

Ascletis Pharma(HK.1672)

2023 Annual Results

April 3rd 2024





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Contents

- Overview of 2023 Results
- Pipeline Highlights
- Summary & Outlook

Overview of 2023 Results

Overview of 2023 Results

Pipeline

Milestones Achieved from 2023 To Date

| | |
|------------|---|
| ASC40 Acne | PhII met primary and secondary endpoints, Phase III enrollment is ongoing |
| ASC22 HBV | Positive Interim Data from Phase IIb Expansion Cohort |
| ASC40 rGBM | Over 120 patients enrolled in Phase III |
| ASC40 NASH | Positive topline results from Phase 2b trial in biopsy-confirmed F2/F3 NASH |
| ASC41 NASH | Positive Phase II interim results:93% pts achieved ≥30% liver fat decrease |

Innovation Committed

- R&D exp.~220mm RBM in 2023
- Focus on pipeline with FIC/BIC potential
- Strengthen the advantages in liver and metabolism diseases

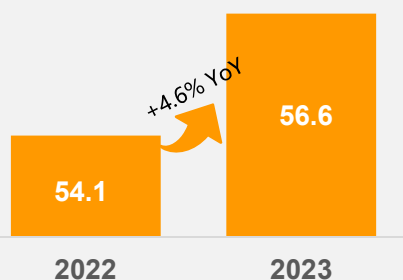


Efficient Operation

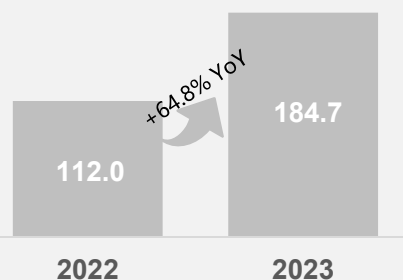
- Continued efforts on efficiency
- Admin exp. decrease as lean operation in place
- Sufficient cash secures operation and R&D in next 5 yrs

Financials mm RMB

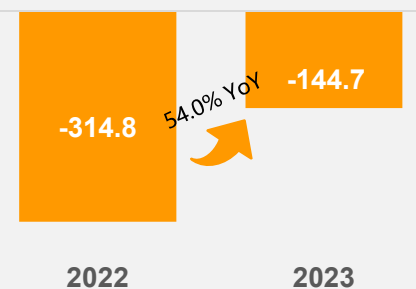
Revenue



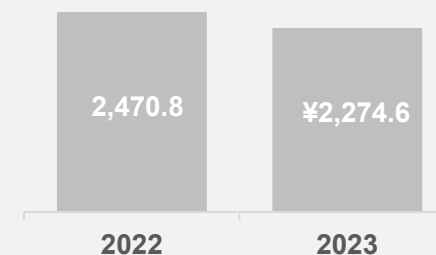
Other Income and Gains



Loss



Cash& Equivalents*



*As of Dec .31 2023

Pipeline Updates

ASC41: 52-week Phase II Study in Biopsy-confirmed NASH patients*



Primary Objective

To evaluate the efficacy of ASC41 tablet in biopsy-confirmed noncirrhotic NASH patients by a histological reduction in NAS ≥ 2 points that results from reduction of necro-inflammation (inflammation or ballooning) without worsening fibrosis.

Secondary objectives

1. NASH resolution; 2. Fibrosis improvement.

*Phase II study protocol was agreed by both US FDA and China NMPA

**Pre-specified interim analysis conducted when 42 patients completed 12-week treatment of ASC41/placebo.

Summary of Interim Week 12 Data from 52-Week ASC41 Tablet Study

■ Mean liver fat reduction

Up to **68.2%** mean liver fat reduction from baseline in biopsy-confirmed NASH patients receiving 12-week treatment of ASC41 tablet

■ ALT Reduction

At Week 12, placebo-adjusted mean reductions in alanine aminotransferase (ALT) from baseline was up to **37.8%**

■ Safety

Adverse events (AEs), including gastrointestinal (GI)-related AEs, were similar among the cohorts receiving ASC41 tablet treatment versus the placebo

■ Respond Rate

Up to **93.3%** patients achieved at least a 30% relative reduction in liver fat after 12-week treatment

■ AST Reduction

At Week 12, placebo-adjusted mean reductions in AST from baseline was up to **41.5%**

■ Lipids Decrease

At Week 12, placebo-adjusted mean reductions in LDL-C, TC and TG from baseline were up to

27.7%, 23.4%

and **46.5%**, respectively

Reduction in Liver Fat Content from Baseline at Week 12 by MRI-PDFF

| | Placebo (n = 14) | ASC41 Tablet | |
|---|---------------------|-----------------------------------|-----------------------------------|
| | | 2 mg, QD (n = 13) | 4 mg, QD (n = 15) |
| Mean baseline liver fat content | 18.2% | 17.8% | 18.9% |
| Mean relative change in liver fat content from baseline | -13.1% | -55.0% (p = 0.0001 vs placebo) | -68.2% (p < 0.0001 vs placebo) |
| Median relative change in liver fat content from baseline | -5.8% | -48.8% | -70.1% |
| Percentage of patients achieving ≥ 30% relative reduction in liver fat content from baseline | 21.4% | 92.3% (p = 0.0002 vs placebo) | 93.3% (p < 0.0001 vs placebo) |
| Percentage of patients achieving ≥ 50% relative reduction in liver fat content from baseline* | 21.4% | 46.2% (p = 0.24) | 86.7% (p = 0.0004) |
| Percentage of patients achieving normalized liver fat (≤5% absolute liver fat content)* | 0.0% | 30.8% (p = 0.16) | 66.7% (p = 0.0017) |

≥ 30% reductions in liver fat content is highly associated with patients achieving histologic improvement in NASH



Statistically Significant, Clinically Meaningful Reductions in ALT & AST at Week 12 Differentiate ASC41 from Other THR β Agonists In Development

| | Placebo (n = 14) | ASC41 Tablet | |
|--|---------------------|----------------------|------------------------|
| | | 2 mg, QD (n = 13) | 4 mg, QD (n = 15) |
| ALT | | | |
| Mean baseline ALT | 77.6 U/L | 65.9 U/L | 84.8 U/L |
| Mean relative change in ALT from baseline* | 5.2% | -8.5% (p = 0.61) | -32.6% (p = 0.0051) |
| Percentage of patients achieving mean ALT decrease > 17 U/L* | 21.4% | 30.8% (p = 0.68) | 73.3% (p = 0.0052) |
| AST | | | |
| Mean baseline AST | 47.9 U/L | 44.2 U/L | 53.8 U/L |
| Mean relative change in AST from baseline* | 17.3% | -3.6% (p = 0.67) | -24.2% (p = 0.041) |

Decline in ALT in NASH patients is associated with improvement in liver histology

*p-value vs placebo

Reduction in Lipids from Baseline at Week 12

| | Placebo (n = 14) | | |
|----------------------------------|---------------------|-----------------------------------|-----------------------------------|
| | | 2 mg, QD (n = 13) | 4 mg, QD (n = 15) |
| LDL-C, mean change from baseline | 4.3% | -19.4% (p = 0.0002 vs placebo) | -23.4% (p < 0.0001 vs placebo) |
| TC, mean change from baseline | 3.4% | -16.8% (p < 0.0001 vs placebo) | -20.0% (p < 0.0001 vs placebo) |
| TG, mean change from baseline | 3.9% | -30.6% (p = 0.0001 vs placebo) | -42.6% (p < 0.0001 vs placebo) |

- HDL-C remained unchanged from baseline among the cohorts receiving ASC41 tablet treatment or placebo.
- Reductions in these lipids improve a patient's overall cardiometabolic profile and may reduce the risk of cardiovascular-related events.

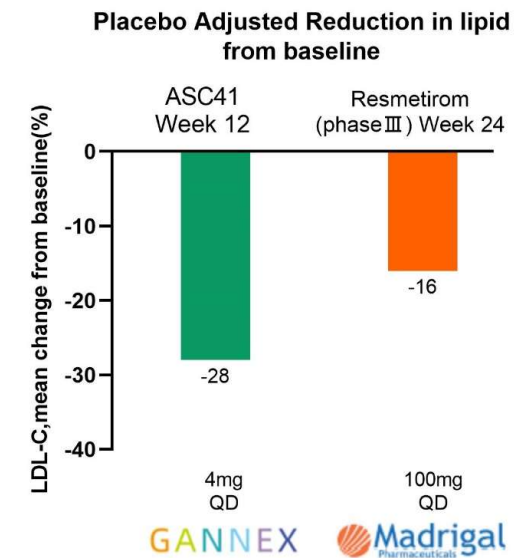
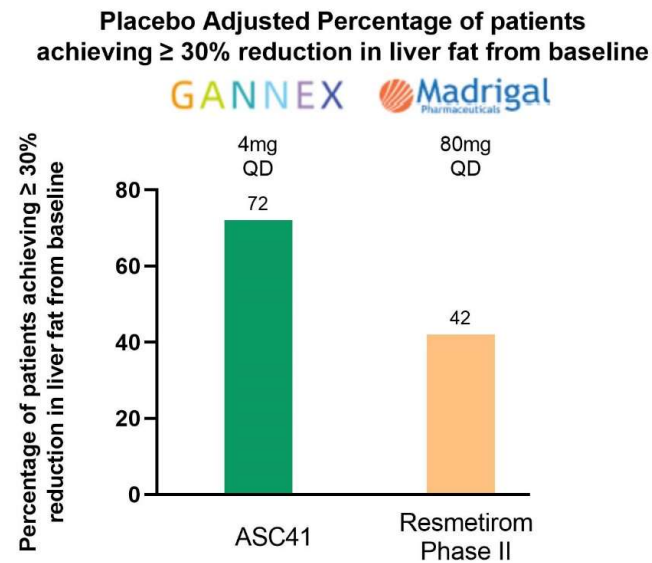
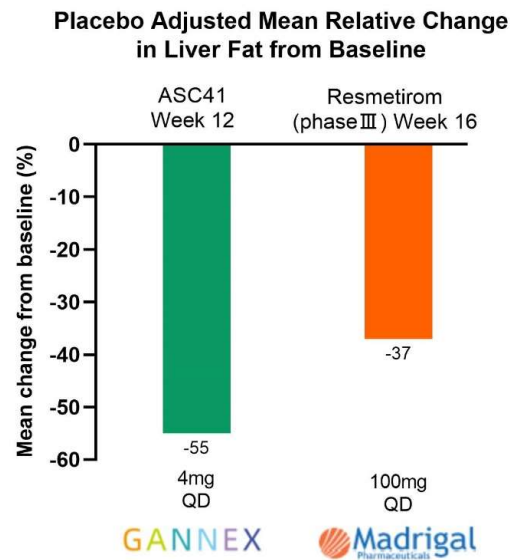
Safety and Tolerability

| | Placebo (n = 14) | ASC41 Tablet | |
|--|----------------------|----------------------|----------------------|
| | | 2 mg, QD (n = 13) | 4 mg, QD (n = 15) |
| TEAEs ^[1] Number of subjects (%) | 13(92.9%) | 13(100%) | 15(100%) |
| Drug-related TEAEs ^[2] | 6(42.9%) | 7(53.9%) | 7(46.7%) |
| Grade 1 | 6(42.9%) | 7(53.9%) | 7(46.7%) |
| Drug-related GI AEs | 2(14.3%) | 3(23.1%) | 1(6.7%) |
| Nausea | 0(0.0%) | 0(0.0%) | 0(0.0%) |
| Vomiting | 0(0.0%) | 0(0.0%) | 0(0.0%) |
| Diarrhea | 1(7.1%) | 3(23.1%) | 1(6.7%) |
| Abdominal distension | 1(7.1%) | 0(0.0%) | 0(0.0%) |
| Abdominal pain (upper) | 0(0.0%) | 0(0.0%) | 0(0.0%) |
| Constipation | 0(0.0%) | 0(0.0%) | 0(0.0%) |
| Dyspepsia | 0(0.0%) | 0(0.0%) | 0(0.0%) |
| Frequent bowel movements | 0(0.0%) | 0(0.0%) | 0(0.0%) |

- Levels of thyroid axis hormones, including thyroid stimulating hormone (TSH), free triiodothyronine (fT3) and free thyroxine (fT4) were relatively unchanged from baseline among the cohorts receiving ASC41 tablet treatment versus the placebo.
- Changes in vital signs and electrocardiogram (ECG) were similar among patients receiving ASC41 tablet treatment versus placebo.

[1]Data as of November 22, 2023;[2] Deemed by investigator as possibly, probably, or definitely related to study drug

THRβ Agonists: ASC41 vs Resmetirom

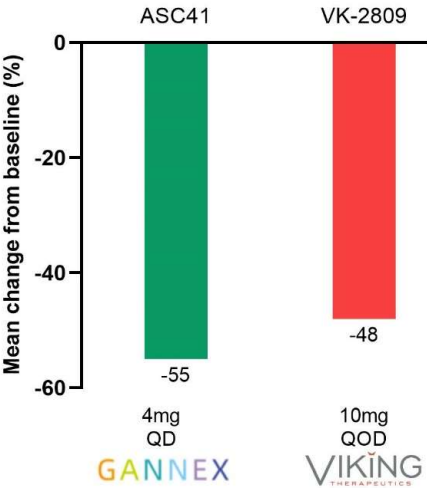


[1] Week 12 data from 36-week phase 2 and 52-week phase 3
 [2] NA:Not available

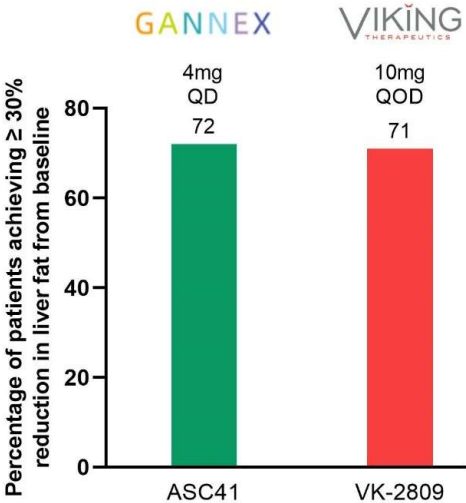
Resmetirom: Stephen A. Harrison, et al. EASL 2023 abstract number GS-001; Harrison, S. A., et al.[J] Lancet, (2019).DOI: 10.1016/s0140-6736(19)32517-6

THRβ Agonists : ASC41 vs VK2809:

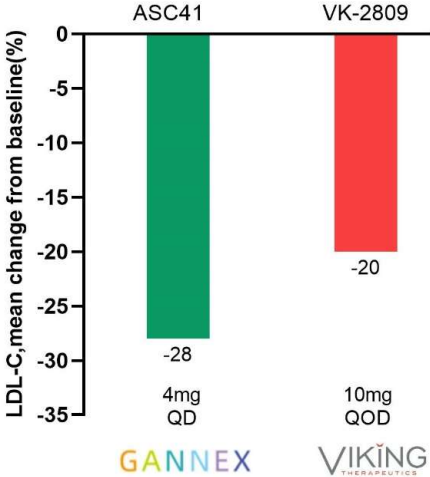
Placebo Adjusted Mean Relative Change in Liver Fat from Baseline (MRI-PDFF at Week 12)



Placebo Adjusted Percentage of patients achieving ≥ 30% reduction in liver fat from baseline



Placebo Adjusted Reduction in lipid from baseline at Week 12

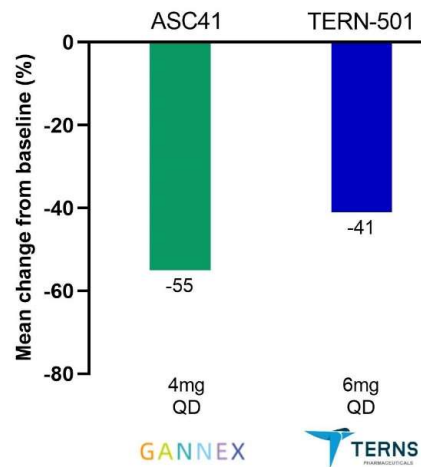


[1]Viking press release, May 2023
[2]NA:Not available

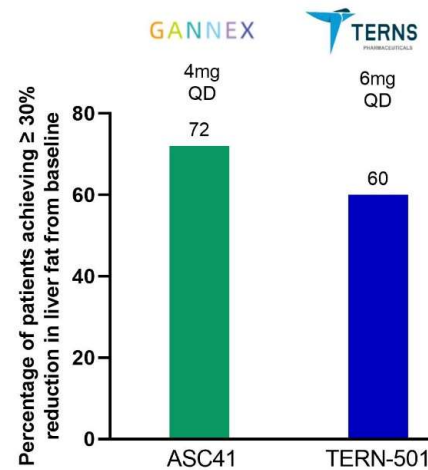
VK-2809: Rohit Loomba, et al. AASLD 2023 abstract number 5016-C;<https://ir.vikingtherapeutics.com/2023-11-13-Viking-Therapeutics-Presents-New-Data-from-Phase-2b-VOYAGE-Study-of-VK2809-in-Patients-with-Biopsy-Confirmed-Non-Alcoholic-Steatohepatitis-NASH-at-The-Liver-Meeting-R-2023>;
<https://ir.vikingtherapeutics.com/corporatepresentation>, November 2023

THR β Agonists: ASC41 vs TERN-501

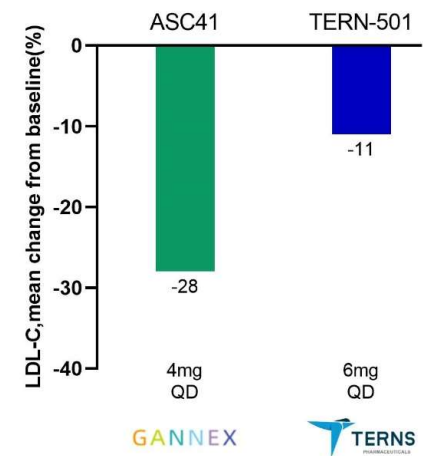
Placebo Adjusted Mean Relative Change
in Liver Fat from Baseline(MRI-PDFF at Week 12)



Placebo Adjusted Percentage of patients
achieving $\geq 30\%$ reduction in liver fat from baseline



Placebo Adjusted Reduction in lipid
from baseline at Week 12



[1] Terns press release, August 2023

[2] NA: Not available

TERN-501: <https://ir.ternspharma.com/events/event-details/terns-duet-top-line-results>

Favorable Reduction in Liver Inflammatory Biomarkers Compared to other THR β Agonists at 12 Weeks

| Placebo-adjusted mean reductions in liver inflammatory biomarkers from baseline at Week 12 | ASC41 tablet, stable at room temperature | Resmetirom tablet ^[1] , stable at room temperature | VK2809 Capsule ^[2] , stable only under refrigeration | Tern-501 ^[3] , formulation and storage condition unknown |
|--|---|---|---|---|
| ALT | Up to 37.8% (Statistically significant difference vs placebo) | No statistically significant difference vs placebo | Similar to placebo | Similar to placebo |
| AST | Up to 41.5% (Statistically significant difference vs placebo) | No statistically significant difference vs placebo | Similar to placebo | Similar to placebo |

[1] Week 12 data from 36-week phase 2 and 52-week phase 3

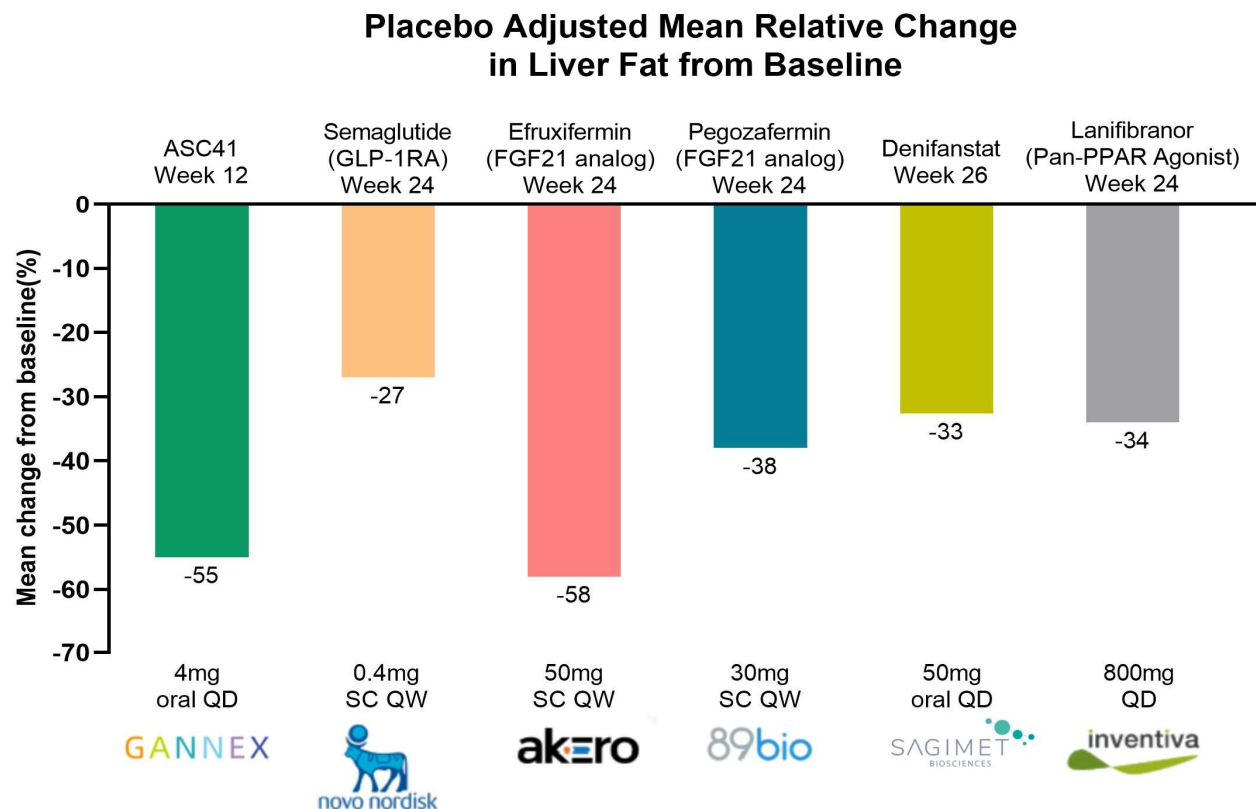
[2] Viking press release, May 2023

[3] Terns press release, August 2023

Favorable Safety Profile Compared to other THRβ Agonists

| | ASC41 tablet | | Resmetirom tablet Phase III | | VK2809 Capsule | | Tern-501 | |
|--|----------------------|----------------------|--------------------------------|---------------------|---------------------|--------------------|---------------------|------------------|
| | Placebo (n = 14) | 2mg/4mg QD (n=28) | Placebo (n = 321) | 100mg QD (n=323) | Placebo (n = 65) | 10mg QOD (n=61) | Placebo (n =24) | 6mg QD (n=22) |
| TEAEs Number of subjects(%) | 13(92.9%) | 28(100%) | 269 (92.2%) | 296 (91.6%) | 47(72.3%) | 54(88.5%) | NA | NA |
| Drug-related TEAEs | 6(42.9%) | 14(50%) | 86 (26.8%) | 134 (41.5%) | 22(33.8%) | 23(37.7%) | NA | NA |
| Drug-related TEAEs leading to study discontinuation | 0(0.0%) | 1(3.6%) | 8 (2.5%) | 22 (6.8%) | 5(7.7%) | 5(8.2%) | 1(4.2%) | 1(4.5%) |
| Drug-related GI AEs | 2(14.3%) | 4(14.3%) | NA | NA | 12(18.5%) | 7(11.5%) | 2(8.3%) | 2(9.1%) |
| Nausea | 0(0.0%) | 0(0.0%) | 40 (12.5%) | 62 (19.2%) | 5(7.7%) | 3(4.9%) | 0(0.0%) | 0(0.0%) |
| Diarrhea | 1(7.1%) | 4(14.3%) | 50 (15.6%) | 109 (33.7%) | 2(3.1%) | 3(4.9%) | 1(4.2%) | 1(4.5%) |
| Vomiting | 0(0.0%) | 0(0.0%) | 17 (5.3%) | 35 (10.8%) | NA | NA | 1(4.2%) | 0(0.0%) |
| Abdominal distension | 1(7.1%) | 0(0.0%) | NA | NA | NA | NA | 0(0.0%) | 0(0.0%) |

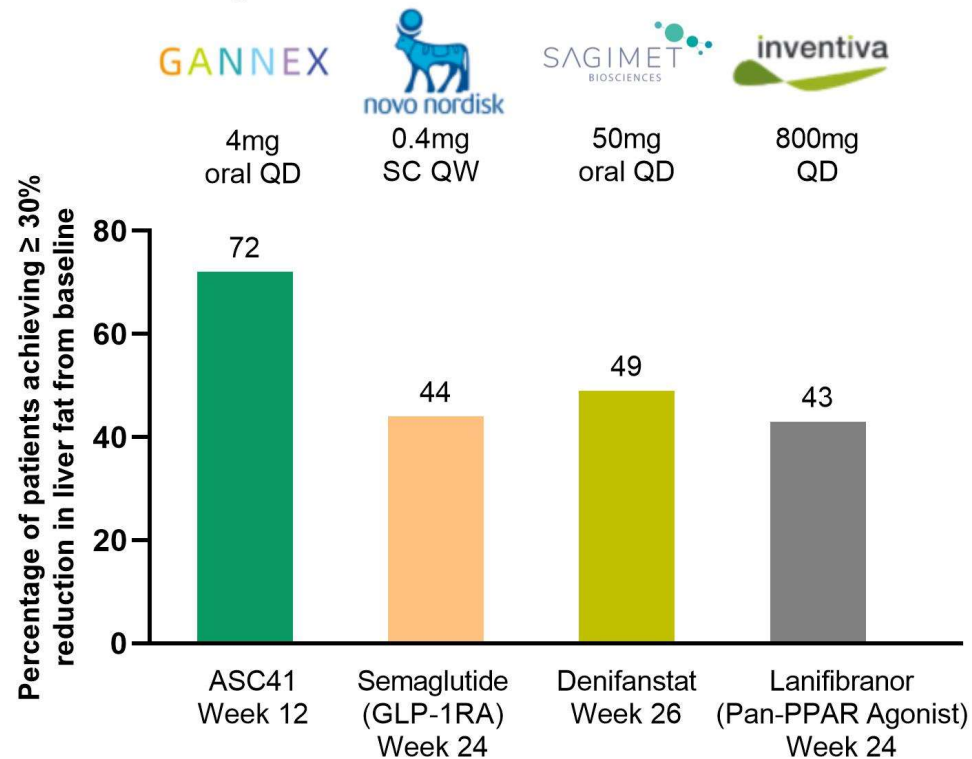
ASC41 vs GLP-1, FGF21, FASN and PPAR: Liver Fat Reduction



1. Semaglutide: Flint, A., et al.[J] Aliment Pharmacol Ther, (2021).DOI: 10.1111/apt.16608;
2. Efruxifermin: Stephen A. Harrison., et al. AASLD 2022 Abstract #39094;
3. Pegzofermin: <https://ir.89bio.com/news-releases/news-release-details/89bios-phase-2b-enliven-trial-pegzofermin-non-alcoholic>;
4. Denifanstat: Rohit Loomba, et al. EASL 2023 Abstract #OS-061;
5. Lanifibranor: <https://inventivapharma.com/wp-content/uploads/2023/06/IVA-Topline-results-lanifibranor-in-T2D-and-NASH-06282023.pdf>

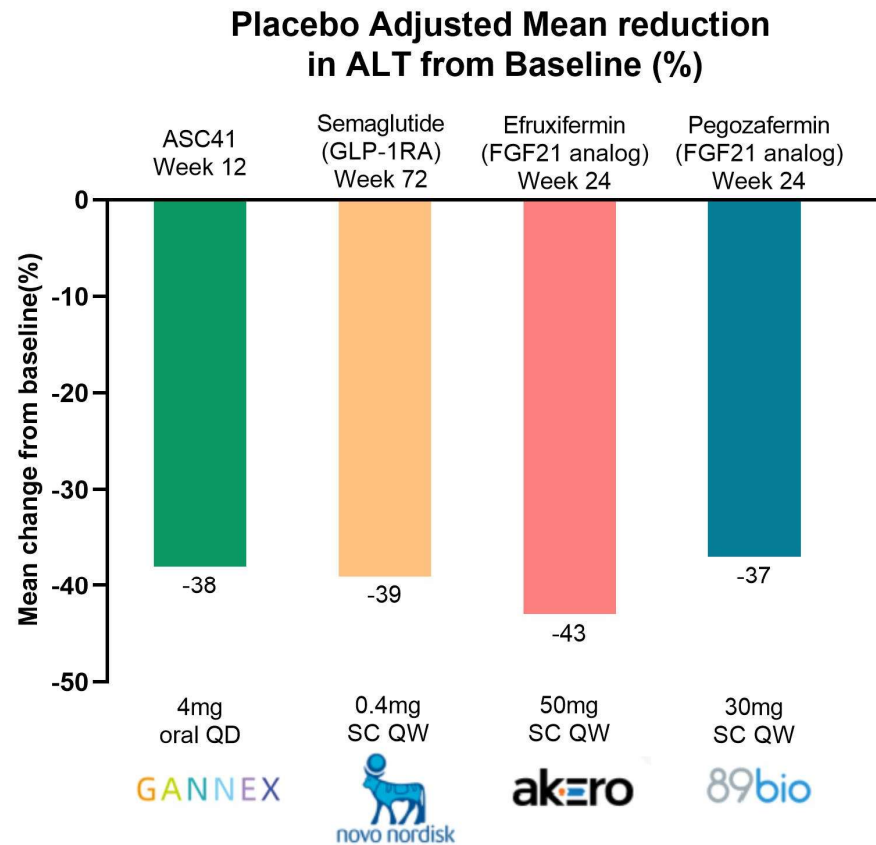
ASC41 vs GLP-1, FASN and PPAR: $\geq 30\%$ Liver Fat Reduction

Placebo Adjusted Percentage of patients achieving $\geq 30\%$ reduction in liver fat from baseline



1. Semaglutide: Flint, A., et al. [J] Aliment Pharmacol Ther, (2021). DOI: 10.1111/apt.16608;
2. Denifanstat: Rohit Loomba, et al. EASL 2023 Abstract #OS-061;
3. Lanifibranor: <https://inventivapharma.com/wp-content/uploads/2023/06/IVA-Topline-results-lanifibranor-in-T2D-and-NASH-D-06282023.pdf>

ASC41 vs GLP-1 and FGF21: Reduction in ALT



1. Semaglutide: Newsome, P. N., et al. [J] N Engl J Med, (2021). DOI: 10.1056/NEJMoa2028395;
2. Efruxifermin: Stephen A. Harrison., et al. AASLD 2022 Abstract #39094;
3. Pegzofermin: <https://ir.89bio.com/news-releases/news-release-details/89bios-phase-2b-enliven-trial-pegzofermin-nonalcoholic>;

Conclusions of ASC41 Interim Data



- Interim data in liver fat and lipids at Week 12 demonstrated ASC41 as a potential best-in-class THR β Agonist vs other THR β agonists currently at clinical or registration stages



- Statistically significant and clinical meaningful reductions in ALT and AST in patients receiving ASC41 tablet treatment notably differentiate ASC41 from other THR β agonists



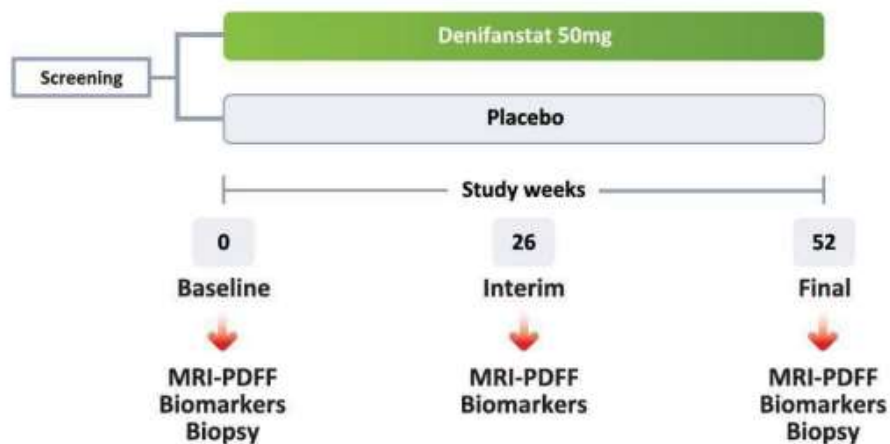
- ASC41 tablet showed excellent safety and tolerability profile, including GI.

Patents of ASC41

| | Application Date | Publication Number | Patents Applied | Patents Authorized | Pending |
|-----------------------------------|------------------|---|--------------------------|--------------------|--------------------|
| Formulation Patent(Tablet) | 2020/3/27 | US20210308155A1 (U.S.) CN115427022A (China) WO2021190624A1(PCT) | U.S., China and Globally | U.S. | China and Globally |
| Crystal Patent | 2020/9/30 | CN114315902A (China) WO2022067602A1 (Globally) | China and Globally | \ | China and Globally |
| Synthesis Patent | 2020/2/18 | US11292805B2 (U.S.) US20220332738A1 (U.S.) CN113336792A (China) | U.S. and China | U.S. | China |
| Composition Patent | 2021/7/6 | WO2023280152A1 (PCT) | U.S., China and Globally | \ | U.S., China |

ASC40(FASN)NASH | Phase IIb Clinical Trial Design

FASCINATE-2 Phase 2b trial design



- Biopsy confirmed F2-F3 NASH patients
- 52 weeks, 2:1 50mg or placebo, double-blind

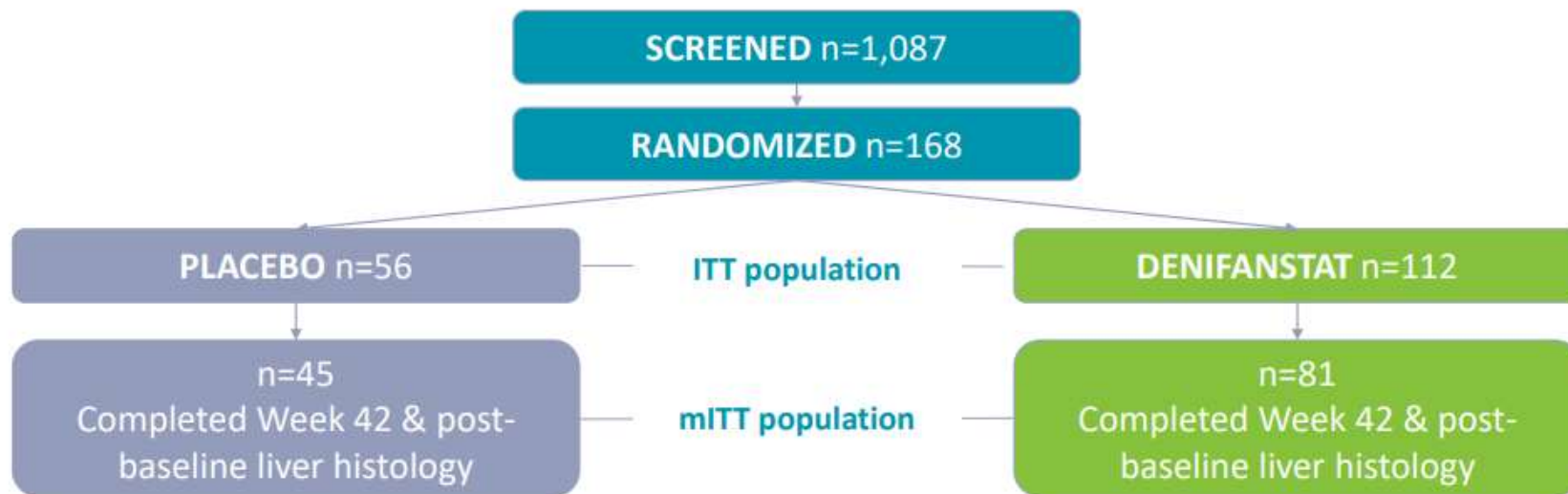
Primary endpoints

- NAS ≥ 2 points improvement w/o worsening of fibrosis OR
- NASH resolution + NAS ≥ 2 improvement w/o worsening of fibrosis

Other selected endpoints

- Improvement in liver fibrosis ≥ 1 stage without worsening of NASH (Bx)
- Digital AI pathology
- MRI-PDFF: absolute decrease, % change from baseline, % pts $\geq 30\%$ reduction from baseline (responders)

ASC40(FASN) NASH | Phase IIb Screening and Randomization



ASC40(FASN)NASH | Baseline

| Parameter | Placebo, n=45 | Denifanstat, n=81 |
|--------------------------------------|---------------------|---------------------|
| Age, years | 59.6 (+/- 10.9) | 56.1 (+/- 10.8) |
| Sex, female | 27 (60%) | 48 (59%) |
| Race, White | 41 (91%) | 73 (90%) |
| Ethnicity, Hispanic or Latino | 15 (33%) | 27 (33%) |
| BMI, kg/m ² | 36.5 (+/- 6.7) | 34.6 (+/- 6.1) |
| Type 2 diabetes | 27 (60%) | 55 (68%) |
| ALT (alanine aminotransferase) U/L | 67 (+/- 33) | 57 (+/- 29) |
| AST (aspartate aminotransferase) U/L | 52 (+/- 27) | 48 (+/- 29) |
| Liver Fat Content (MRI-PDFF), % | 19.0 (+/- 7.0) | 16.6 (+/- 7.1) |
| Baseline liver biopsy NAS ≥ 5 | 34 (76%) | 63 (78%) |
| Baseline liver biopsy F2/F3 | 22 (49%) / 23 (51%) | 34 (42%) / 47 (58%) |
| Statin (at baseline) | 21 (47%) | 38 (47%) |
| GLP1-RA (at baseline) | 4 (9%) | 12 (15%) |
| LDL, mg/dL | 103 (+/- 39) | 96 (+/- 34) |
| Triglycerides, mg/dL | 153 (+/- 67) | 173 (+/- 79) |
| ELF (Enhanced Liver Fibrosis) Score | 9.8 (+/- 0.8) | 9.6 (+/- 0.8) |
| FAST (Fibroscan AST) Score | 0.6 (0.19) | 0.6 (0.20) |

ASC40(FASN)NASH | Phase IIb Biopsy Results

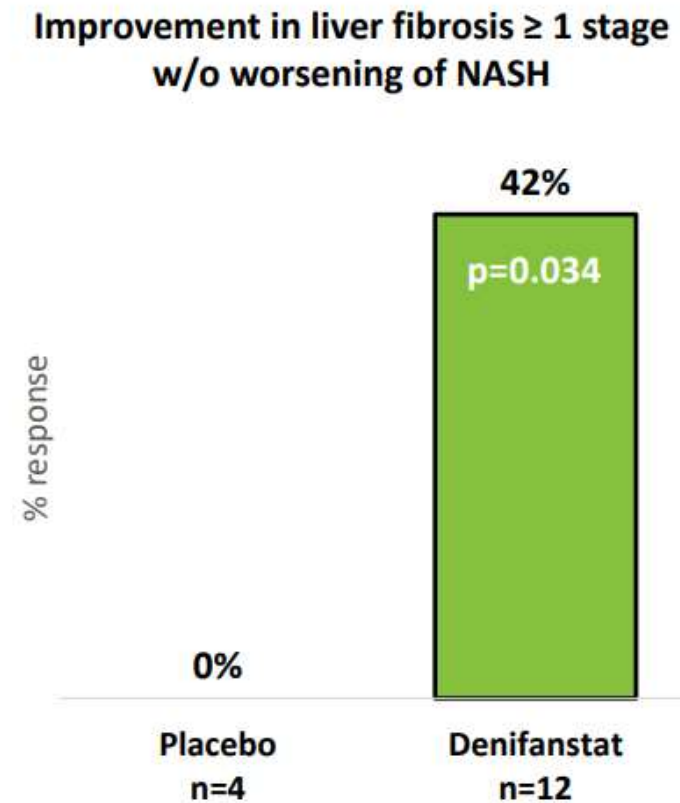
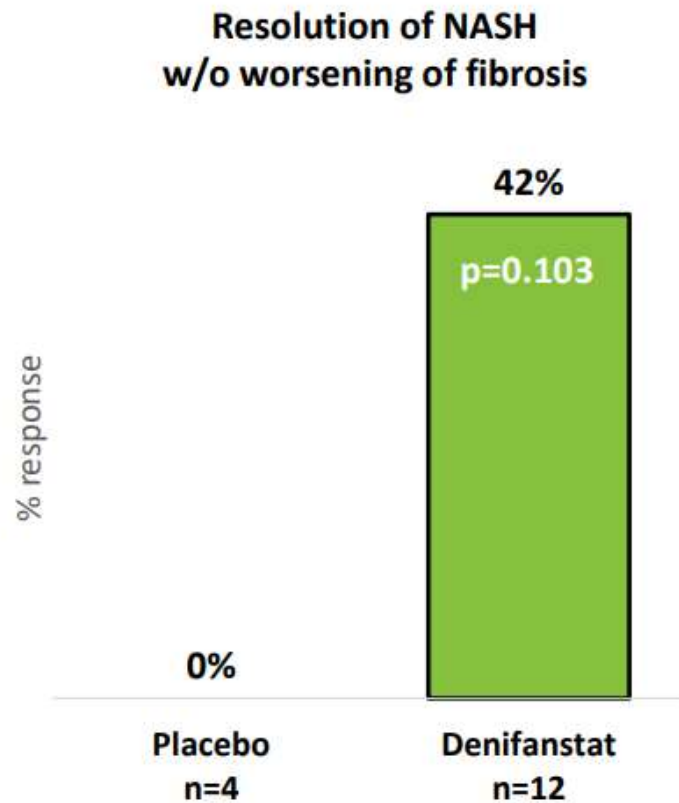
| | Placebo (n=45) | ASC40 50 mg (n=81) | Placebo adjusted | <i>P value</i> |
|---|-------------------|-----------------------|------------------|----------------|
| Primary Endpoints | | | | |
| NASH resolution + NAS ≥ 2 improvement w/o worsening of fibrosis | 13% | 36% | 23% | 0.0022 |
| NAS ≥ 2 points improvement* w/o worsening of fibrosis | 20% | 52% | 32% | 0.0001 |
| Other Endpoints | | | | |
| Improvement in liver fibrosis ≥ 1 stage w/o worsening of NASH | 18% | 41% | 23% | 0.0051 |
| Resolution of NASH w/o worsening of fibrosis | 16% | 38% | 22% | 0.0021 |
| AI Digital Pathology (qFibrosis)** | 0.1 | -0.3 | -0.4 | 0.0023 |
| ALT % from baseline | -17.2% | -30.5% | -13.3% | 0.0300 |
| MRI-PDFF respond rate (>30% reduction) | 21% | 65% | 44% | <0.0001 |
| FibroScan AST (FAST) 评分 | -0.1 | -0.3 | -0.2 | <0.0001 |
| LDL-C (mg/dL)*** | -9.1 | -19.1 | -10.0 | -- |

* ≥ 1 -point improvement in ballooning or inflammation.

**least squares mean. HistolIndex platform. mITT population.

***For LDL-c, baseline > 100 mg/dL.

ASC40(FASN)NASH | Patient Subset on Stable GLP1-RA at Baseline: Liver Biopsy ASC40 Improves NASH Resolution and Fibrosis



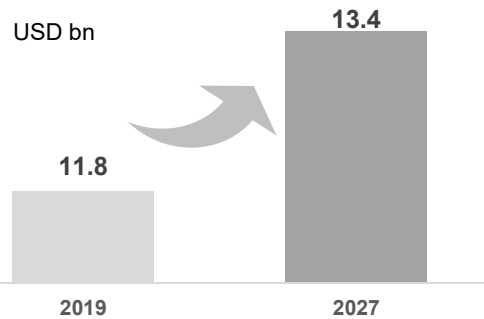
ASC40(FASN)NASH | Phase IIb Safety Profile

| Parameter | Placebo n=56 | Denifanstat N=112 |
|--|-----------------|----------------------|
| Any TEAE (treatment emergent adverse event) | 45 (80.4%) | 96 (85.7%) |
| TEAE related to study drug | 20 (35.7%) | 51 (45.5%) |
| Most common TEAE related to study drug in $\geq 5\%$ of patients by system organ class | | |
| eye disorders | 9 (16.1%) | 17 (15.2%) |
| gastrointestinal disorders | 5 (8.9%) | 13 (11.6%) |
| skin and subcutaneous tissue disorders | 4 (7.1%) | 25 (22.3%) |
| TEAE leading to study drug discontinuation | 3 (5.4%) | 22 (19.6%) |
| TEAE with CTCAE Grade 3 (Severe) or higher* | 3 (5.4%) | 13 (11.6%) |
| SAE (none related to treatment) | 3 (5.4%) | 13 (11.6%) |
| Fatal TEAE | 0 | 0 |

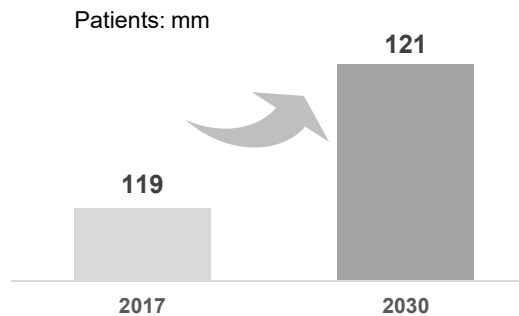
* No treatment-related AE was Grade 3 or higher

Acne: the Eighth Most Prevalent Disease with 640+ mm Patients Globally

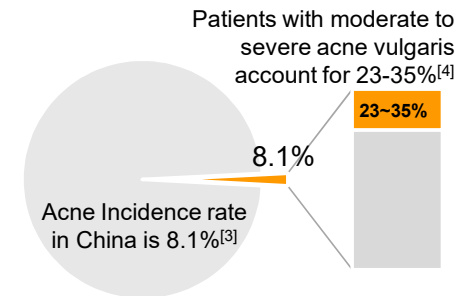
Global Acne Market Forecast^[1]



Acne Patients Growth in China^[2]



High Prevalence in China



Multiple Factors Contribute to the Incidence Rise^[2]

- Work and life pressure
- High sugar, spicy and greasy diet
- Pollution
- Unhealthy lifestyle
- endocrine disorder
- excessive sebum production
- inflammation

Limitations of Current Treatment

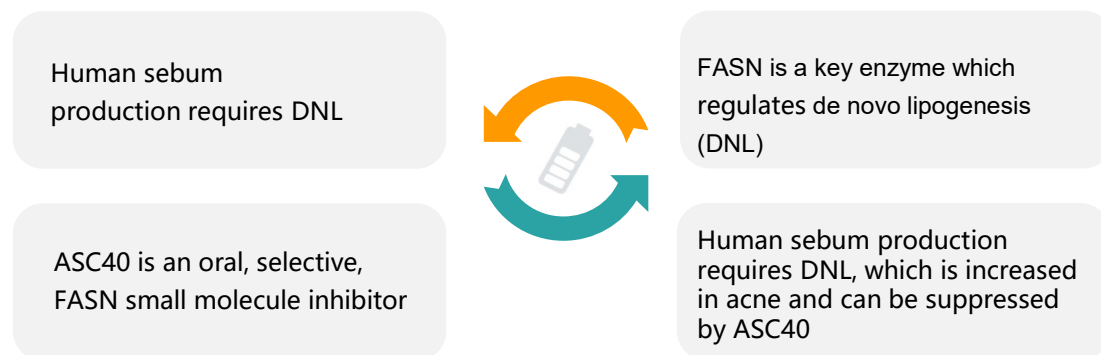
- Oral antibiotics**
 - antibiotic resistance^[5]
 - Side effects including GI reactions /rash/liver damage
- Oral isotretinoin** ^[5]
 - Over 10 kinds of side effects^[6]
 - Liver damage^[6]
- Topical medications**
 - Light sensitive
 - 30% to 40% of patients do not adhere to their topical treatments ^[7]

References:

- Allied Market Research
- Frost & Sullivan Report
- Li D, Chen Q, Liu Y, et al. BMJ Open. 2017 Apr;7(4):e015354. DOI: 10.1136/bmjopen-2016-015354.
- Shen Y, Wang T, Zhou C, et al. Acta Derm Venereol. 2012;92(1):40-44. doi:10.2340/00015555-1164
- Guideline for Diagnosis and Treatment of Acne (The 2019 Revised Edition)
- Brzezinski P, Borowska K, Chiriac A, Smigielski J. Dermatol Ther. 2017;30(4):10.1111/dth.12483. doi:10.1111/dth.12483
- Purvis CG, Balogh EA, Feldman SR. Ann Pharmacother. 2021;55(10):1297-1299.

ASC40 (FASN) for Acne: Phase III Clinical Trial Initiated in Dec 2023

ASC40: Innovative Mechanism for Acne Treatment



ASC40 Acne Phase III Trial

- Phase III trial of ASC40 initiated in Q4, 2023
- Plan to enroll 480 pts in China



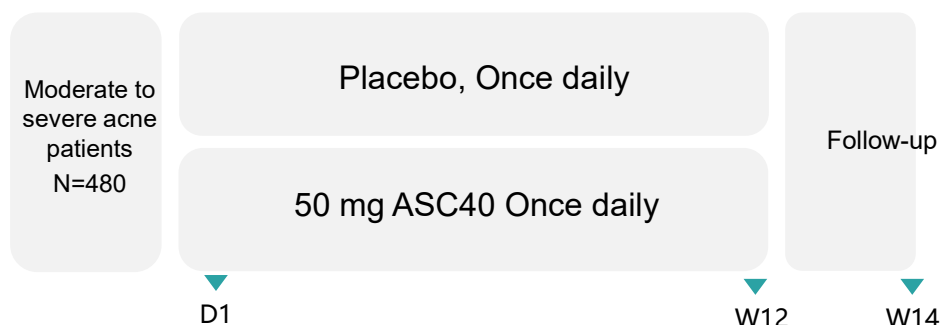
China's top dermatology clinical center –Huashan Hospital, Fudan University– leads the study

1.Guideline for Diagnosis and Treatment of Acne (The 2019 Revised Edition)

Inclusion Criteria

- ◆ 18-40 years old (including 18 and 40); baseline IGA score of 3-4
- ◆ Subjects should have facial lesions counted as follows:
Inflammatory lesions 30~75 (30 ~ 75 papules, pustules, and nodules, among which no more than 2 nodules)
- ◆ Non-inflammatory lesions 30 ~ 100 (30 ~ 100 open and closed pimples)

Phase III Clinical Trial Design




Primary Endpoints


- ◆ % change in total lesion count from baseline at week 12 of the treatment
- ◆ % change in inflammatory lesion count from baseline at week 12 of the treatment
- ◆ % of patients with a decrease of ≥ 2 points from baseline in the investigator's overall static score (IGA) and reached 0 or 1 point at week 12 of the treatment

Placebo Adjusted Efficacy of 50 mg ASC40, Oral, Once daily is Superior to Placebo Adjusted Efficacy of 1% Clascoterone cream, twice daily for 12 weeks

| Endpoints | 50 mg ASC40, oral, once daily (n=44), placebo adjusted | 1% Clascoterone cream twice daily for 12 weeks, placebo adjusted | |
|---|--|--|-----------|
| | Phase II | Phase II | Phase III |
| % change from baseline in total lesion count at week 12 [§] (primary endpoint) | -27.1 | NA | -11.9 |
| % change from baseline in inflammatory lesion count at week 12 [§] (key secondary endpoint) | -33.6 | -13.4 | -12.8 |
| Absolute change from baseline in inflammatory lesion count at week 12 (key secondary endpoint) | -13 | -3.2 | -5.6 |
| % Treatment success at week 12 | 14.3 | 7.5 | 11.6 |

 **Efficacy:** Compared to placebo, all ASC40 groups (25, 50 and 75 mg) showed statistically significant benefits to acne patients in % change from baseline in total (primary) and inflammatory (key secondary) lesion counts at week 12

 **Safety:** At all doses, oral ASC40 with once-daily, 12-week treatment was safe and well tolerated

 **In Comparison with Winlevi® :** 1%, twice daily, placebo adjusted efficacy of 50 mg ASC40, oral, once daily is superior to Winlevi® in terms of % change from baseline in total and inflammatory lesion counts at week 12 as well as % treatment success at week 12

Safety Data Analysis: ASC40 (FASN) for Acne is Safe and Well Tolerated

| Category | 25mg dose group (n=45) | | 50mg dose group (n=44) | | 75 mg dose group (n=45) | | Placebo group (n=45) | |
|--|---------------------------|--------------|---------------------------|--------------|----------------------------|--------------|-------------------------|--------------|
| | Number | Incidence(%) | Number | Incidence(%) | Number | Incidence(%) | Number | Incidence(%) |
| Drug-related TEAE | 22 | 48.89% | 21 | 47.73% | 28 | 62.22% | 22 | 48.89% |
| Drug-related TEAE of severity Grade 3 or higher | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% |
| Drug-related severe adverse event (SAE) | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% |
| Drug-related TEAE leading to discontinuation of the study drug | 1 | 2.22% | 1 | 2.27% | 3 | 6.67% | 0 | 0.00% |
| Drug-related TEAE leading to subject withdrawal from the study | 1 | 2.22% | 0 | 0.00% | 3 | 6.67% | 0 | 0.00% |
| Drug-related TEAE leading to death | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% |

TEAE: treatment-emergent adverse event.

Sarecycline Phase II vs ASC40 Phase II in ILC & NILC

| Parameters | Sarecycline (1.5mg/kg) | ASC40 (50mg) | |
|--|---------------------------|--------------------|------------------|
| | Phase 2, LSM[1] | Phase 2, Median[2] | Phase 2, Mean[2] |
| Patient number | 70 | 44 | 44 |
| change from baseline in percentage ILC: vs PBO, % | 52.7 vs 38.3 | 65.0 vs 31.4 | 56.7 vs 36.5 |
| p | 0.02 | 0.003 | 0.003 |
| change from baseline in absolute ILC: ILC vs PBO | 16.9 vs 12.5 | 26 vs 13 | 24.9 vs 15.3 |
| p | 0.03 | 0.003 | 0.003 |
| change from baseline in percentage NILC: vs PBO, % | 37.5 vs 35.2 | 58.0 vs 42.9 | 46.6 vs 35.0 |
| p | 0.68 | 0.113 | 0.113 |
| change from baseline in absolute NILC: ILC vs PBO | 19.4 vs 17.9 | 28.5 vs 24.0 | 28.5 vs 22.1 |
| p | 0.63 | 0.196 | 0.196 |

Sarecycline is an oral, tetracycline derivatives antibiotic acne drug developed by Almirall . It was launched in the US in October 2018 and is mainly used to treat patients aged 9 years and older with moderate to severe acne vulgaris

ILC: Inflammatory Lesion Counts; NILC: Non-Inflammatory Lesion Counts; LSM: least squared mean; NA: not available; CSR: clinical study report; PR: from press release.

[1]. Leyden, J. J., et al.[J] J Drugs Dermatol, (2018); [2] Data from CSR;

Sarecycline Phase III vs ASC40 Phase II in ILC & NILC

| Parameters | Sarecycline (1.5mg/kg) | | ASC40 (50mg) | |
|--|---------------------------|------------------------|--------------------|------------------|
| | SC1401 Phase3, Mean[1] | SC1402 Phase3, Mean[1] | Phase 2, Median[2] | Phase 2, Mean[2] |
| Patient number | 483 | 519 | 44 | 44 |
| change from baseline in percentage ILC: vs PBO, % | 52.2 vs 35.2 | 50.8 vs 36.4 | 65.0 vs 31.4 | 56.7 vs 36.5 |
| p | <0.001 | <0.001 | 0.003 | 0.003 |
| change from baseline in absolute ILC: ILC vs PBO | 15.3 vs 10.2 | 15.5 vs 11.1 | 26 vs 13 | 24.9 vs 15.3 |
| p | <0.001 | <0.001 | 0.003 | 0.003 |
| change from baseline in percentage NILC: vs PBO, % | 25.1 vs 22.2 | 28.5 vs 22.5 | 58.0 vs 42.9 | 46.6 vs 35.0 |
| p | 0.579 | NA | 0.113 | 0.113 |
| change from baseline in absolute NILC: ILC vs PBO | 14.7 vs 11.2 | 16.6 vs 14.7 | 28.5 vs 24.0 | 28.5 vs 22.1 |
| p | 0.001 | NA | 0.196 | 0.196 |

ILC: Inflammatory Lesion Counts; NILC: Non-Inflammatory Lesion Counts; LSM: least squared mean; NA: not available; CSR: clinical study report; PR: from press release.

[1]. Sarecycline review file 209521Orig1s000

[2]. Data from CSR;

rGBM: Huge Unmet Medical Needs Globally



GBM: One of the Most Malignant

48%

GBM as 48% of total CNS cancer

15k^[1]

Incidence in US

40~64k^[2]

Incidence in China

~100%^[2]

Recurrent rate

5.8%^[3]

5yr survival rate

12~14 months^[3]

Median OS

WHO IV

High malignant grade

No SoC

For rGBM patients

SoC: standard of care



MoA of FASN: Lipid Metabolism^[4]

- Tumor cells rely on de novo synthesis of fatty acids for growth
- FASN plays a crucial role in maintaining energy metabolism and cell membrane structural homeostasis in tumor cells
- FASN is the only enzyme in the human body that can convert glucose metabolites to palmitate
- Palmitate saturated fatty acids are important components of the growth chain, polyunsaturated fatty acids, and essential components of cell signaling
- FASN is highly expressed in a variety of tumors, supports tumor cell growth and proliferation, and is associated with tumor invasion

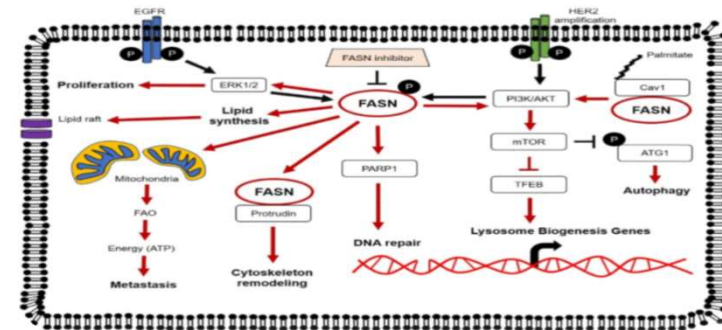


rGBM Treatments are Limited

- **Surgical resection** : *lack of high-level evidence-based medical evidence for the benefit of surgical treatment of recurrent glioma*
- **Radiation therapy**: *radiation may cause severe brain damage*
- **chemotherapy**: *no standard chemotherapy for rGBM patients*
- **TTF**: *no OS improvement compared with chemotherapy^[6], low affordability*



FASN Plays A Key Role in Cancer^[5]



(Molecules. 2020 Sep; 25(17): 3935.)

1. Ostrom, Quinn T et al. "CBTRUS Statistical Report: Primary Brain and Other Central Nervous System Tumors Diagnosed in the United States in 2015-2019." Neuro-oncology vol. 24, Suppl 5 (2022): v1-v95. doi:10.1093/neuonc/noac202
2. 中国卫健委, 脑胶质瘤诊疗指南 (2022年版)
3. Stupp R, Mason W P, van den Bent M J, et al. Radiotherapy plus concomitant and adjuvant temozolomide for glioblastoma [J]. Kelly, William et al.
4. Tan A C, Ashley D M, Lopez G Y, et al. Management of glioblastoma: State of the art and future directions [J]
5. Fhu CW, Ali A.):3935. doi:10.3390/molecules25173935
6. Stupp R, Wong ET, Kanner AA, et al. NovoTTF-100A versus physician's choice chemotherapy in recurrent glioblastoma: a randomised phase III trial of a novel treatment modality. Eur J Cancer. 2012;48(14):2192-2202

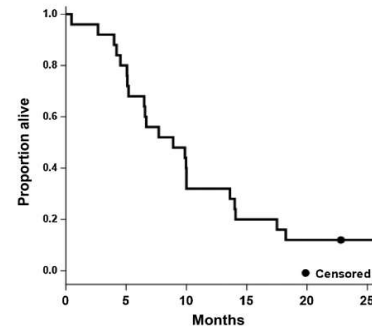
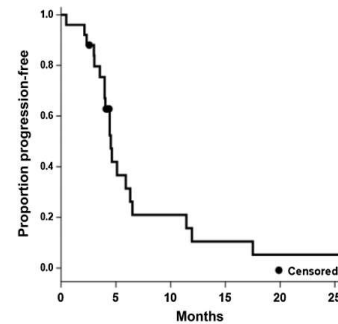
ASC40(FASN) for rGBM: Phase III Interim Analysis Expected in 2H 2024

ASC40(TVB-2640)+BEV Phase II Study^{[1]*}

Objective Response Rate 56%
Complete Response 17%
Partial Response 39%^[1]

- 25 patients enrolled
- All treated with ASC40 (TVB-2640) (100 mg/m² PO QD) plus BEV (10 mg/kg IV D1, 15) until disease progression or toxicity was intolerable

Phase II Results: mPFS=4.6, mOS=8.9

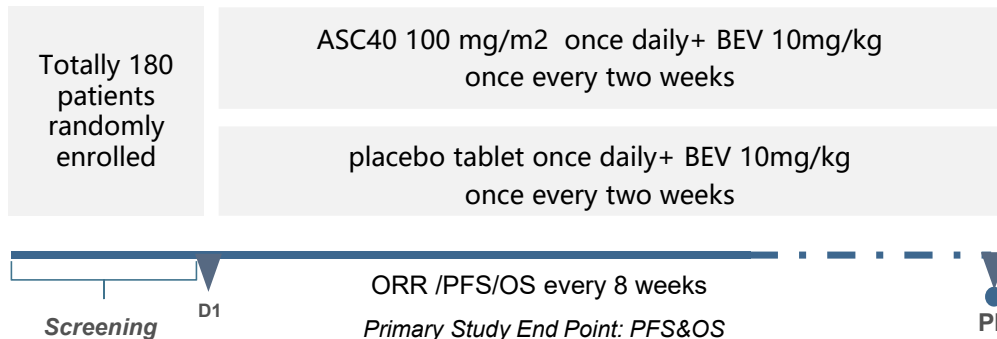


PFS6 Improvement & Safety

- **PFS6=31.4%**, representing a statistically significant improvement in PFS over the historical Bevacizumab monotherapy PFS of 16% (BELOB Trial) (P=0.008)
- **Safe and tolerated:** ASC40 (TVB-2640) in combination with BEV was safe and well tolerated for the treatment of rGBM pts
- Results have been published on **CLINICAL CANCER RESEARCH**

Clinical Phase III Trial of ASC40 + BEV to Treat rGBM

Study Design



China's prestigious brain cancer center--Beijing Tiantan Hospital--leads the study. Other 28 top-tier hospitals participated in clinical research



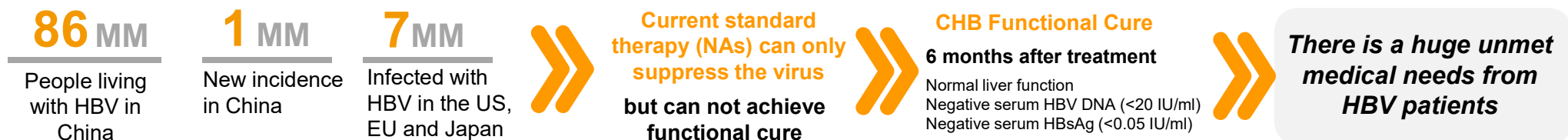
120 patients enrollment --the basis for pre-planned interim analysis (93 PFS events)-- completed as of Q3,2023



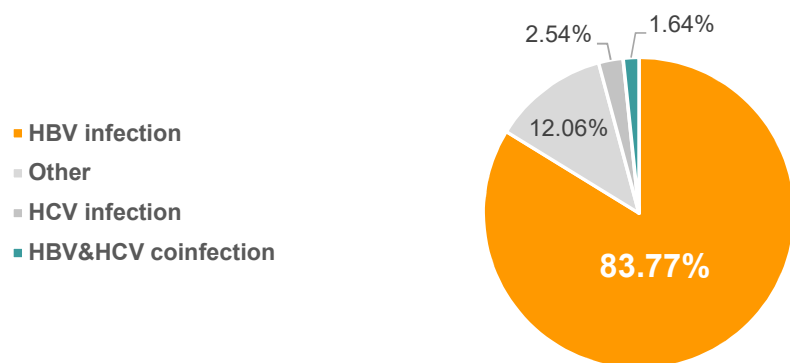
If Phase III interim results shows PFS is significant improved, ASC40 for rGBM may obtain the conditional approval

1. Kelly, William et al. "Phase II Investigation of TVB-2640 (denifanstat) with Bevacizumab in Patients with First Relapse High-Grade Astrocytoma." *Clinical cancer research: an official journal of the American Association for Cancer Research*, CCR-22-2807.

ASC22(PD-L1) for Chronic Hepatitis B Functional Cure

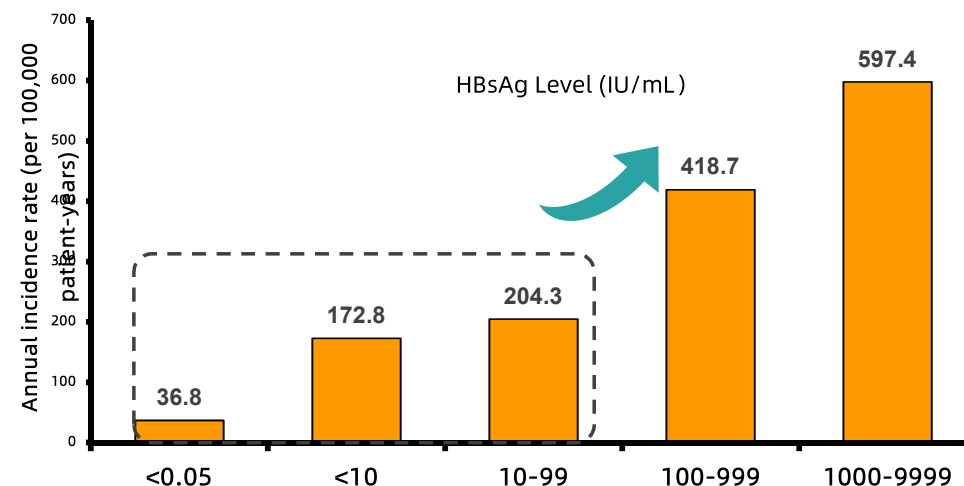


HBV Infection is the Leading Cause of liver cancer



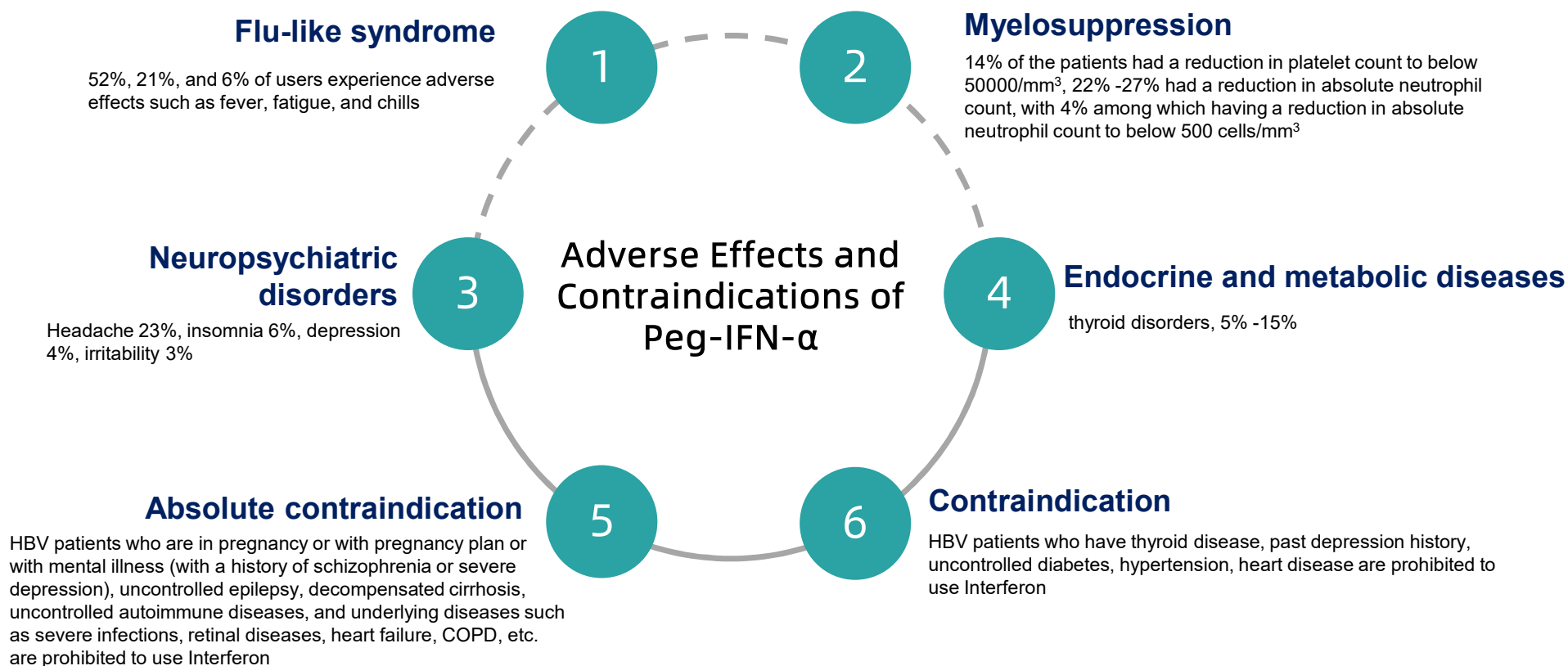
- ◆ The relative risk of HCC in patients with chronic HBV is **14~223** times higher than in the normal population¹
- ◆ The lifetime HCC prevalence in HBV carriers ranges from 10% to 25%²
- ◆ Over 80%³ HCC patients in China are caused by HBV infection

Patients with low HBsAg levels remain at high risk of hepatocellular carcinoma (HCC)



1.Mak LY, et al. Am Soc Clin Oncol Educ Book. 2018. ;
 2.McGlynn KA. Clin Liver Dis. 2015 May ; 19(2): 223-238.
 3.秦叔逵, 中国原发性肝癌临床登记调查 (CLCS) 的中期报告, 2020CSCO

Interferon: Various Adverse Effects and Contraindications When Used for HBV



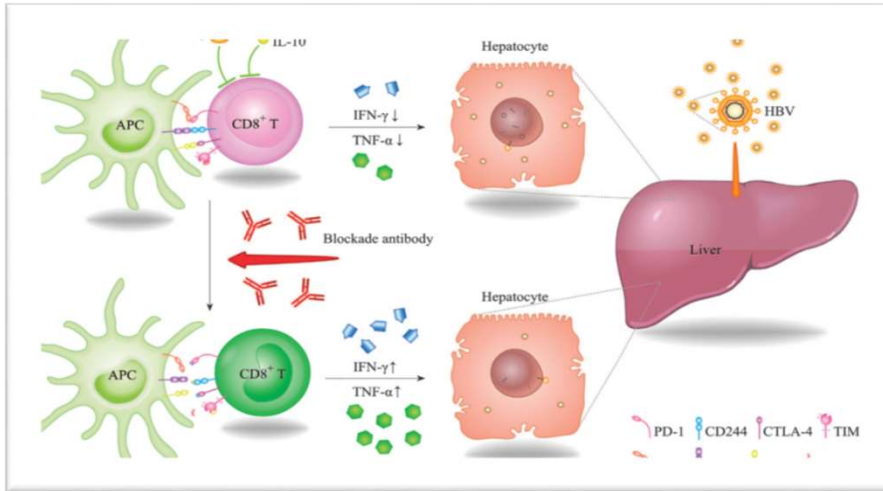
1. Chinese Journal of Infectious Diseases, 2023,41(1) : 3-28.

2. From the specification of Peginterferon α-2a

3. Expert Committee on Clinical Management of Adverse Reactions of Interferon-α Therapy for Chronic Viral Hepatitis [J] Chinese Journal of Experimental and Clinical Infectious Diseases (Electronic Edition), (2014).

21.6% Patients (Baseline HBsAg≤100) Achieved HBsAg Loss at End of 24-Wk Treatment

Mechanism of PD-1/PD-L1 Pathway for Treatment of CHB



ASC22 is the Leading Candidate of PD-1/PD-L1 for CHB Treatment

| Pipeline | Company | Target | Clinical stage | Clinical trial No. |
|--------------------|-----------|-------------------------------|----------------|---------------------|
| ASC22 | Ascleitis | PD-L1 | Phase IIb | NCT04465890 |
| RG6084 (RO7191863) | Roche | CpAM/TLR7/siRNA/PEG-IFN/PD-L1 | Phase II | NCT0422571 |
| GS4224 | Gilead | PD-L1 | Phase I | ACTRN12618001957280 |
| AB-101 | Arbutus | PD-L1 | Phase I | NCT05960240 |
| ARB-272572 | Arbutus | PD-1 | Pre-IND | NA |
| ALG-093453 | Aligos | PD-L1 | Pre-IND | NA |
| ALG-093702 | Aligos | PD-L1 | Pre-IND | NA |

ASC22 Phase IIb Expansion Cohort: enrolled 49 patients with baseline HBsAg≤100 IU/mL

| | |
|-------------------------------|-----------|
| 1.0mg/kg ASC22 Q2W+NAs (n=40) | Follow-Up |
| Placebo Q2W+NAs (n=9) | Follow-Up |

D0

W24

W48

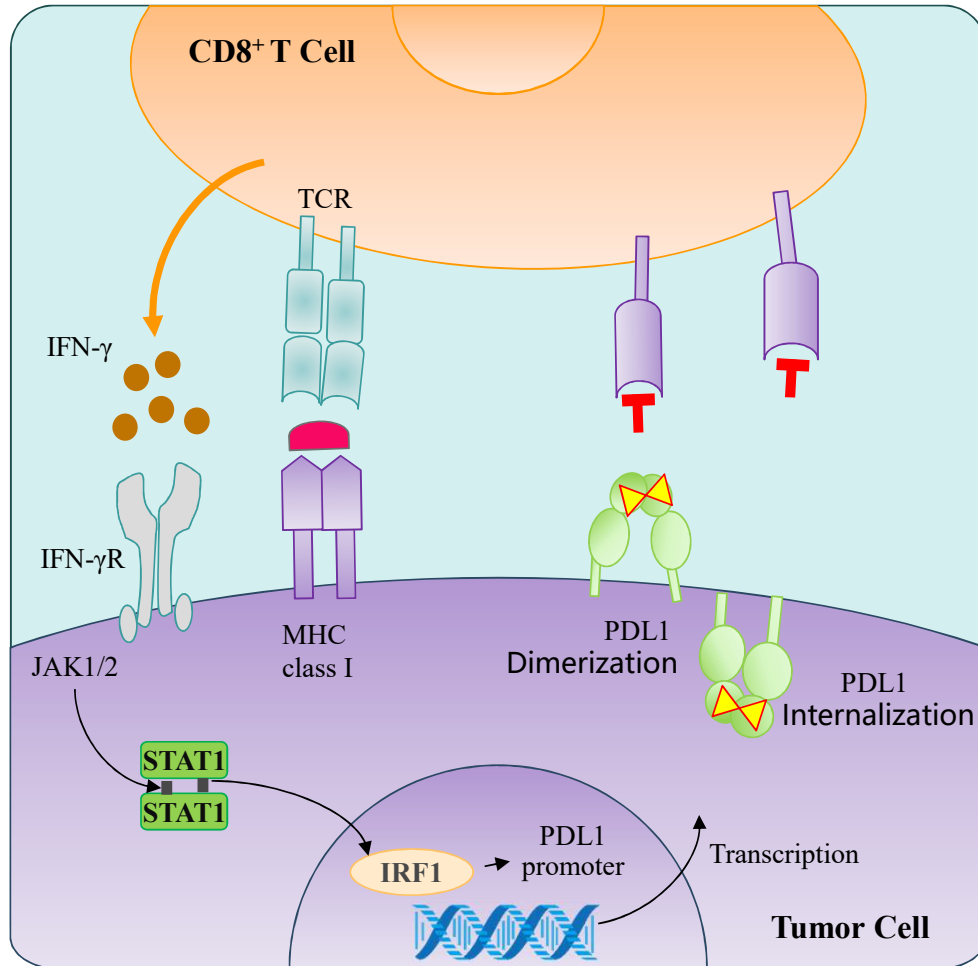
Interim results from Phase IIb expansion cohort of ASC22

| | Rate of HBsAg loss after 24-week treatment | HBsAg loss after 24-week follow-up | Safety profile |
|-----------|--|------------------------------------|---|
| ASC22+NAs | ASC22 Cohort: 21% (4/19) Placebo Cohort: 0 (0/6) | In follow-up, unknown | Generally safe and well tolerated. Most of drug related AE were Grade 1 or 2. |

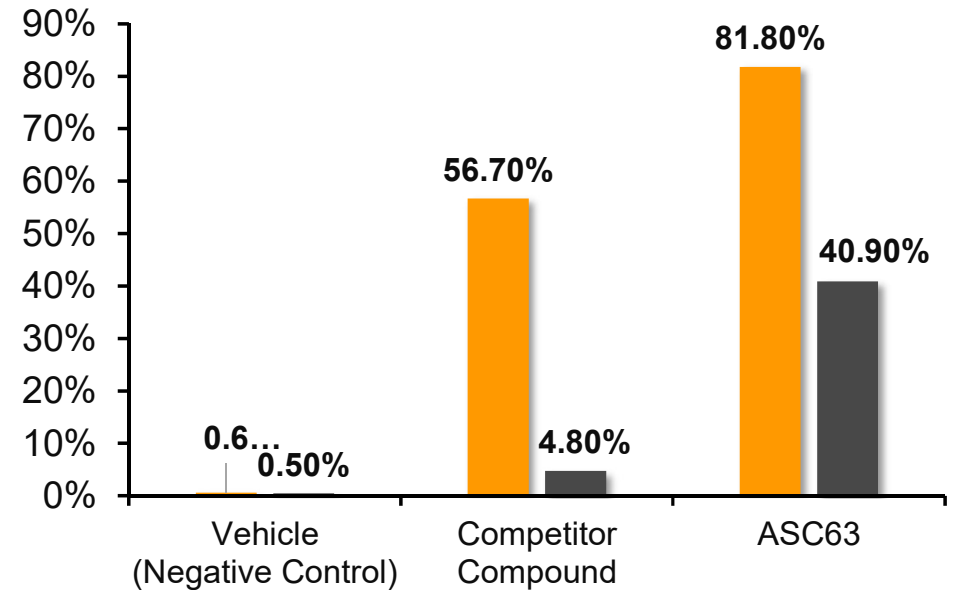
*Interim analysis was conducted when approximately 50% of enrolled patients completed 24-week treatment of ASC22 or placebo

- Peng G, et al. PD-1 upregulation is associated with HBV-specific T cell dysfunction in chronic hepatitis B patients. Mol Immunol. 2008;45(4):963-70.
- B Ye, et al. T-cell exhaustion in chronic hepatitis B infection: current knowledge and clinical significance. Cell Death Dis. 2015 Mar 39;6:e1694.

ASC61: Induce PD-L1 Dimerization and Sustained Internalization



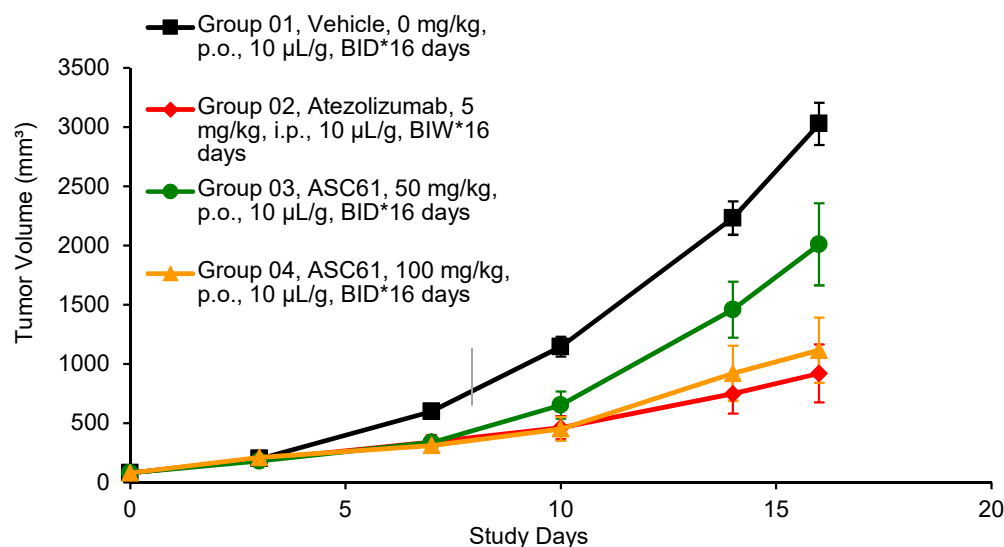
Cell Surface PD-L1 Signal Loss



ASC61

- Potently induce PD-L1 dimerization and internalization (orange)
- Induce long-lasting PD-L1 signal loss from cell surface (after compound removed from medium for 16 hours, still resulted in 40% PD-L1 signal loss) (black)

ASC61 showed comparable antitumor activities as the FDA- approved PD-L1 antibody, Atezolizumab, in mouse tumor models



Note: PD-1/PD-L1 dKI HuGEMM mice with human PD-1 and PD-L1 gene double knock-in are an ideal model for testing human-specific PD-1/PD-L1 immune checkpoint inhibitor drugs.

| Description | Tumor Size (mm ³) ^a on day 16 | T/C (%) on day 16 ^b | TGI (%) on day 16 | p value compare with G1 ^c | p value compare with G2 ^d |
|--|--|--------------------------------|-------------------|--------------------------------------|--------------------------------------|
| Vehicle, p.o., 10 μ L/g, p.o., BID*3 weeks | 3027.54±179.16 | - | - | - | - |
| Atezolizumab, 5 mg/kg, i.p., BIW*3 weeks | 919.73±244.00 | 30.38 | 69.62 | <0.001 | - |
| ASC61, 50 mg/kg, p.o., BID*3 weeks | 2009.72±346.48 | 66.38 | 33.62 | 0.0954 | 0.0362 |
| ASC61, 100 mg/kg, p.o., BID*3 weeks | 1115.61±275.17 | 36.85 | 63.15 | <0.001 | 0.954 |

Note: a. Mean \pm SEM; b. tumor volume treatment/control; c. compared with group 1 tumor volume on day 16 using Tukey's HSD test; d. compared with group 2 tumor volume on day 16 using Tukey's HSD test.

- Oral administration of ASC61 resulted in significant tumor growth inhibitions in mouse tumor models. Antitumor activity of ASC61 was shown to be dose-dependent.
- No significant difference of body weight was observed among all groups during studies, indicating that ASC61 was generally well-tolerated in mice.

Summary & Outlook

R&D Pipeline

| Therapeutical Area | Product (Modality) | Target | Indication | Commercial Rights | Pre-IND | IND | Phase I | Phase II | Phase III |
|--------------------|---|------------|------------------------|----------------------------|---------|-----|---------|----------|-----------|
| Viral Diseases | ASC22 (Subcutaneous mAb) | PD-L1 | CHB functional cure | Global ¹ | | | | | |
| | ASC40 (Oral small molecule) | FASN | NASH | Greater China ² | | | | | |
| NASH | ASC41 (Oral small molecule) | THRβ | NASH | Global | | | | | |
| Oncology | ASC40 (Oral small molecule) + Bevacizumab | FASN+ VEGF | Recurrent glioblastoma | Greater China ² | | | | | |
| | ASC61 (Oral small molecule) | PD-L1 | Advanced solid tumor | Global | | | | | |
| Acne | ASC40 (Oral small molecule) | FASN | ACNE | Greater China ² | | | | | |

Notes:

1. ASC22 is licensed from Suzhou Alphamab Co.,Ltd. ("Alphamab") for the worldwide exclusive rights.
2. ASC40 is licensed from Sagimet Biosciences Inc. for the exclusive rights in the Greater China.

Focus on Unmet Medical Needs

| China Patients | Therapeutic Area | Current Situation | Highlights | Ascletis Updates |
|----------------|------------------|--|--|--|
| 120mm | Acne | <ul style="list-style-type: none"> x Moderate and severe acne patients account for 23-35% x Isotretinoin and antibiotics have many side effects | <ul style="list-style-type: none"> • Innovative mechanism inhibits sebum secretion • Excellent phase II clinical trial data, good safety profile; oral once daily, convenient for administration | <ul style="list-style-type: none"> • Phase III trial of ASC40 initiated in Q4, 2023 • China's top dermatology clinical center –Huashan Hospital, Fudan University– leads the study |
| 86mm | HBV | <ul style="list-style-type: none"> x NAs: high relapse rate once off treatment x Interferon: various side effects | <ul style="list-style-type: none"> • ASC22 is the world's fastest-progressing immunotherapy for the treatment of hepatitis B through PD-1/PD-L1 mechanism | <ul style="list-style-type: none"> • Interim data of ASC22 IIb expansion cohort: 21.6% pts with baseline HBsAg≤100 reached HBsAg loss with 24 wk treatment |
| 48mm | NASH | <ul style="list-style-type: none"> x No NASH drug approved by FDA,EMA,NMPA yet x GLP-1 has no improvements for liver fibrosis | <ul style="list-style-type: none"> • THR-β: ASC41 First-in-China/ Third-in-Global • FASN: ASC40 First-in-class in the world | <ul style="list-style-type: none"> • ASC41: positive interim data of Phase II potentially BIC THR-β agonist globally • ASC40: Phase II liver biopsy data to release soon |
| 40~60k | GBM | <ul style="list-style-type: none"> x 5-year survival rate is extremely low(5.8%) for GBM x High relapse rate after surgery, limited effective treatments | <ul style="list-style-type: none"> • Novel lipid metabolism mechanisms for the treatment of solid tumors • Phase II clinical data : PFS6=31.4% | <ul style="list-style-type: none"> • Over 120 patients enrolled in Phase III (180 totally) • May have enough events for interim analysis of PFS |

High Efficiency of R&D



2023 R&D expense: ~220 mm RMB



Continue to strengthen IP protection

- 1** Phase III clinical trial initiated
- 3** Phase II clinical trials completed
- 4** Phase II or Phase III trials ongoing
- 6** IND approvals from China NMPA or FDA

| | |
|------------------------------------|------------|
| 2023 patents granted | 12 |
| 2023 patents applications* | 61 |
| Total patents granted | 31 |
| Total patents applications to date | 154 |

*As of March. 25, 2024

Corporate Strategy--Focus on Differentiation



Pipeline Prioritizing

- ✓ Completed existing pipeline review and assessment
- ✓ Made a strategic optimization of resources on 12 clinical stage assets
- ✓ focuses on the pipeline which has global FIC or BIC potential



Commercialization Repositioning

- ✓ Sales team for HCV dismissed in H1 2023 due to market shrinkage
- ✓ Now the majority staff is for discovery and clinical development
- ✓ Co-commercialization with partners in the future



FIC/BIC as Core Competiveness

- ✓ Allocate increasing resources to early discovery and clinical development
- ✓ More global FIC/BIC candidates with edges in the world or in China



Value Creating Oriented

- ✓ Ascletis has a proven track record of BD capabilities
- ✓ Seek out-license partnership to maximize the value of the pipeline



Focus on Advantages + Unmet Needs + Core Pipeline



Differentiation

Shareholders Returns Increasing as ~130+mm HK\$ Repurchased and Cancelled *



Communications



Expand channels to enhance investor understanding



Timely, sincere, and transparent



Take investor opinions and feedback seriously



Market Confidence



Approved 200mm HK\$ forbuyback



75+mm shares repurchased to date*



130+mm HK\$ used*



Intrinsic Value



✓ early discovery & clinical development well progressing

✓ ASC40 acne Phase III initiation
✓ ASC41 positive Phase II interim data

✓ ASC40 positive Phase IIb biopsy results



中信建投证券
CHINA SECURITIES
证券研究报告·港股公司简评
肝病领域新星，
关注 NASH 研发进展

事件

NASH 药物治疗靶点 THRβ 有望实现突破
公司 12 月 21 日公告，全资子公司甘美制药有限公司自主研发的甲状腺素受体激动剂 (THRβ) 激动剂 ASC41 用于治疗非酒精性脂肪肝 NASH 患者的 52 周 II 期临床试验顺利推进。



首次评级
贺蔚颖
hejuying@csc
SAC 执证编号
SFC 中央
袁清静



歌礼
ascletis
SAGIMET
BIOSCIENCES

2023 年 10 月 23 日

行业研究

掘金百亿美元市场，NASH 赛道扬帆起航

——NASH 行业深度报告

观点

NASH 治疗赛道市场空间广阔：非酒精性脂肪肝病(NASH)是一种多因素引起的复杂代谢性肝病，全球遭受非酒精性脂肪肝病(NALFLD)NASH 的人群大概占总人口 1%，患者数量庞大。由于 NASH 病程进展复杂，临床治疗难度大，至今尚未有以有效药物获批上市。Resmetirom 作为首个 FDA 批准的 NASH 治疗药物，在 23 年 6 月正式提交 FDA 申请，有望打开全球非酒精性脂肪肝病 NASH 治疗市场。以歌礼制药、中国生物制药为代表的中国药企也在积极布局 NASH 赛道，占据国内市场份额。

多个靶点药物研发进展：根据公开临床数据和在研药物管线，我们筛选出有望实现突破的靶点，主要聚焦 GLP1、泛甲状腺受体 (THR)、PPAR 和 THRβ。其中，THRβ 激动剂 Resmetirom (3 期成功) 及 VK-2809 (2 期成功) 验证了该靶点，歌礼制药的甲状腺素受体 ASC41 有望获得突破成功。中国生物制药布局的 PPAR 激动剂 Lanifibranor 在国内进展最快，已经推进至临床 3 期。此外，GLP1 激动剂、FGF21 激动剂等产品也已经公布了成功临床 2 期数据，有望进一步实现突破。未来随着 NASH 发病机制研究进展，我们可以期待 NASH 治疗“双管齐下”多个靶点联合给药治疗，出现多个销售大单品。



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分析师：陈少卿

执业证书：S1505230100000000

010-57212815

chen.shaoqing@ebsc.com

分析师：孙晨露

执业证书：S1505230100000000

010-57212817

sun.chenlu@ebsc.com

行业与沪深 300 涨跌幅对比图

10%

0%

-10%

-20%

-30%

-40%

-50%

-60%

-70%

-80%

-90%

-100%

2023/10/23

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Goldman Sachs
SACHS

30 January 2024 4:30PM HKT

Ascleitis Pharma Inc. (1672.HK): Robust PoC data of ASC40 in NASH;

upgrade from Sell to Neutral

We upgrade Ascleitis Pharma from Sell to Neutral, to reflect our strengthened view on the NASH franchise led by two drug candidates ASC40/ASC41. With

positive phase 2 results published recently (April 1, 2023), which presented

robust proof-of-concept (POC) data that, in our view, details below, represent

solid clinical progress for the NASH franchise. We believe the current downside for

the company is becoming narrowed with 1) the robust POC data in NASH and 2) the

solid cash position (rmb4.5bn target to cover through 2027) to support further

clinical progress with the company's strategic focus shifted from MNC franchise to

the critical R&D of NASH franchise. Meanwhile, we note that further upside may

need more meaningful catalysts to trigger. 1) the upcoming phase III in NASH

could take time (2-3 years for biopsy data), and 2) the remaining year of 2024

appears overvalued for Ascleitis.

Positive NASH phase data readout of ASC40: Ascleitis' partner Sagimet (SGMT)

announced that Phase IIb data showed robust efficacy results in NASH from

FACINATE 2 trial in P3/P3 NASH patients where demecolm (ASC40) (RAGN inhibitor)

showed statistically significant improvements relative to placebo across key

endpoints, and we highlight:

■ **Significant benefit on two primary endpoints:** 1) NASH resolution without

worsening of fibrosis with >2 point reduction in NAS (NAFLD Activity Score) in

38% of ASC40-treated patients vs 12% with placebo (p=0.002) and 12.5-point







reduction in fUS without worsening of fibrosis with 52% vs 20% (p=0.0001)

were achieved.

*As of March.25, 2024

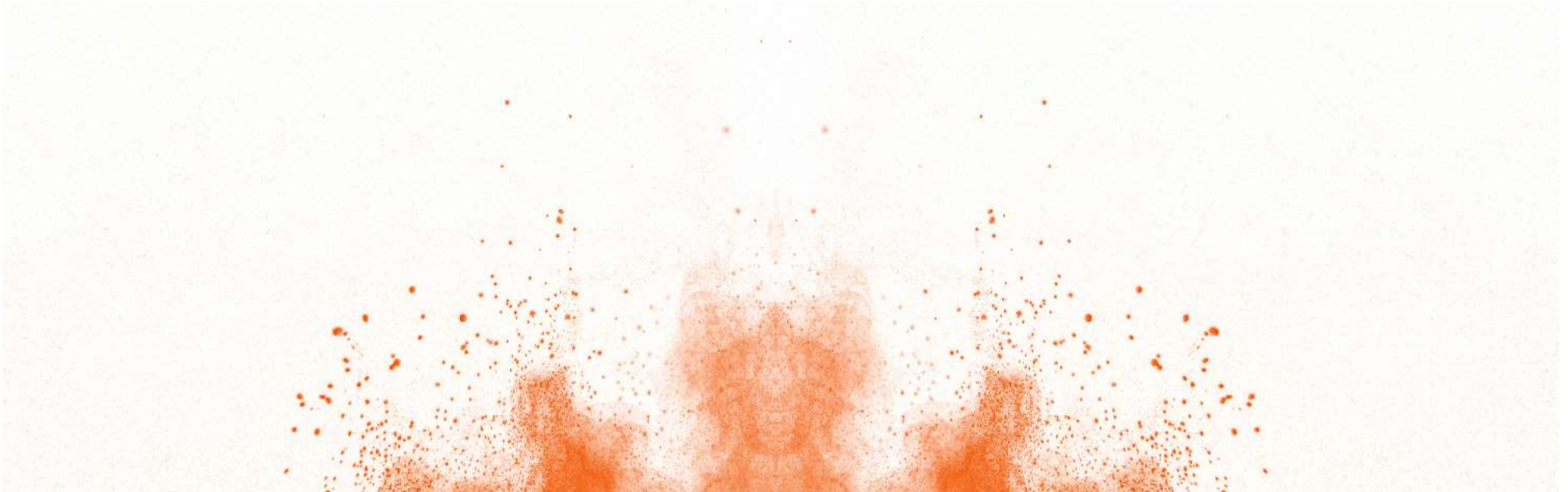


Execution—All Key Milestones Delivered

| | Indication | Catalysts | Progress |
|--------|------------|--|---|
| 2023Q2 | acne | Topline Phase II clinical results of ASC40 (FASN) for treatment of acne |  |
| 2023Q3 | rGBM | Complete the enrollment of ~120 rGBM patients in Phase III clinical of ASC40(FASN), which is needed for the planned interim analysis with 93 PFS events. |  |
| 2023Q3 | HBV | Topline interim results from Phase IIb expansion cohort of ASC22 (PD-L1) for functional cure of CHB in patients with the baseline HBsAg \leq 100 |  |
| 2023Q4 | acne | Initiation of Phase III clinical trial of ASC40 (FASN) for treatment of acne |  |
| 2024Q1 | NASH | Topline interim results from Phase II clinical trial of ASC41(THR- β) of liver fat reduction, LDL-C reduction, liver enzymes and biomarkers of approximately 40 NASH patients after 12-week treatment |  |
| 2024Q1 | NASH | Phase IIb topline clinical results from 168 biospy-proven NASH patients of Phase II clinical trial of ASC40(FASN) after 52 weeks of treatment |  |

Expected Milestones in 2024

| Indications | Catalysts | Status |
|-------------|---|--------|
| NASH | ASC41(THR-β)NASH—Complete Phase II enrollment | » |
| NASH | ASC40(FASN)NASH-Submit the Phase IIb data from US and initiate discussion with China NMPA for Phase III trial of NASH | » |
| Acne | ASC40(FASN)acne—Complete Phase III enrollment | » |
| rGBM | ASC40(FASN)rGBM--Complete pre-specified interim analysis of Phase III | » |
| Oncology | ASC61(PD-L1)solid tumors—Continue to conduct the Phase I multiple ascending dose clinical trial of ASC61 in the U.S | » |



Thanks

Innovative cures liberate life to the fullest

