



Ascletis Pharma(1672.HK) Corporate Presentation& Recent Update Oct 17, 2023

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Summary of 2023 Interim Results

Pipeline

Clinical Development

 Phase II clinical trials for HBV/PBC/NASH and Phase III clinical trials for acne/rGBM progressed well as planned

More Assets into Late Stage

- HBV / acne Ph2 trial completed
- PBC Ph2 enrollment completed
- acne Ph3 to initiate soon

Financials

- Revenue
- 46.50mm, +21.7% YoY

Loss

• 16.56mm, -81.2% YoY

- R&D Expense
- ~92.00mm

Cash 2.51bn



RMB

Pipeline	Progress in 2023 H1*
ASC40 NASH	Topline interim results from Phase IIb clinical trial were presented at EASL CONGRESS 2023
ASC40 Acne	Phase II clinical results were released
ASC22 HBV	Enrollment of 50 patients for the expansion cohort was completed
ASC40 rGBM	Phase III clinical trial has enrolled 108 patients
ASC42 PBC	Phase II enrollment for PBC completed

R&D

Pipeline Prioritizing

• Focus on global FIC/BIC

New Projects

• 5 IND* approvals in 2023 H1

Intellectual Property

- 37 new patent applications*
- 7 patents granted*

Capital Market

IR Communication

• Keep close contact with investors

Boost Market Confidence

 To buyback up to HKD 200mm, repurchased 14+ millions shares* so far

Included in Hang Seng HK-Listed Biotech Index

Date	Milestones in 6-9 Months
2023Q3	ASC40(FASN)-rGBM Phase III to finish enrollment of 120 pts
2023Q3	ASC22(PD-L1)-HBV-Phase IIb expansion cohort interim results
2023Q4	ASC40(FASN)-acne-Phase III clinical trial starts
2023Q4	ASC41(THR- β)-NASH-Phase II topline interim results after 12-wk treatment
2024Q1	ASC40(FASN)-NASH-Phase IIb topline clinical results from biospy-proven NASH patients

ASC41(THR-β) for NASH: Third-in-class in US and First-in-class in China





ASC41 Phase II Design



ASC41-Phase II Clinical Trial is Progressing Quickly

ASC41 Owns Multiple Patents^[3] VK2809^[4] Patents Patents ASC41^[3] MGL3196^[5] Publication Number Date Applied Authorized Tablet. Tablet. US20210308155A1 Capsule, U.S., China U.S., China room temp storage, room temp storage, Formulation (U.S.) refrigerated Formulation 2020/3/27 and ١ and commercially ready commercially ready CN115427022A (China) Patent (Tablet) Globally Globally WO2021190624A1(PCT) Once every two Dosing <u>א</u>צ CN114315902A (China) Once a day Once a day China and China and frequency days 2020/9/30 WO2022067602A1 ١ **Crystal Patent** Globally Globally (Globally) Drug-Drug US11292805B2 (U.S.) Weak Strong Weak Ø Interaction US20220332738A1 U.S. and Synthesis Patent 2020/2/18 U.S. China (U.S.) China CN113336792A (China) Dose needed 1 mg 2.5 mg 50 mg for>30%TG LF Composition WO2023280152A1 2021/7/6 Globally ١ ١ reduction Patent (PCT)

1.Sheka A C, Adeyi O, Thompson J, et al. Jama 2020, 323(12): 1175-83. 4.EASL2020 Abstract No. AS073.

2.J Hepatol. 2018 Oct;69(4):896-904. 3.EASL 2021 Abstract No. PO-1851

5. Stephen A Harrison et al. Resmetirom (MGL-3196) for the treatment of non-alcoholic steatohepatitis; a multicentre, randomised.

double-blind, placebo-controlled, phase 2 trial, https://doi.org/10.1016/S0140-6736(19)32517-6

6. Patents and patent applications information released as of Aug 20, 2023

ASC41 VS MGL-3196 VS VK2809

ascleti

ASC41 vs Resmetirom on Reduction of LDL-C

Study Design of Ascletis' ASC41 Phase II VS Madrigal's Resmetirom Phase III

	ASC41 Phase II	Resmetirom Phase III
Target	ΤΗRβ	ΤΗRβ
Dosage	Placebo, ASC41 2 mg, ASC41 4 mg, once daily	Placebo, Resmetirom 80 mg, Resmetirom 100 mg, once daily
Liver-biopsy proven?	Yes	Yes
Treatments	52 weeks	52 weeks
Enrollments	180 patients	around 1000 patients
Ratio	1:1:1	1:1:1
Inclusion	NASH on liver biopsy: NASH F1 (up to 15%), F2, or F3, NAS≥4	NASH on liver biopsy: NAS≥4 with fibrosis stage 1A (up to 3%) 1B, total F1 up to 15%; F3, at least 50%, the rest F2
Histology efficacy endpoints	Resolution of NASH at Week 52 with at least 2 point reduction in NAS (improvement in inflammation or ballooning) with no worsening of fibrosis; OR reduction in fibrosis stage by 1-point with no worsening of NAS	Resolution of NASH at Week 52 with at least 2 point reduction in NAS with no worsening of fibrosis; OR reduction in fibrosis stage by 1-point withno worsening of NAS
Key secondary endpoint	LDL-C lowering at Week 12, Week 24 , and Week 52	LDL-C lowering at Week 24

Comparison of Key Secondary Endpoint LDL-C Reduction (Not Head to Head))

Dosage	2 mg	5 mg	5 mg	10 mg	20 mg	50 mg	80 mg	100 mg
Drug Candidates	ASC41*	ASC41*	Resmetirom**	ASC41***	Resmetirom**	Resmetirom**	Resmetirom**	Resmetirom**
% Change from baseline after 14-day (mean)	-32.8%	-40.8%	3.2%	-44.8%	8.8%	-11.3%	-25.4%	-20.9%

* Data derived from ASC41 Phase 1 study ** Data derived from Taub et al. Atherosclerosis 230 (2013) 373-380 *** Data derived from ASC41 Phase 1b study

ASC40 (FASN) for NASH: Phase IIb Interim Results Showed Significant Liver Fat Reduction

Interim Data from Phase 2b Clinical Trial: 67% of Patients Reduced Liver Fat by More Than 30%

ASC40 50 mg (n=30)	ASC40 50 mg (n=30)	Placebo (n=22)	P-value vs placebo
Relative reduction in liver fat	- 34.1%	- 1.5%	p<0.001
≥30% reduction of liver fat (responder rate)	67%	18%	p<0.01
ALT (U/L)	- 16.5	- 4.0	p<0.05
Dual liver fat & ALT responder >30% + >17U/L decrease	37.0%	9.0%	p<0.05
PRO-C3	- 8.2%	-1.5%	p<0.05
Enhanced liver fibrosis (ELF) score*	- 0.34	- 0.02	p<0.05
LDL cholesterol (mg/dL)	-12.4	0.0	p<0.05
FGF21	+73.1%	+ 0.9%	p<0.01

*approximately half of denifanstat responders decreased liver fat by \geq 50%

Sources:

ASC40-IIb Results in Comparison with Other NASH Candidates



ASC40 26-week Treatment VS Resmetirom 36-week Treatment Significant Improvements Across Key Disease Markers are Comparable



Baseline MRI-PDFF were similar across cohorts with mean of 19-209

CMH test for response rate, and two sided ANCOVA for ALT. Resmetirom w36 LSM from Ph2, Harrison et al., 2019, Lancet 394:2021-2024.

Sagimet Biosciences Presents Positive Phase 2b FASCINATE-2 Clinical Trial Interim Data for Denifanstat for the Treatment of NASH at EASL Congress 2023 - Sagimet Biosciences

Baseline ALT were similar across cohorts with mean 50-69 U/L Data sources: Denifanstat w26 from FASCINATE-2 Interim Analysis. Two-sided

ASC40 (FASN) for Acne: Phase II Results Met Primary and Secondary Endpoints

Outlook on Global Acne Market



and is expected to reach

\$13.35 billion by 2027



ASC40 Phase II Clinical Trial Design



ASC40: Innovative Mechanism for Acne Treatment



Baseline Characteristics are Comparable Among All Groups

Catagory/Characteristic	25 mg ASC40, oral, QD (n=45)	50 mg ASC40, oral, QD (n=44)	75 mg ASC40, oral, QD (n=45)	Placebo, oral , QD (n=45)
Sex				
Male	19(42.2)	16(36.4)	17(37.8)	20(44.4)
Female	26(57.8)	28(63.6)	28(62.2)	25(55.6)
Age, median (range), y	22.0(18-35)	22.0(18-34)	22.0(18-30)	23.0(18-39)
Baseline IGA score				
3 (moderate)	31(68.9)	29(65.9)	34(75.6)	32(71.1)
4 (severe)	14(31.1)	15(34.1)	11(24.4)	13(28.9)
Total lesion count, mean (SD)	103.6(25.55)	101.1(22.47)	100.0(27.31)	105.0(22.94)
Non inflammatory lesion count, mean (SD)	58.9(21.51)	57.7(21.01)	58.2(23.76)	61.4(21.17)
Inflammatory lesion count, mean (SD)	44.6(13.55)	43.4(11.56)	41.8(9.65)	43.7(13.81)

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

	25mg dose group (n=45)		50mg dose group (n=44)		75 mg dose group (n=45)		Placebo group (n=45)					
Category		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%



Placebo Adjusted Efficacy of 50 mg ASC40, Oral, Once daily is Superior to Placebo Adjusted Efficacy of Winlevi[®] (not head-to-head comparison)

Endpoints	50 mg ASC40, oral, once 1% Clascot daily (n=44), twice daily f placebo adjusted placebo		oterone cream y for 12 weeks, oo adjusted	Phase II Placebo Adjusted Efficacy of ASC40 is % better than	Phase III Placebo Adjusted Efficacy of ASC40 is % better than
	Phase II	Phase II	Phase III	Winlevi®	Winlevi®
% change from baseline in total lesion count at week 12 [§] (primary endpoint)	-27.1	NA	-11.9	NA	128%
% change from baseline in inflammatory lesion count at week 12 [§] (key secondary endpoint)	-33.6	-13.4	-12.8	151%	163%
Absolute change from baseline in inflammatory lesion count at week 12 <i>(key secondary endpoint)</i>	-13	-3.2	-5.6	306%	132%
% Treatment success at week 12	14.3	7.5	11.6	91%	23%

50 mg, oral, once-daily dose is recommended for the Phase III trial which is expected to be initiated in the second half of 2023

- Mechanism: ASC40 is a first-in-class oral once-daily drug candidate for acne with novel mechanisms of action
- Dosage: Clinical efficacy of ASC40 was dose-dependent and efficacy was maxed out at 50 mg dose
- 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
- 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: At all doses, oral ASC40 with once-daily, 12week treatment was safe and well tolerated



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

86 mm

People living with HBV in China 1 MM 7 MM New incidence

HBV in the US, EU and Japan Current standard therapy (NAs) can only suppress the virus but can not achieve functional cure

CHB Functional Cure 6 months after treatment

Normal liver function Negative serum HBV DNA (<20 IU/ml) Negative serum HBsAg (<0.05 IU/ml) There is a huge unmet medical needs from HBV patients

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

in China



Global PD-1/PD-L1 Candidates for CHB

Mechanism of Action	Drug Candidate	Company	Target	Target Clinical Stage	
PD-L1 inhibitor	ASC22	Ascletis	PD-L1	Phase 2b	NCT04465890
CpAM/TLR7 agonist/ HBV siRNA/PD-L1 LNA	RG6084 (RO7191863) etc.	Roche	CpAM/TLR7/si RNA/PEG- IFN/PD-L1	Phase 2	NCT0422571
PD-L1 inhibitor	GS4224	Gilead	PD-L1	Phase 1	ACTRN126180 01957280
PD-L1 inhibitor	AB-101	Arbutus	PD-L1	Phase 1	NCT05960240
PD-1 inhibitor	ARB-272572	Arbutus	PD-1	Pre-IND	NA
PD-L1 inhibitor	ALG-093453	Aligos	PD-L1	Pre-IND	NA
PD-L1 inhibitor	ALG-093702	Aligos	PD-L1	Pre-IND	NA

Blockade of PD-1/PD-L1 pathway restores T cell function, which may eliminate HBV

- 1. 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.
- 2. B Ye, et al. T-cell exhaustion in chronic hepatitis B infection: current knowledge and clinical significance. Cell Death Dis. 2015 Mar 19;6:e1694.



ASC22(PD-L1) for CHB: Phase IIb Trial Demonstrated 26.9% Patients with Baseline HBsAg ≤ 100 IU/mL Achieved HBsAg Loss after 24-Week Treatment

ASC22 (Envafolimab) is the most advanced clinical-stage immunotherapy globally for CHB functional cure through blocking PD-1/PD-L1 pathway.

- Efficacy: In the Phase IIb study, 3/7 of patients with baseline HBsAg ≤ 100 IU/mL obtained HBsAg loss and no rebound. IIb Expansion Cohort Interim results: 4/19 patients with baseline HBsAg ≤ 100 IU/mL obtained HBsAg loss. In combine: 26.9%((3+4)/(7+19)) patients with baseline HBsAg ≤ 100 IU/mL obtained HBsAg loss after 24 wk treatment
- Safety: 1 mg/kg ASC22 Q2W plus NAs group had a rate of any adverse events of 75% which was comparable to that of the placebo Q2W plus NAs group.

The pathway to the registration of ASC22 has been agreed: Phase Ilb study will enroll more patients to confirm whether the functional cure rate of ASC22 meets the regulatory requirement (about 30%).

Phase IIb Expansion Cohort: enrolled 49 patients with baseline HBsAg≤100 IU/mI)

1.0mg/kg ASC22 Q2W+NAs (n=40)	Follow-Up
Placebo Q2W+NAs (n=9)	Follow-Up
W	24 W48

ASC22 Phase IIa study: "Best of The Liver Meeting's Summary" (2021 AASLD),
ASC22 Phase IIb abstract: Oral Presentation at EASL ILC 2022

Drug Candidate	Modality	Treatments	Enrollment	HBsAg Loss at End of Treatment	Functional Cure Rate at End of Follow-Up
ASC22	PD-L1 antibody	Q2W, 24 weeks	1.0 mg/kg: N=26, Baseline HBsAg≤100	26.9%	Unknown, follow-up is ongoing.
GSK836	ASO	Q4W, 24 weeks	300mg: N=68	26%	9%
BRII-835+BRII- 179±interferon	siRNA+vacci ne±interferon	BRII-835×9, Q4W+BRII-179×9, Q4W ±interferon×9,QW, 40weeks	N=20 N=20	5% 5%	Unknown, follow-up is ongoing.
BRII-835± interferon	siRNA+ interferon	BRII-835x6,Q4W + PEG-IFNα x24, QW BRII-835x6,Q4W + PEG-IFNα x≤48,QW BRII-835x13,Q4W + PEG-IFNα x≤44,QW	N=18 N=18 N=13	0% 22.2% 30.8%	0% 16.7% 15.4

ASC22(PD-L1) VS Other Drug Candidates for CHB Functional Cure

1.Wang GQ, et al, APASL 2023 abstract FP05-26; 2.Yuen MF, et al. N Engl J Med. 2022.; 3.Yuen MF. et al, APASL 2023 abstract FP13-68



rGBM: Huge Unmet Medical Needs Globally





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



- 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 chemotherapty^[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): v1v95. doi:10.1093/neuonc/noac202

2.中国卫健委, 脑胶质瘤诊疗指南 (2022年版本)

- 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 chFatty Acid Synthase: An Emerging-Jarget in Cancer. Molecules. 2020;25(17emotherapy in recurrent glioblastoma: a randomised phase III trial of a novel treatment modality. Eur J Cancer. 2012;48(14):2192-2202



^{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.

ASC40(FASN) for rGBM: Phase III Enrolled 120 Patients as of Sept 2023

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





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 is Progressing in China

The Phase III Clinical Trial of ASC40 for Treatment of rGBM





Beijing Tiantan Hospital as the leading institute, 28 wellknown hospitals participated in clinical research



120 patients enrollment is the basis for pre-planned interim analysis (93 PFS events)



If Phase III interim results shows PFS is significant improved, ASC40 for rGBM may get 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.

High Efficiency of R&D



High Output with Relatively low R&D Expense of RMB 90 mm in 2023 H1



Continuous Efforts to Enhance In-house R&D and IP Protection



2023 H1:

IND approvals from China NMPA and FDA



Phase II or Phase III trials are advancing

- New patents granted during 2023 H1*
- **37** New patent applications during 2023 H1*

24 Patents granted to date

107 Patent applications to date



Company 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

Sales team for HCV dismissed in H1 2023 due to market shrinkage

Repositioning

Commercialization

- Now the majority staff is for discovery and clinical development
- Co-commercialization with partners in the future

FIC FIC/BIC as Core BIC Competiveness

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



- 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





R&D Pipeline

	Product (Modality)	Target	Indication	Commercial Rights	Pre-IND	IND	Phase I	Phase II	Phase III
	ASC22 (Subcutaneous mAb)	PD-L1	CHB functional cure	Global ¹					
Viral Diseases	ASC22 (Subcutaneous mAb)	PD-L1	HIV functional cure	Global ¹					
	ASC10 (Oral small molecule)	Viral polymerase	Respiratory syncytial virus	Global					
	ASC10 (Oral small molecule)	Viral polymerase	COVID	Global					
	ASC11 (Oral small molecule)	3CL	COVID	Global					
	ASC40 (Oral small molecule)	FASN	NASH	Greater China ²	U	.S. FDA F	ast Track		
	ASC41 (Oral small molecule)	THRβ	NASH	Global					
NASH/FBC	ASC43F FDC (Oral small molecule)	THR β + FXR	NASH	Global					
	ASC42 (Oral small molecule)	FXR	PBC	Global					
Oncology	ASC40 (Oral small molecule) +Bevacizumab	FASN+ VEGF	Recurrent glioblastoma	Greater China ²					
Cheblogy	ASC61 (Oral small molecule)	PD-L1	Advanced solid tumor	Global					
ACNE	ASC40 (Oral small molecule)	FASN	ACNE	Greater China ²					

Notes:

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

Key Milestones

	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≤ 100	
2023Q4	acne	Initiation of Phase III clinical trial of ASC40 (FASN) for treatment of acne	
2023Q4	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	

