

# LPCN 1144

for Non-Cirrhotic NASH

## Open Label Extension (OLE) Study – Topline Results

May 2022

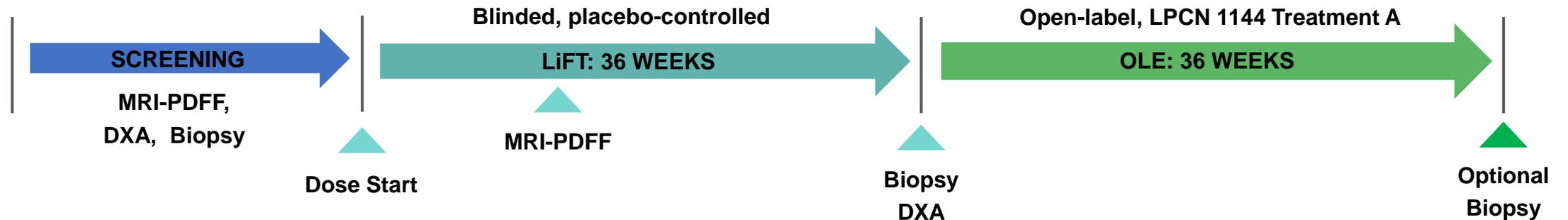


# LPCN 1144: NASH Open Label Extension Study

## Objective & Design

Objective: To evaluate the safety and tolerability of extended (up to 72 weeks) treatment with LPCN 1144 in subjects with biopsy confirmed Nonalcoholic Steatohepatitis (NASH)

- A multicenter study (NCT04685993) to provide LPCN 1144 treatment to subjects from the LiFT study (NCT04134019) who chose to participate



# LPCN 1144: NASH Open Label Extension Study

## Disposition and Analysis Sets

- ❑ Biopsy confirmed male NASH subjects (N=25, OLE-SS, OLE-Safety Set) who completed LiFT study
- ❑ Extended LPCN 1144 treatment subjects (n=16): Total of 72-weeks of LPCN 1144 treatment
  - 36 weeks of LPCN 1144 treatment in LiFT + 36 weeks of LPCN 1144 treatment in OLE
- ❑ Subjects initiated LPCN 1144 treatment (n=9) for 36 weeks after placebo run-in for 36 weeks in the LiFT study
- ❑ Six subjects (OLE Biopsy Set, OLE-BS) elected to have an optional liver biopsy at the end of the OLE at week 72
  - Extended LPCN 1144 treatment subjects (n=3)
  - Subjects initiated LPCN 1144 treatment after placebo run-in (n=3)
  - Biopsy changes in the subjects assessed utilizing NASH CRN (Clinical Research Network) scoring
- ❑ Twenty-three subjects completed the study and one subject discontinued due to non-drug related treatment emergent adverse event (TEAE)

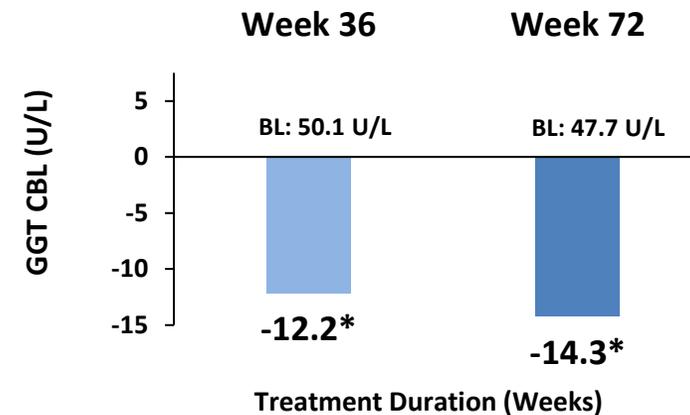
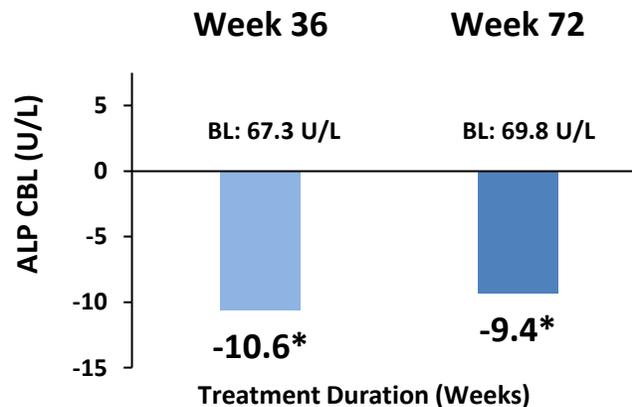
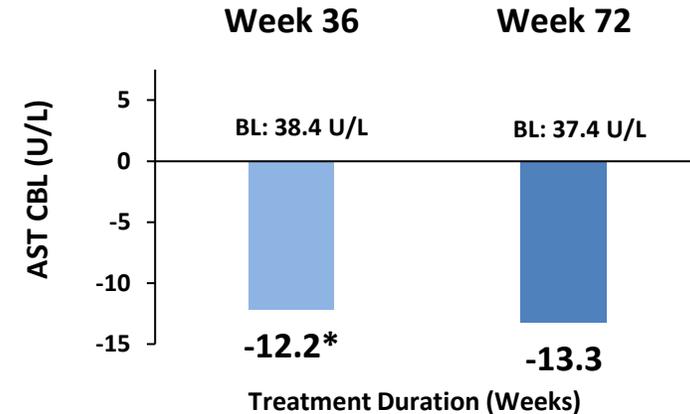
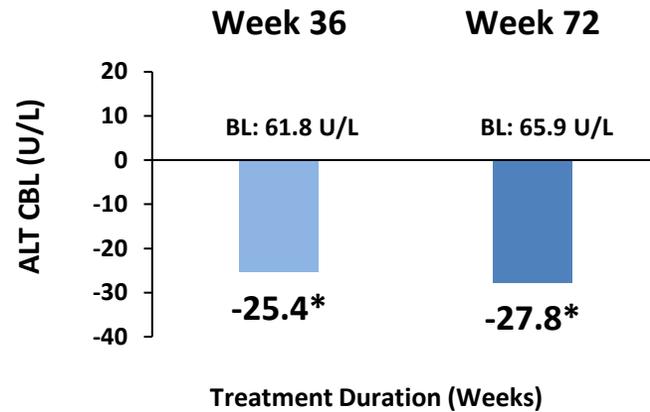
# Safety Overview of LPCN 1144 in OLE

## Well-Tolerated with No Observed Safety Signals

- ❑ In the OLE-SS, the frequency and severity of TEAEs were comparable to those observed in the LiFT study
- ❑ There were no reported cases of cardiovascular events, thromboembolic events, hepatocellular carcinoma, or drug induced liver injury ("DILI")
- ❑ Weight change from baseline was minimal and comparable to the LiFT results
- ❑ A GI adverse event was reported in one subject, and pedal edema was also reported in one subject, neither of which were considered related to study drug
- ❑ Additionally, no clinically meaningful changes in lipids were observed

# Observed Key Liver Injury Markers Change from Baseline

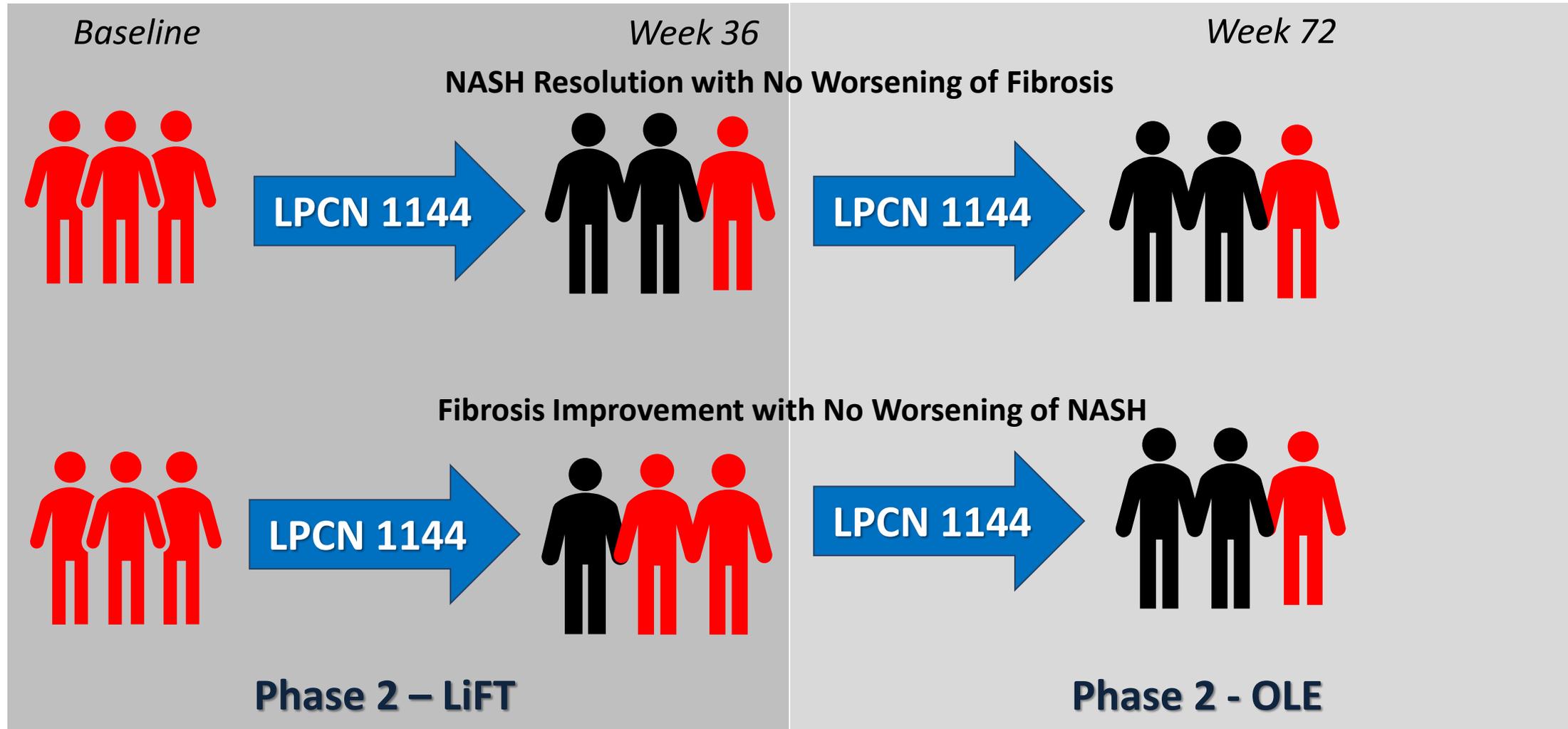
Liver Injury Markers were Reduced Significantly and Maintained with Extended LPCN 1144 Treatment



CBL= Change from Baseline; Baseline was measured at LPCN 1144 pretreatment; \* p<0.05; N = 25 for week 36 data and 16 for week 72 data

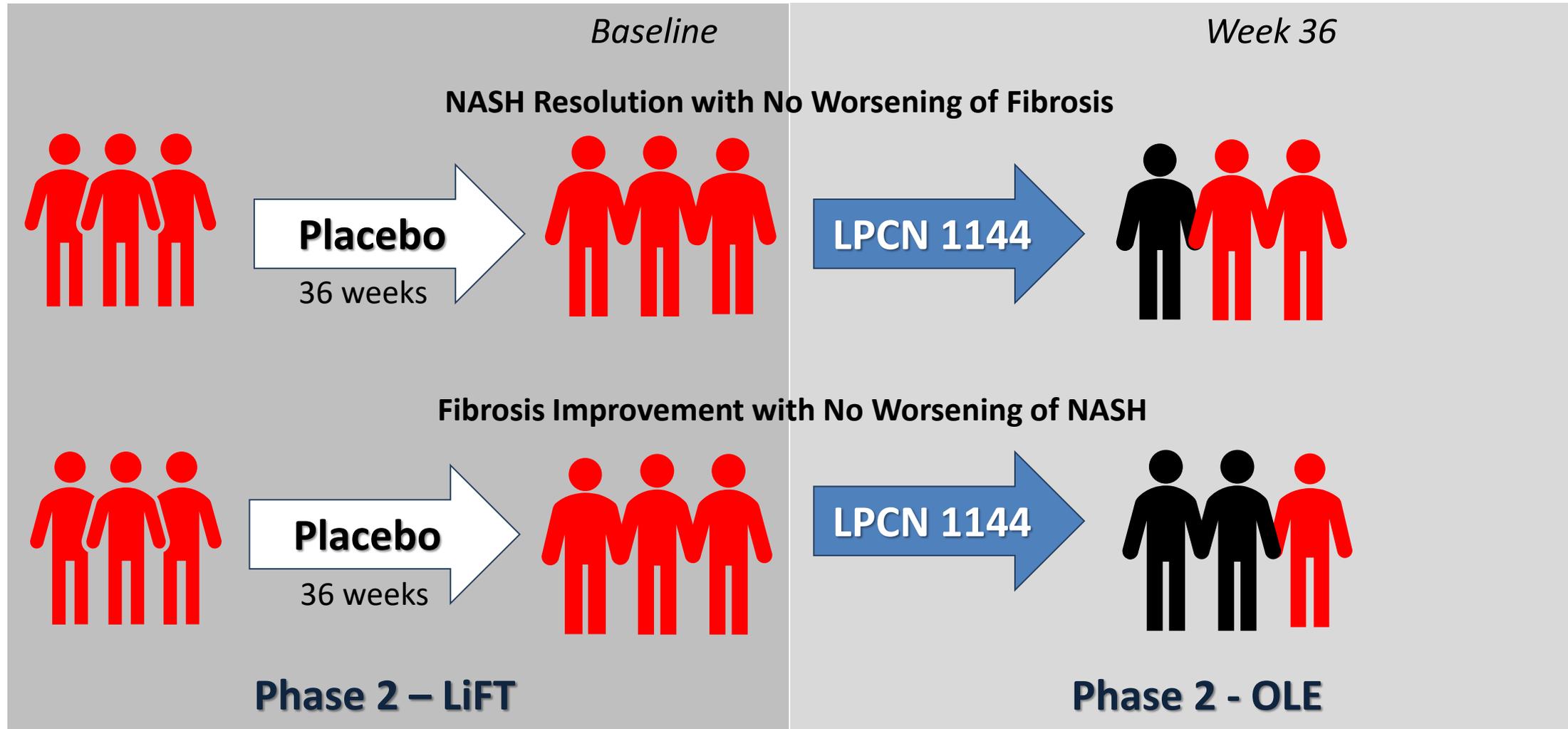
# Histological Changes\* in OLE Subjects with EOS Biopsy

Extended LPCN 1144 treatment subjects



# Histological Changes\* in OLE Subjects with EOS Biopsy

Subjects Initiated LPCN 1144 Treatment after Placebo Run-In



# Summary

## Positive LPCN 1144 NASH Open Label Extension Study Results



Well tolerated over 72-week exposure with no observed safety signals



Liver injury markers were reduced significantly and maintained with extended treatment



Observed liver histology improvements support further development