IN016 is designed to address the root cause of PFIC resulting from gene mutations, potentially restoring defective proteins, normalizing bile excretion, and possibly improving symptoms in PFIC patients.

About Innorna

Founded in 2019, Innorna aims to develop a globally leading lipid nanoparticle (LNP) delivery technology platform and innovative RNA therapies to address unmet clinical needs. The company has established a Diversity-Oriented Lipid Library (DOLL), encompassing over 5,000 ionizable lipids, to develop various innovative therapies, including mRNA vaccines and drugs, gene editing, and cell therapy. Leveraging its proprietary mRNA and LNP technology platform, Innorna has established multiple internal R&D pipelines for infectious disease vaccines, rare diseases, and tumor immunotherapy. The company has also partnered with several multi-national biopharmaceutical and biotechnology companies to explore the potential for broader treatment applications.

Since its establishment, Innorna has gained wide recognition from the investment and industrial sectors and has received numerous awards, including being named among MIT Technology Review's global top 50 smartest companies and Fortune China's most socially influential startup companies.

At Innorna, we value INNOVATION, INTEGRITY, EFFICIENCY, and OPENNESS. We are committed to exploring the frontier of mRNA application based on platform technologies and leading the revolutionary step toward expanding the clinical application of mRNA in various therapeutic approaches to fulfill the unmet medical needs of patients worldwide. Please visit the Innorna website at www.innorna.com for more information.

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