**Morepen to Launch Resmetirom- a New Drug for Fatty Liver**

**CDSCO clears BE Study proposal for Resmetirom**

*Among the first few Indian companies set for Global Launch*

**Gurugram, April 29, 2025:** In a key development reinforcing its leadership in the Indian pharmaceutical landscape, **Morepen Laboratories Ltd.** has got clearance from Subject Expert Committee (‘SEC’) of Central Drugs Standard Control Organization **(‘CDSCO’)** to conduct **Bioequivalence (‘BE’) studies** for **Resmetirom** 60 mg, 80 mg and 100 mg tablets as per the protocol submitted. This will be followed by clinical trials as per approved protocols.

Resmetirom is a highly promising therapy under development for non-alcoholic steatohepatitis **(‘NASH’)**, a serious form of non-alcoholic fatty liver disease **(‘NAFLD’)** characterized by **inflammation, liver damage, and fat accumulation in the liver**, potentially leading to scarring (fibrosis), cirrhosis, and even liver cancer. It is often associated with obesity, metabolic syndrome, and type 2 diabetes, and while it can be a silent disease in the early stages, it can progress to severe liver damage if left untreated.

*“This is a critical step forward in our journey to bring a much-needed innovation to the hepatology market,” said* ***Sanjay Suri, Executive Director, Morepen Laboratories****. “We are proud to be one of the first few Indian companies gearing up to launch the finished formulation of Resmetirom. Our end-to-end integration – from APIs to finished dosage – gives us a unique edge in speed, quality, and scalability.”*

As one of the first Indian companies to foray into this therapeutic area, Morepen is strategically positioned to serve both domestic and international markets and is also evaluating out-licencing opportunities with potential marketing partners.

**NASH**, a progressive liver disease that affects over **115 million people worldwide**. According to industry estimates, the **global NASH treatment market** is projected to grow from **USD 2.5 billion in 2024 to over USD 16 billion by 2032**, driven by increasing prevalence, clinical awareness, and regulatory approvals.

Morepen has a strong global footprint, exporting its APIs and formulations to **over 80 countries**, including regulated markets such as the **U.S., Europe, and Japan**. The company’s API manufacturing facilities are **USFDA, EU-GMP, and WHO-GMP compliant**, underscoring its commitment to international quality standards.

Morepen’s early-mover advantage in Resmetirom, combined with its **scale, integration, and regulatory strength**, make it a compelling investment opportunity in the fast-evolving specialty and chronic care segments. The company’s proven ability to **leverage global trends, manufacture at scale, and meet stringent regulatory requirements** positions it as a trusted partner for global innovators and marketing partners.

**About Morepen Laboratories Ltd.**

With a legacy of over 40 years, Morepen Laboratories Ltd. is a leading Indian pharmaceutical company with a strong global footprint across 82 countries. It is India’s #1 exporter of APIs for six key molecules and is rapidly scaling its formulations business to a ₹1,000 crore target. All APIs are manufactured in-house at USFDA-approved facilities, ensuring global quality standards. Morepen is a leader in medical devices with over 14 million glucometer installations. Backed by integrated capabilities and a forward-looking strategy, Morepen is committed to strengthening India's role as the pharmacy of the world.

For more details, visit [www.morepen.com](http://www.morepen.com).

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***Forward-Looking Statements:***

*This press release contains forward-looking statements based on current expectations and assumptions regarding anticipated developments and other factors affecting the company. These statements are subject to risks and uncertainties that could cause actual results to differ materially from those expressed in the forward-looking statements.*