



# NOVA WELLNESS ANNOUNCES POSITIVE RESULTS FROM HEPAR-P CLINICAL TRIAL IN PATIENTS WITH NON-ALCOHOLIC FATTY LIVER DISEASE

Nova Wellness announces positive results from the recently completed Hepar-P clinical trial to assess its efficacy and safety in patients with Non-Alcoholic Fatty Liver Disease (NAFLD).

The trial results demonstrated the effectiveness and safety of Hepar-P in improving liver stiffness (fibrosis) score and lowering elevated liver specific enzyme ALT in patients with NAFLD. The results also demonstrated that Hepar-P is safe and well-tolerated.

## Proven Efficacy and Safety of Hepar-P in Patients with NAFLD

- Improved liver stiffness (fibrosis) score
- Lowered elevated liver specific enzyme ALT
- Safe and well-tolerated

In this trial, Hepar-P clearly showed a statistically significant difference on NAFLD patients in improving liver stiffness (fibrosis) score and lowering elevated liver specific enzyme ALT compared to placebo. In liver stiffness (fibrosis) score, the statistically significant difference was reported as early as 3 months of treatment and further improved at 12 months of treatment with Hepar-P.

These results provide clear evidence on the effectiveness of Hepar-P to protect against liver injuries, delay liver damage progression and support healthy liver functions in patients with NAFLD.

It also reflects the specific mode of action of Hepar-P in inhibiting liver membrane oxidation from injuring the liver. As a result of this, it improves the liver stiffness score and helps in regression of liver fibrosis. It also normalises the liver specific enzyme ALT.

In this trial, the intake of Hepar-P is proven to be safe and well-tolerated with no significant safety concerns.

## Next Step

Full results from this study will be submitted for future scientific publication and presentation. Nova intends to proceed for regulatory filing with the National Pharmaceutical Regulatory Agency for a therapeutic claim.

## Clinical Trial Conducted at Three Hospitals

The primary objective of this trial was to assess the efficacy and safety of Hepar-P in patients with NAFLD. The clinical trial was a randomised, multi-centered, placebo-controlled, double-blind trial conducted in three hospitals in Malaysia namely; Hospital Sultanah Bahiyah in Alor Setar, Hospital Ampang, and Hospital Selayang. A total of 226 patients above the age of 18 years and confirmed NAFLD were enrolled and administered either Hepar-P at 3,000mg (12 capsules daily) or placebo for 52 weeks.

This trial was led by three Consultant Hepatologist and Gastroenterologist as clinical investigators while Datuk Dr Muhammad Radzi Abu Hassan, a Consultant Physician and Gastroenterologist as the national principal investigator.

## Better Market Acceptance

With the positive trial results, Nova Wellness anticipates better market acceptance and a wider use of Hepar-P especially in clinics and hospitals for liver protection and fatty liver management.

## Prevalence of Fatty Liver Disease

Fatty liver disease is the most common liver disease worldwide. It is a serious and potentially life-threatening condition and is a leading cause of liver failure and liver transplantation globally. Fatty liver may lead to liver stiffness (fibrosis) and scarring that impairs liver functions and it may progress to advanced fibrosis, cirrhosis, and liver cancer. People suffering from obesity, high levels of cholesterol, and high blood sugar are more prone to be diagnosed with fatty liver disease.



Fatty liver disease affects close to a third of the world's population (25%) according to data published in the Clinical Therapeutics Vol.43 in 2021. In 2019, the prevalence of fatty liver in Klang Valley alone has been estimated to be at 37.4% and 23% in the general Malaysian population. There are currently no approved therapies for fatty liver disease.

The global potential market for the treatment of fatty liver disease is estimated to be valued at US\$17.43 billion in 2021 and is projected to reach a market value of US\$62.06 billion by 2031 according to VisionGain Market analysis published in 2019. This is due to the high prevalence of fatty liver disease globally, unhealthy lifestyle behaviours, and the increasing numbers of people with diabetes and obese individuals forecasted for the coming years.

#### **Economic Transformation Programme, NKEA EPP1: Unlocking Value From Malaysia's Biodiversity Through High-Value Herbal Products**

The Malaysian herbal industry has been marked as a new source of growth and identified as one of the entry point projects (EPP) under the agriculture new key economic areas (NKEA) in the economic transformation programme (ETP) which commenced in early 2011.

The EPP1 emphasizes developing high-value herbal products backed with clinical evidence. This is a new initiative undertaken by the government and is considered as a path-breaker for the Malaysian herbal industry and the country.

Nova Laboratories Sdn Bhd, the wholly-owned subsidiary of Nova Wellness Group Berhad, was identified as one of the anchor companies under EPP1 and awarded a research grant to begin the clinical trial on Hepar-P.

#### **Our Vision: A Healthy Liver-World**

Nova is a health and nutrition company dedicated to the discovery, development, and commercialisation of novel solutions to address some of the world's most widespread, devastating, and costly chronic diseases that account for 71% of the total deaths every year globally.

We strive to set the highest standard of quality in everything we do. This clinical trial underpins our core belief in providing high-value natural products that are supported by strong scientific evidence. It is a part of our bigger mission to improve health with evidence-based products.

We believe that this product will be a powerful tool to make the vision of a healthy liver-world a reality and help many individuals with fatty liver disease.