

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

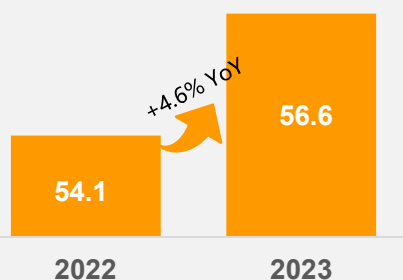


Efficient Operation

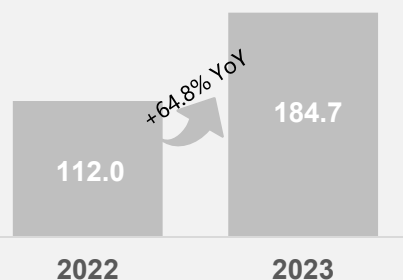
- Continued efforts on efficiency
- Admin exp. decrease as lean operation in place
- Sufficient cash secures operation and R&D in next 5 yrs

Financials mm RMB

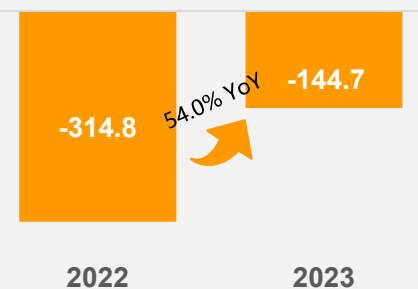
Revenue



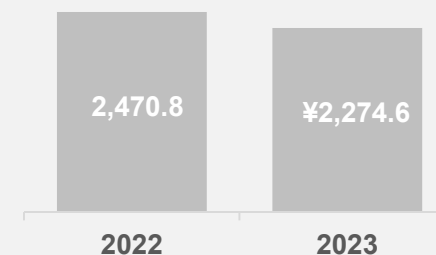
Other Income and Gains



Loss



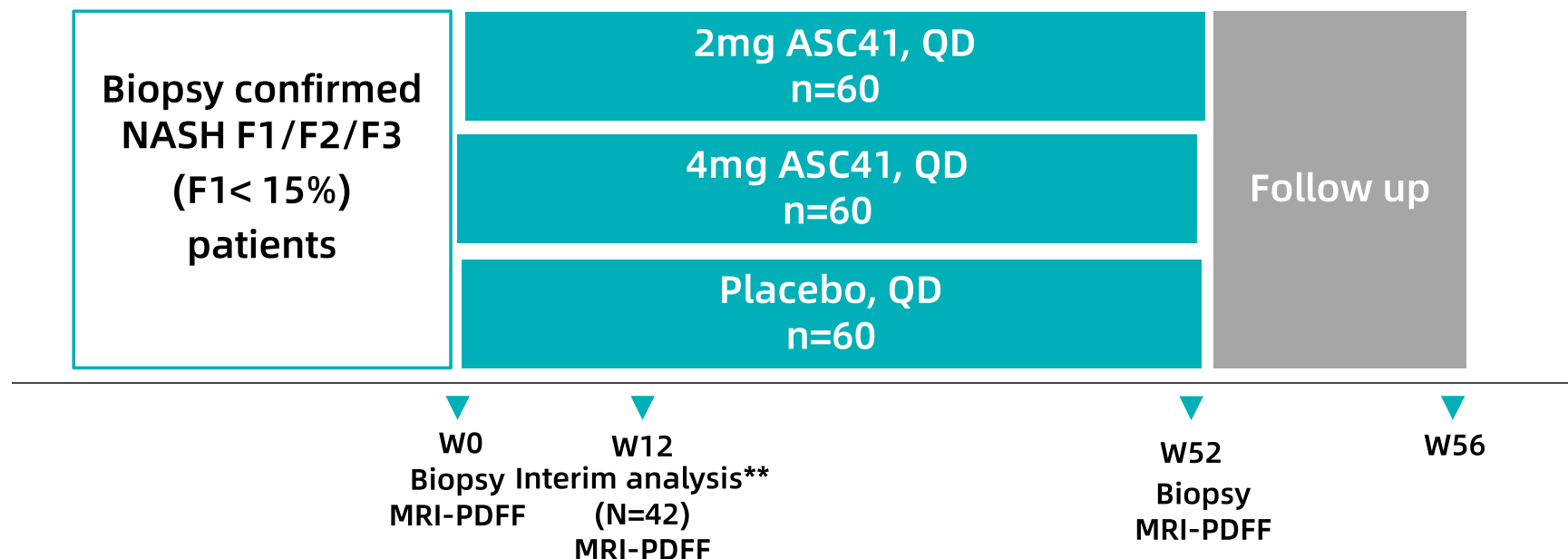
Cash& Equivalents*



*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.

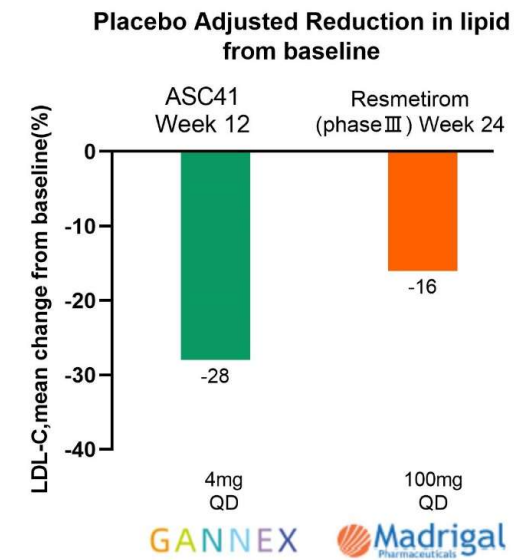
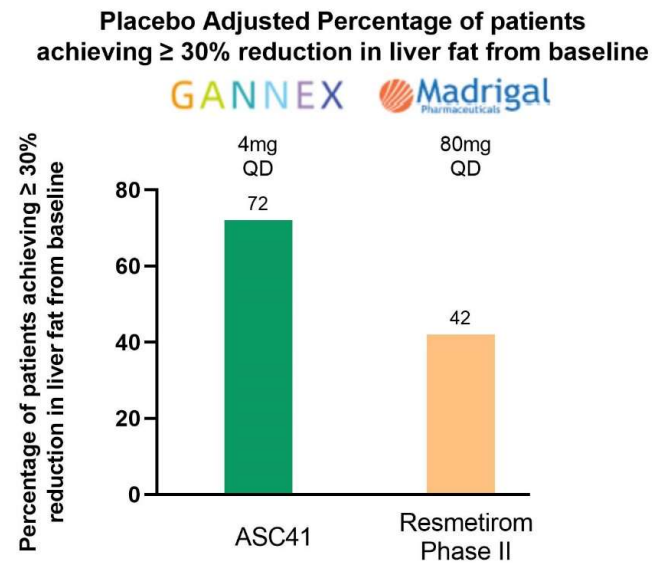
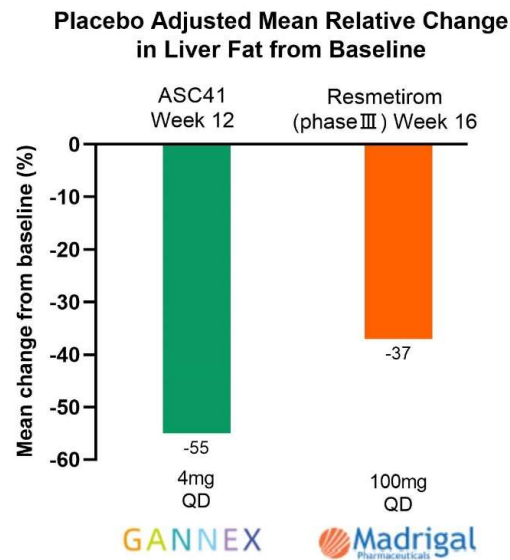
Safety and Tolerability

	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

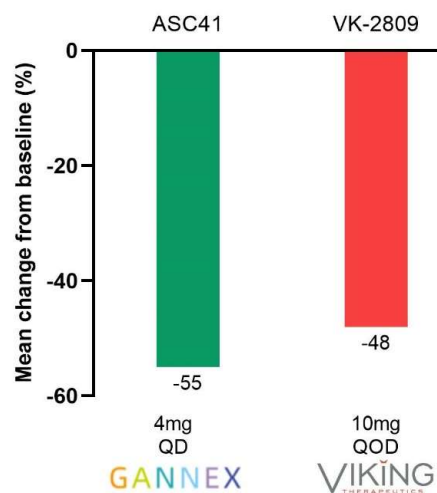


[1] Week 12 data from 36-week phase 2 and 52-week phase 3
 [2] NA:Not available

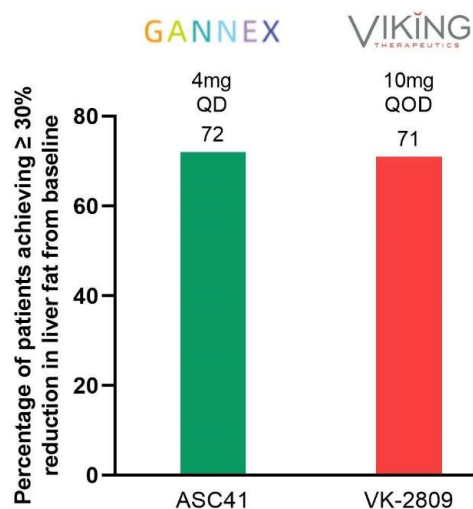
Resmetirom: Stephen A. Harrison, et al. EASL 2023 abstract number GS-001; Harrison, S. A., et al.[J] Lancet, (2019).DOI: 10.1016/s0140-6736(19)32517-6

THR β Agonists : ASC41 vs VK2809:

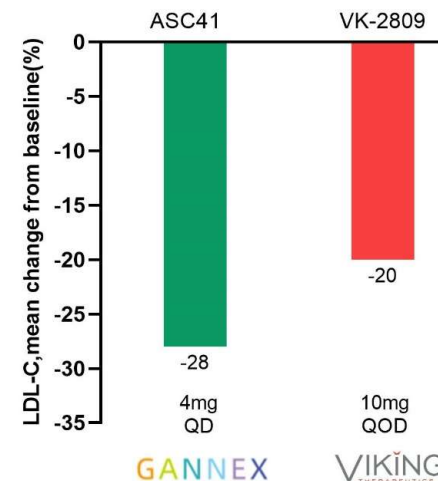
Placebo Adjusted Mean Relative Change
in Liver Fat from Baseline
(MRI-PDFF at Week 12)



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



Placebo Adjusted Reduction in lipid
from baseline at Week 12



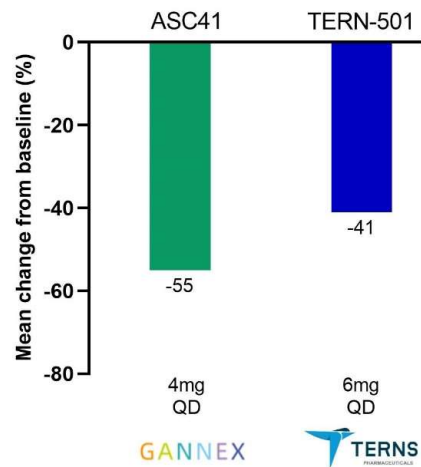
[1]Viking press release, May 2023

[2]NA:Not available

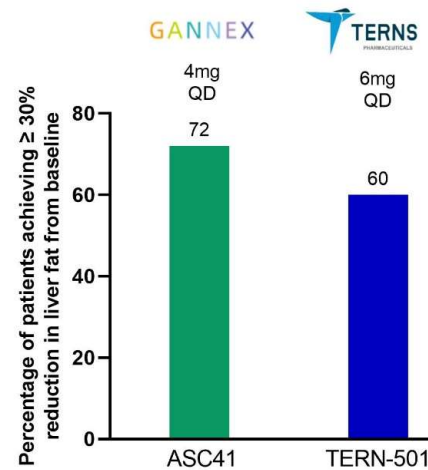
VK-2809: Rohit Loomba, et al. AASLD 2023 abstract number 5016-C; <https://ir.vikingtherapeutics.com/2023-11-13-Viking-Therapeutics-Presents-New-Data-from-Phase-2b-VOYAGE-Study-of-VK2809-in-Patients-with-Biopsy-Confirmed-Non-Alcoholic-Steatohepatitis-NASH-at-The-Liver-Meeting-R-2023>;
<https://ir.vikingtherapeutics.com/corporatepresentation>,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

THR β Agonists: ASC41 vs TERN-501

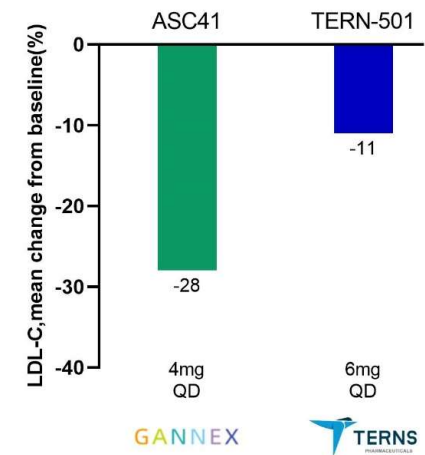
Placebo Adjusted Mean Relative Change
in Liver Fat from Baseline(MRI-PDFF at Week 12)



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

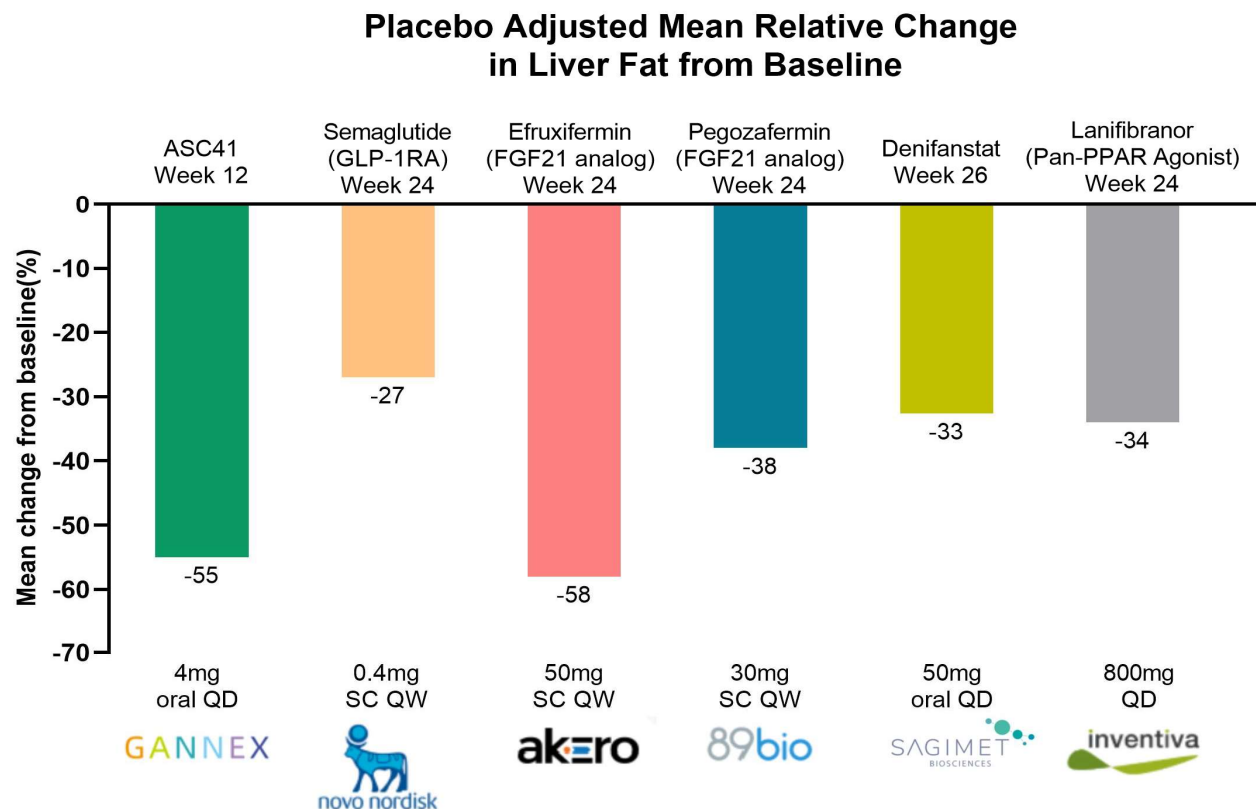
[2] Viking press release, May 2023

[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%)

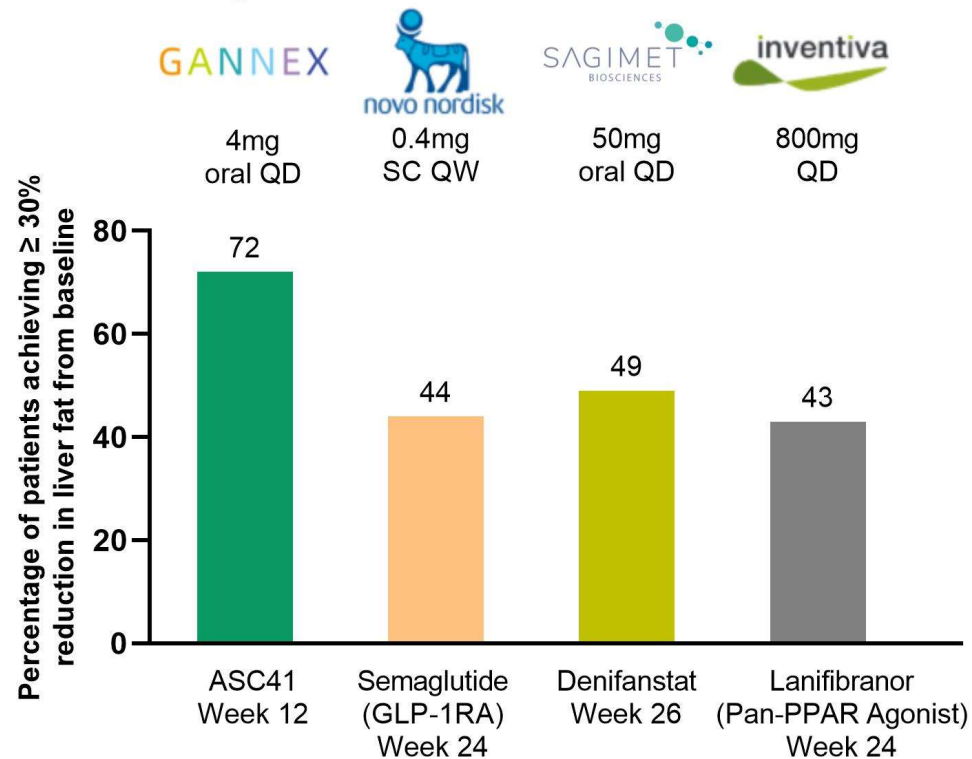
ASC41 vs GLP-1, FGF21, FASN and PPAR: Liver Fat Reduction



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>

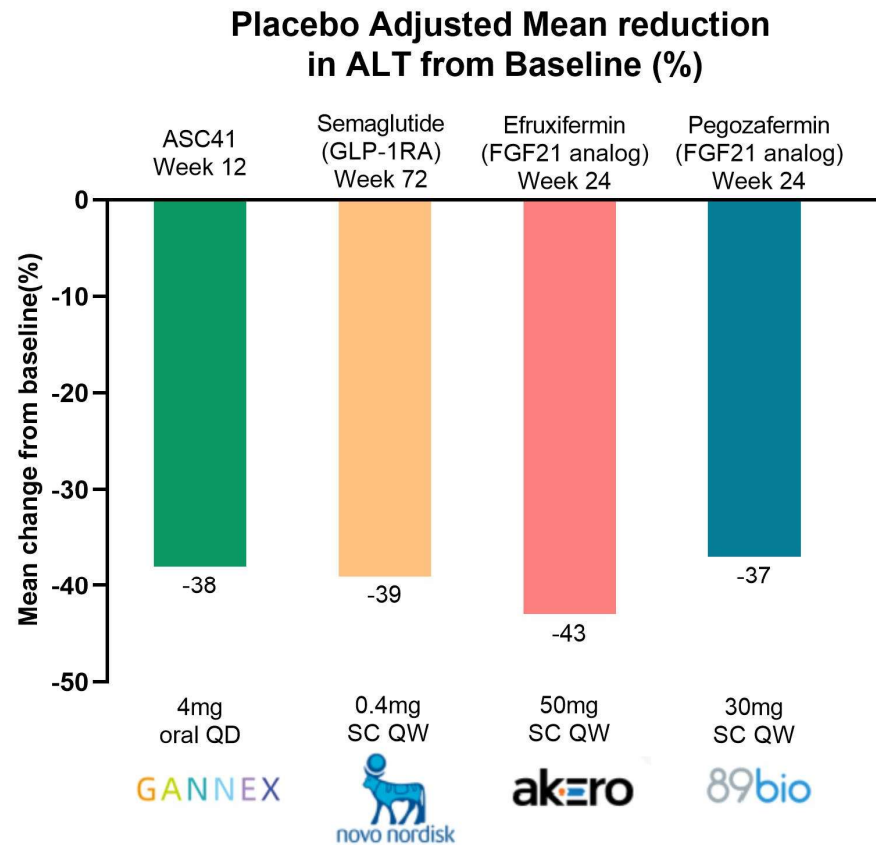
ASC41 vs GLP-1, FASN and PPAR: $\geq 30\%$ Liver Fat Reduction

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



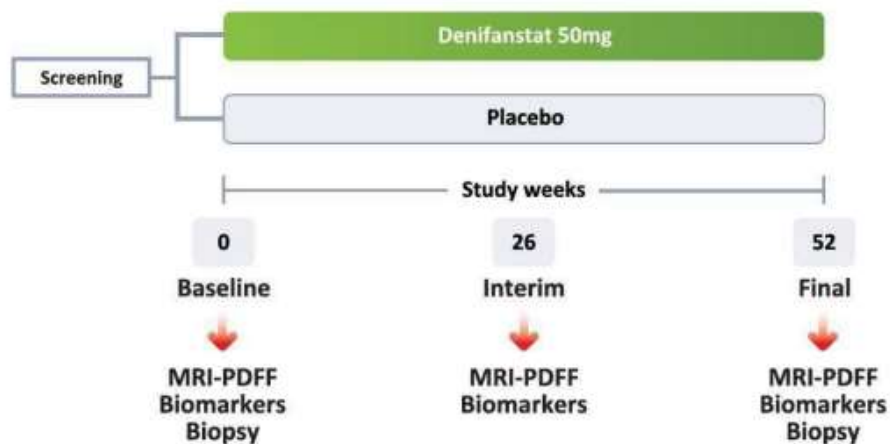
- ASC41 tablet showed excellent safety and tolerability profile, including GI.

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

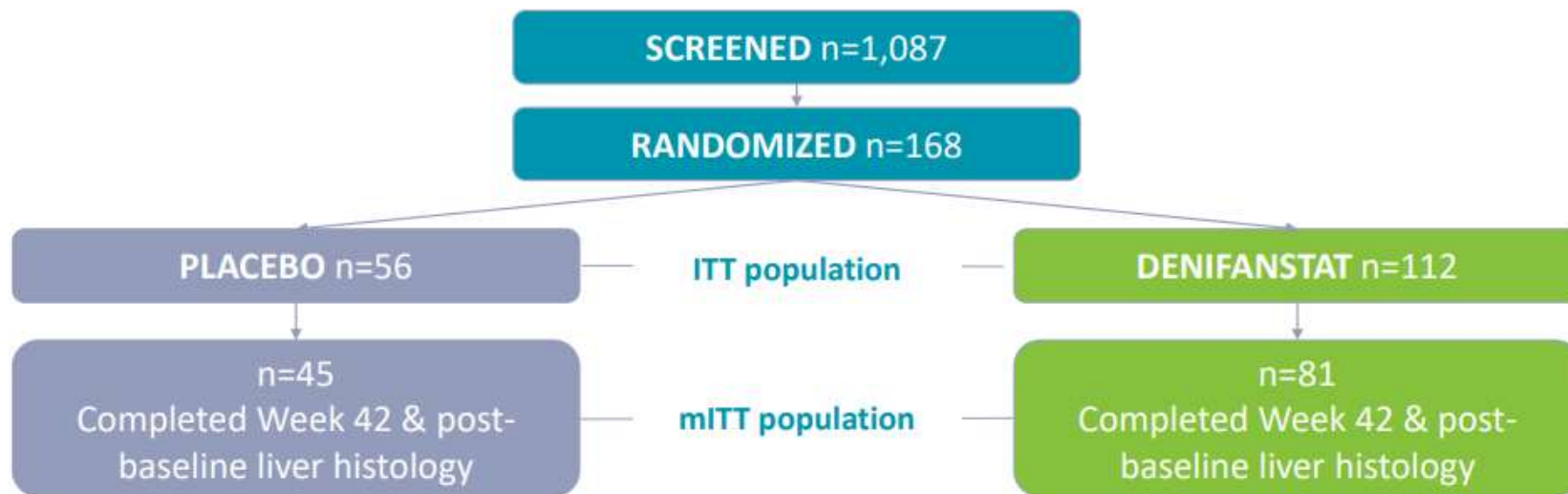
Primary endpoints

- 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

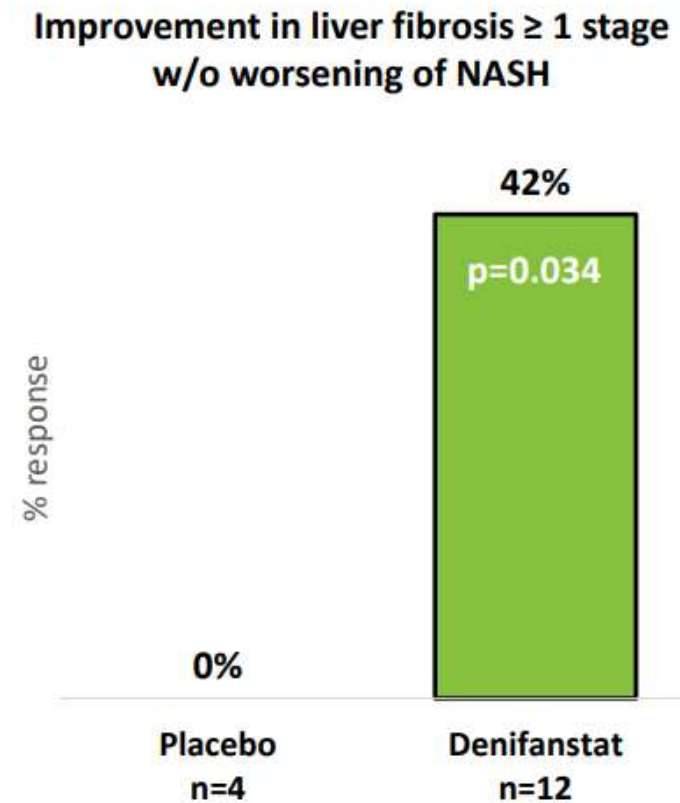
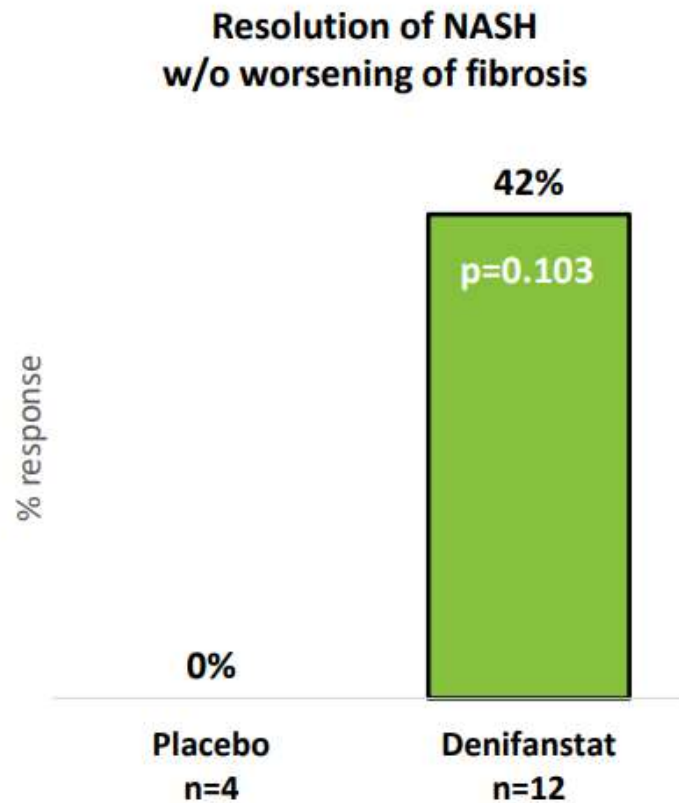
	Placebo (n=45)	ASC40 50 mg (n=81)	Placebo adjusted	<i>P value</i>
Primary Endpoints				
NASH resolution + NAS ≥ 2 improvement w/o worsening of fibrosis	13%	36%	23%	0.0022
NAS ≥ 2 points improvement* w/o worsening of fibrosis	20%	52%	32%	0.0001
Other Endpoints				
Improvement in liver fibrosis ≥ 1 stage 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



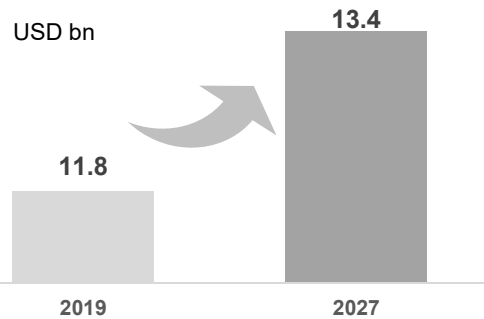
ASC40(FASN)NASH | Phase IIb Safety Profile

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 ≥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

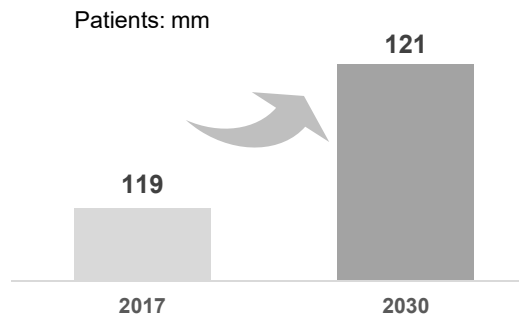
* No treatment-related AE was Grade 3 or higher

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

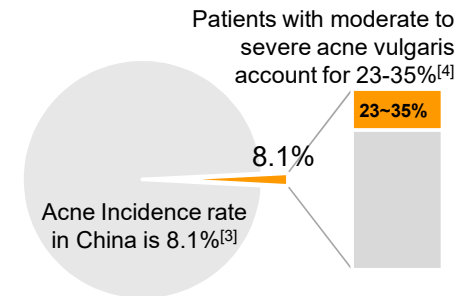
Global Acne Market Forecast^[1]



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

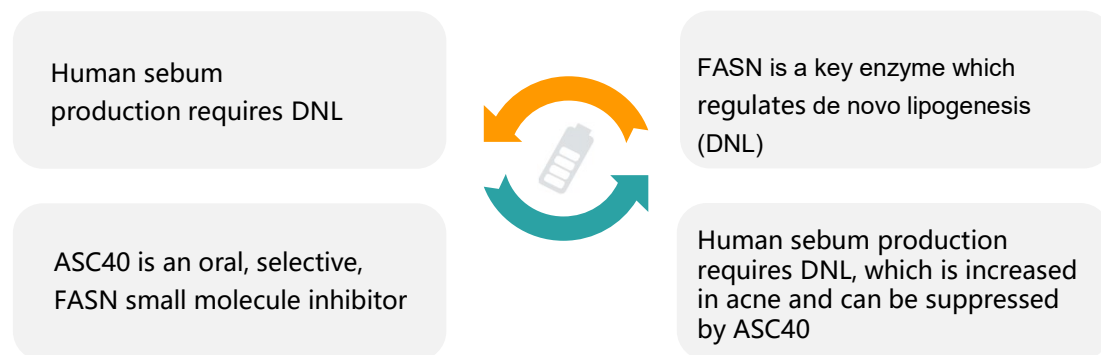
- Oral antibiotics**
 - antibiotic resistance^[5]
 - Side effects including GI reactions /rash/liver damage
- Oral isotretinoin** ^[5]
 - Over 10 kinds of side effects^[6]
 - Liver damage^[6]
- Topical medications**
 - Light sensitive
 - 30% to 40% of patients do not adhere to their topical treatments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

References:

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



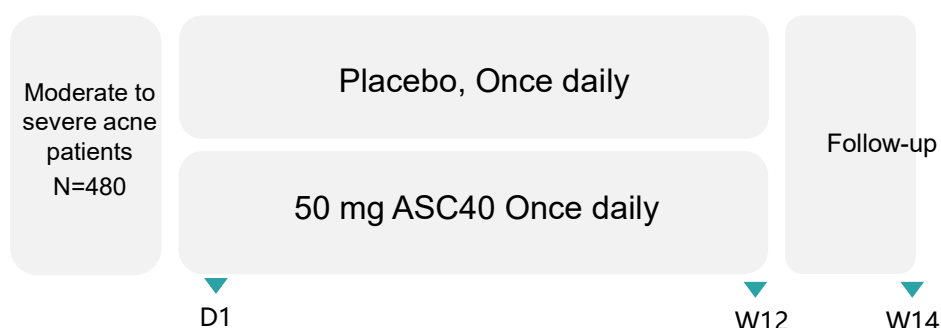
China's top dermatology clinical center –Huashan Hospital, Fudan University– leads the study

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

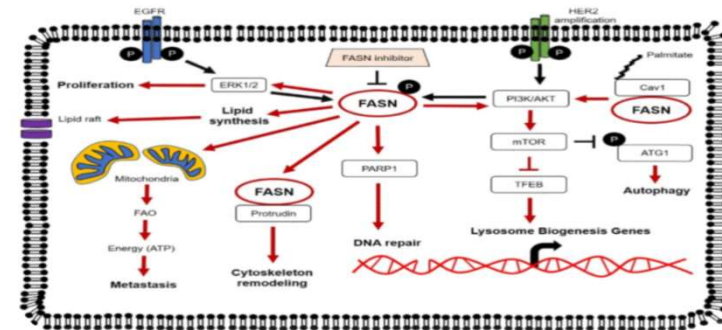


rGBM Treatments are Limited

- 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.)

- 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
- 中国卫健委, 脑胶质瘤诊疗指南 (2022年版)
- 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.
- Tan A C, Ashley D M, Lopez G Y, et al. Management of glioblastoma: State of the art and future directions [J]
- Fhu CW, Ali A.):3935. doi:10.3390/molecules25173935
- 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

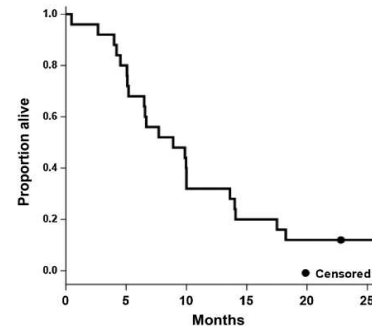
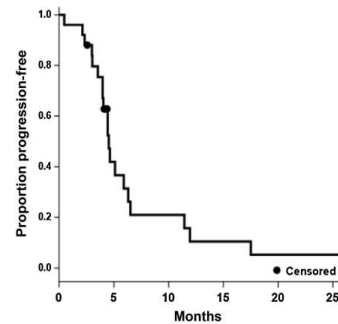
ASC40(FASN) for rGBM: Phase III Interim Analysis Expected in 2H 2024

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

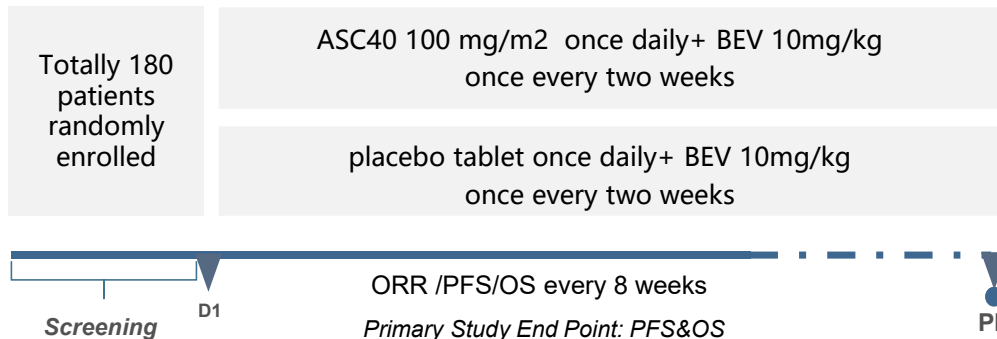


PFS6 Improvement & Safety

- **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



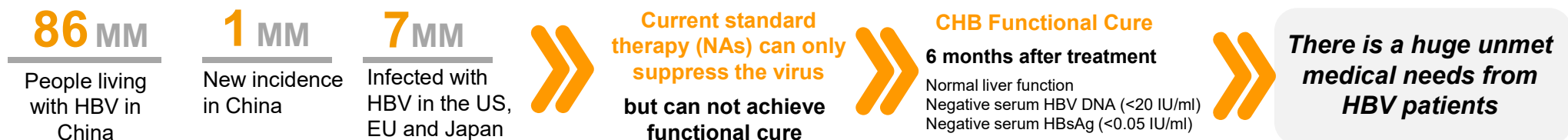
120 patients enrollment --the basis for pre-planned interim analysis (93 PFS events)-- completed as of Q3,2023



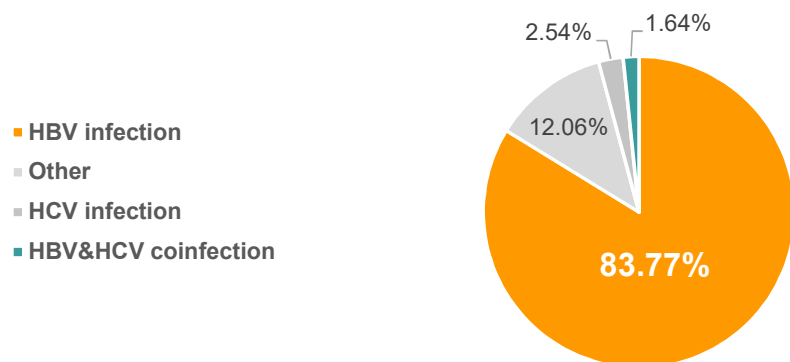
If Phase III interim results shows PFS is significant improved, ASC40 for rGBM may obtain the conditional approval

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

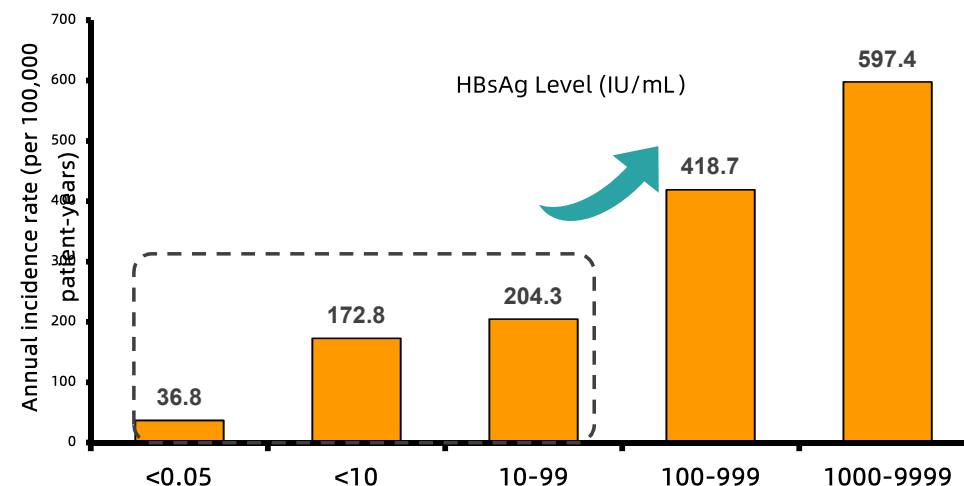


HBV Infection is the Leading Cause of liver cancer



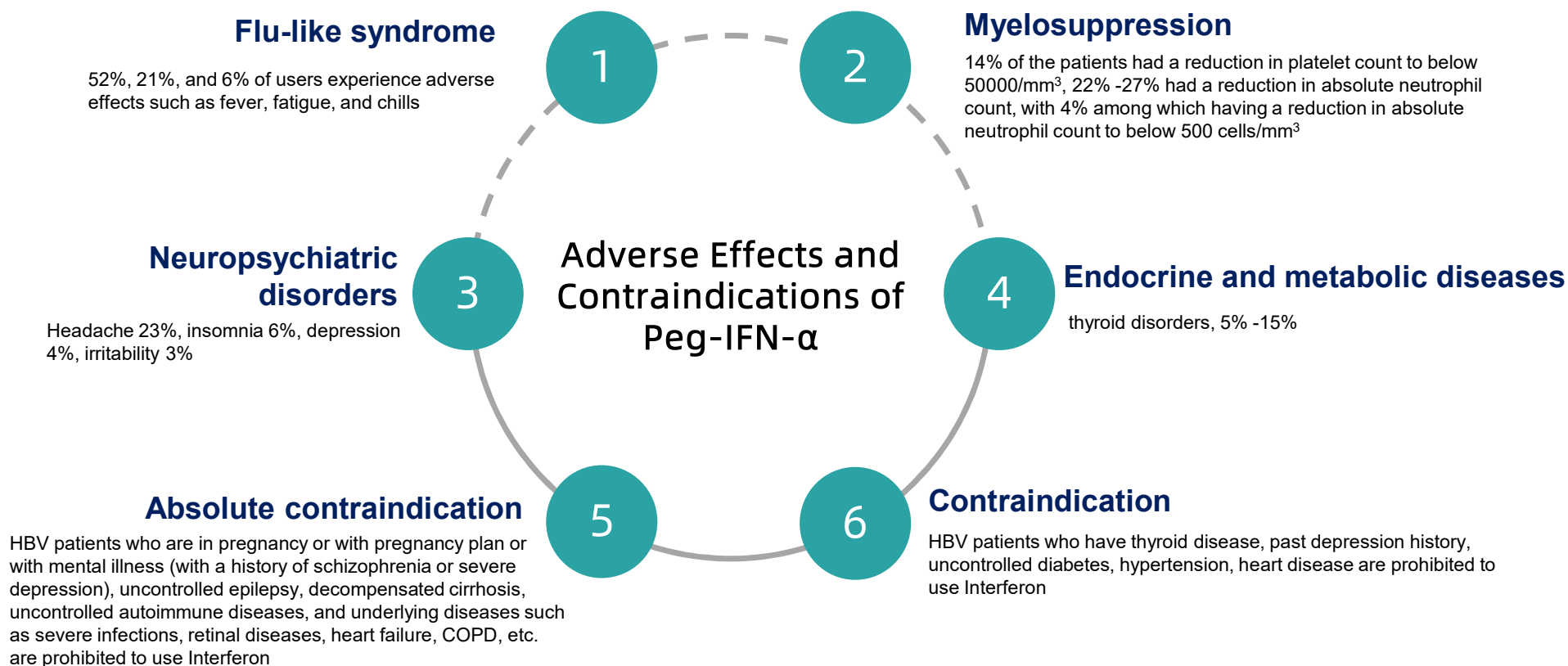
- ◆ The relative risk of HCC in patients with chronic HBV is **14~223** times higher than in the normal population¹
- ◆ The lifetime HCC prevalence in HBV carriers ranges from 10% to 25%²
- ◆ Over 80%³ HCC patients in China are caused by HBV infection

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



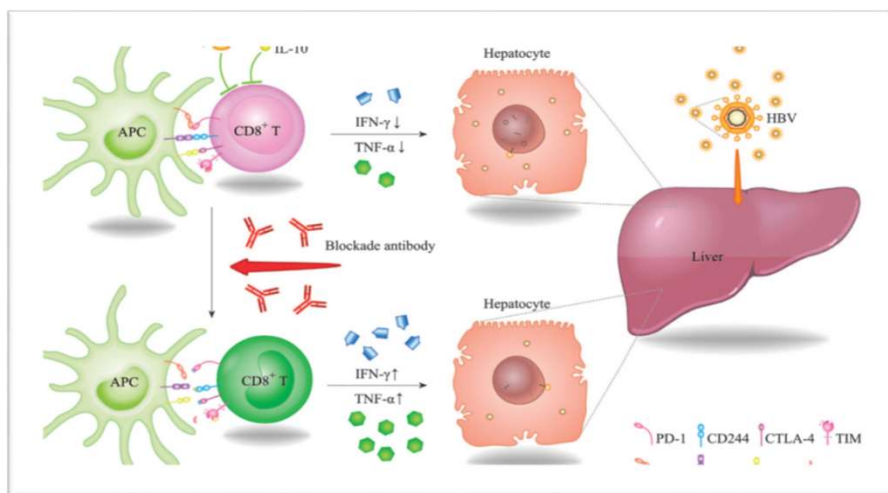
1. Chinese Journal of Infectious Diseases, 2023,41(1) : 3-28.

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

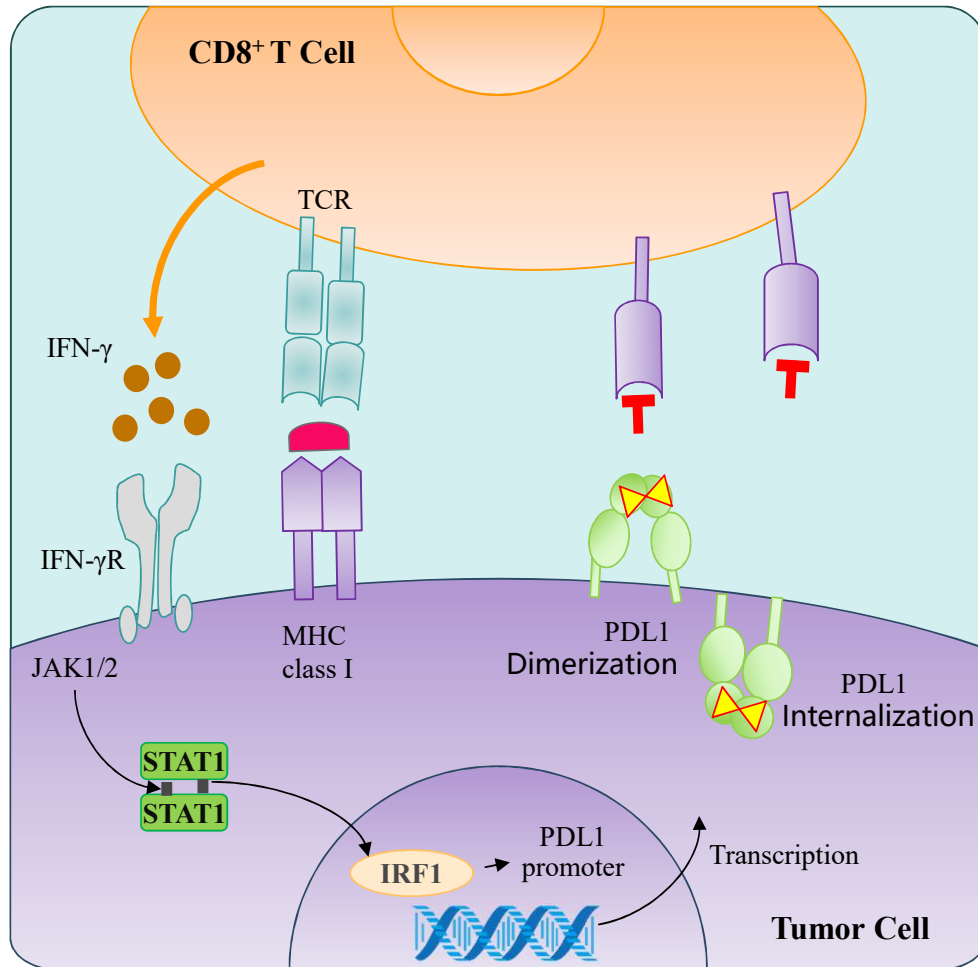
Interim results from Phase IIb expansion cohort of ASC22

	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.

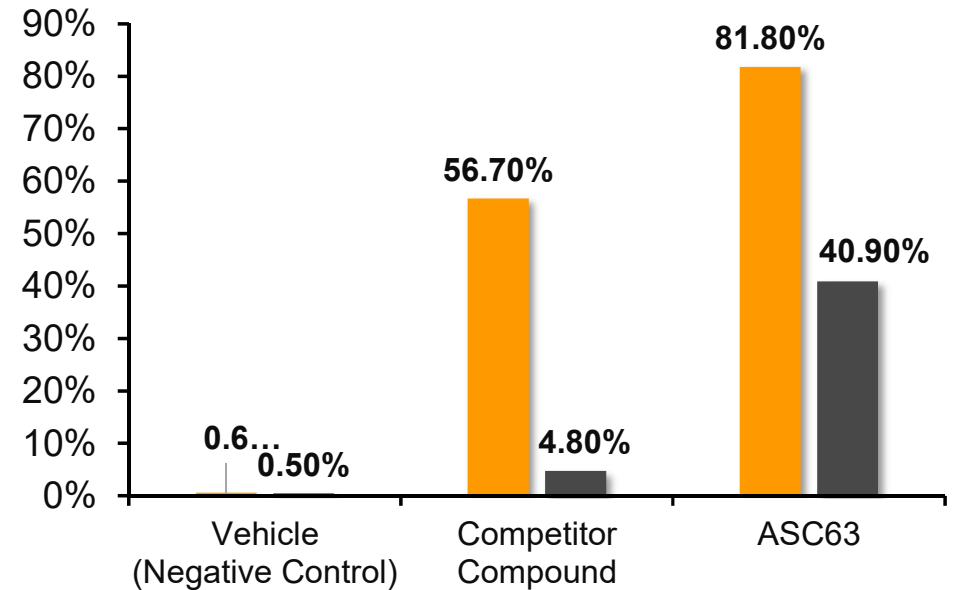
*Interim analysis was conducted when approximately 50% of enrolled patients completed 24-week treatment of ASC22 or placebo

- 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



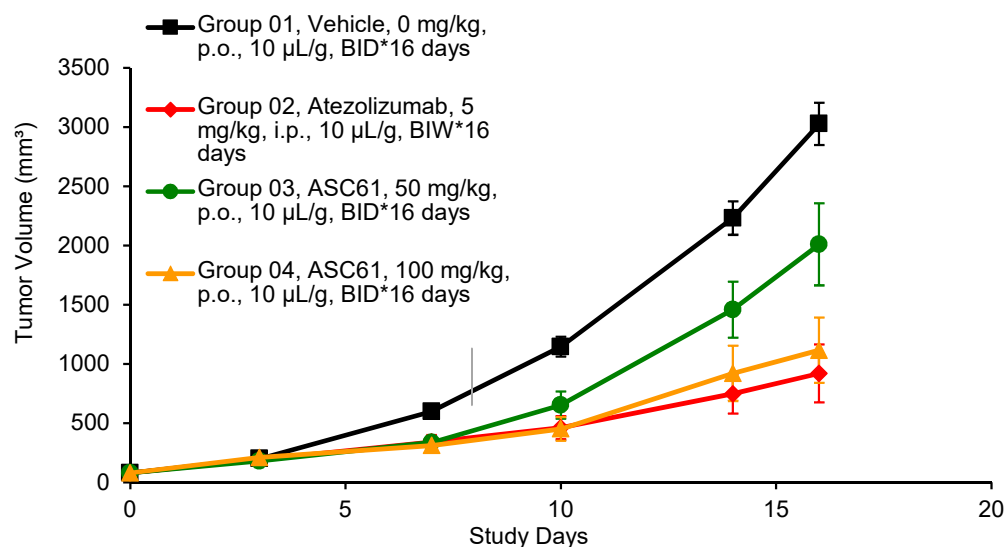
Cell Surface PD-L1 Signal Loss



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\$ for buyback



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自主研发的甲状腺素受体拮抗剂 (THRβ) 激动剂 ASC41 用于治疗非酒精性脂肪肝 NASH 患者的 II 期临床试验顺利推进。



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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：非酒精性脂肪性肝病(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性肝病(NALFLD)NASH 的人群占成人人口 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。Resmetanet 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性肝病 NASH 治疗市场。以赛礼制药、中国生物制药为代表的中国药企也在积极布局 NASH 赛道，占据国内市场先机。

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、泛胆碱受体 (FXR)、PPAR 和 THRβ。其中，THRβ 激动剂 Resmetanet (3 期成功) 及 VK-2809 (2 期成功) 验证了该靶点，赛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 类似物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。未来非 NASH 领域的研发成果有望，我们可以期待 NASH 治疗“百花齐放”多个药物联合给药治疗，出现多个销售大单品。



光大证券

医药生物

增持 (维持)

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行业与沪深 300 涨跌幅对比图

10%

0%

-10%

-20%

-30%

-40%

-50%

-60%

-70%

-80%

-90%

-100%

2023/1/1

2023/12/31

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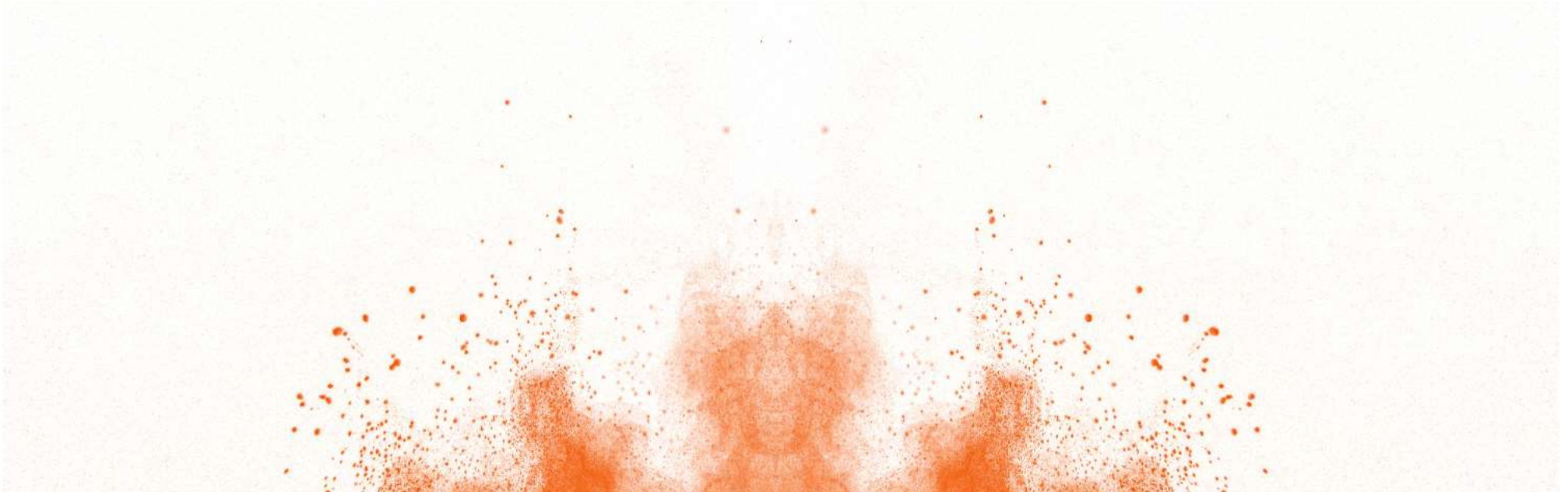
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Execution—All Key Milestones Delivered

	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

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