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# Clinical-stage oncology-focused biopharma with deep pipeline and near-term readouts

Development platform focusing on Asia-prevalent cancers that are orphan in US and Europe allows a potentially faster route to market

#### **Varlitinib**

Oral, reversible pan-HER inhibitor has shown activity in a range of tumour types with differentiated tolerability profile

- Jan 19 1st line GC phase 2 topline data
- Jan 19 1st line BTC phase 1b data
- 2H 19 2<sup>nd</sup> line BTC pivotal topline data

#### ASLAN003

Oral DHODH inhibitor with the potential to be first-in-class therapy for AML

• 1Q 19 – AML phase 2 (dose optimisation)

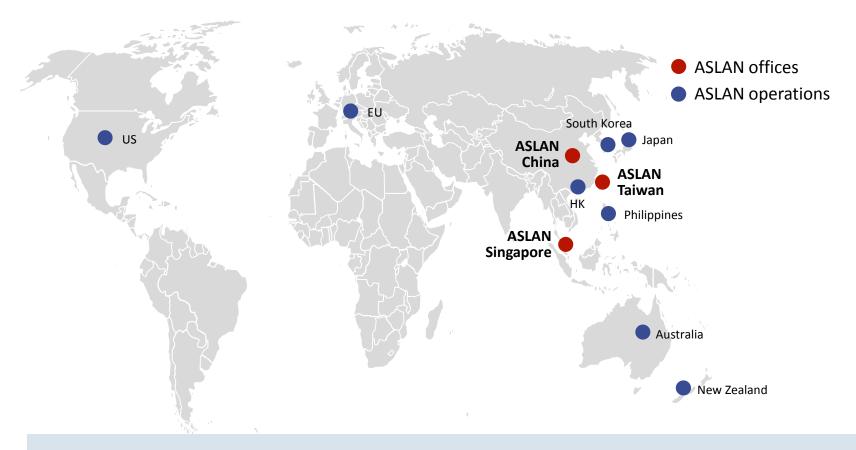
#### ASLAN004

IL-4R / IL-13R inhibitor with the potential to be best-in-class therapy for atopic dermatitis and asthma

• 1H 19 – phase 1 (SAD completion)



## Headquartered in Singapore with global footprint



- Most clinical trials run in Asia where the majority of patients live
- Data is leveraged to seek approvals in US, EU and other global markets
- Building commercial organisation in China, also planning to build in US



### Asia development platform

Asia offers a unique opportunity to accelerate development in diseases where:

- The cancers are more prevalent
- Access to a larger population of patients is easier and more cost-effective
- There are fewer competing trials

Cancer	US prevalence	Asia-Pac prevalence	Difference in prevalence rates
Gastric	32,076	1,027,691	5.6 x
Biliary tract	12,601	200,968	2.8 x
Liver	27,479	422,635	2.7 x
Nasopharyngeal	6,072	112,790	3.2 x

We have built a development platform centered in Asia that enables us to generate data suitable for submission to regulators in the US, Europe, China and Japan

International presence

Extensive knowledge of Asian cancers

Experienced management team

Deep local relationships

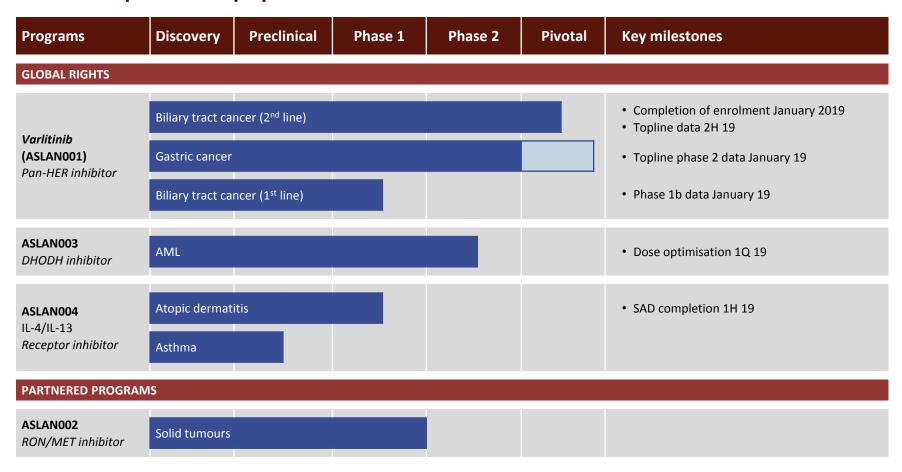


<sup>1</sup> Gastric, liver and nasopharyngeal cancer: as of 2012, based on Globocan (2012); Bray et al (2013), Estimates of global cancer prevalence for 27 sites in the adult population in 2008.

<sup>2</sup> Biliary tract cancer: as of 2016, based on Edison Investment Research, "Novel treatments for worldwide unmet needs," dated November 8, 2017, surveying Randi et al (2008), Epidemiology of biliary tract cancers: an update; Bridgewater et al (2014), Guidelines for the diagnosis and management of intrahepatic cholangiocarcinoma.

<sup>3</sup> In this table, Asia-Pac refers to only China, Japan, Philippines, Singapore, South Korea, Thailand and Vietnam.

### Development pipeline



In August 2017, we initiated a phase 2/3 trial of *varlitinib* in first line gastric cancer. We completed recruitment of 52 patients for the phase 2 part of the study in August 2018 and expect to report topline phase 2 data in January 2019. (The pale blue shaded section represents the phase 3 portion of this ongoing trial. A separate phase 3 clinical trial is not anticipated.)



## Varlitinib (ASLAN001)



# Varlitinib in pivotal studies for BTC and GC with first pivotal read-out in 2019

Pan-HER inhibitor

Highly potent, oral, reversible, small molecule with balanced inhibition across all HER family receptors.

Robust activity

Demonstrated activity in biliary tract, gastric, breast, colorectal cancer. Two phase 2 trials completed, over 500 patients dosed.

Competitive efficacy

60% response rate in randomised 2<sup>nd</sup> line HER2+ breast cancer. Superior to standard of care.

Differentiated safety

Differentiated tolerability for pan-HER class. 5% grade 3/4 diarrhoea across all studies.

Focus on subsets of BTC and GC

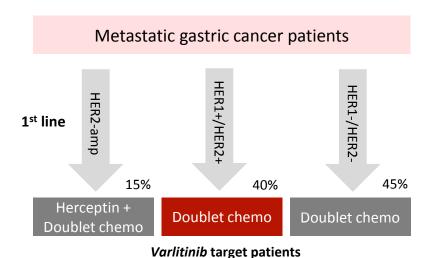
Only pan-HER being developed in BTC and HER1/HER2 GC. US orphan drug designation obtained from the FDA.



#### Opportunities in gastric and biliary tract cancers

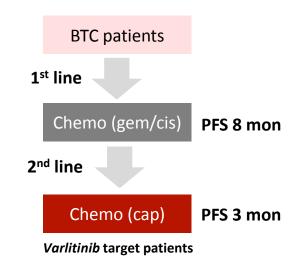
#### **Gastric cancer**

- 5<sup>th</sup> most prevalent cancer globally
- 3<sup>rd</sup> highest cause of cancer mortality
- Median overall survival (OS) 11.1 months
- One approved targeted therapy in 1<sup>st</sup> line:
   Herceptin increases median OS to 13.8 months
- 590,000 patients (China), 30,000 patients (US)



#### **Biliary tract cancer**

- Often considered as subset of HCC, however drugs approved for HCC are not approved for BTC
- Median OS 11.7 months
- No approved targeted therapies
- Around 70% of BTC express HER-family receptors
- 145,000 patients (China), 13,000 patients (US)



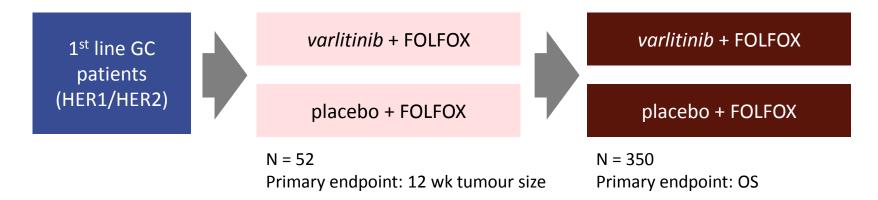
Varlitinib has the potential to be the first targeted therapy for biliary tract cancer and first-line treatment for HER1/HER2 coexpressing gastric cancer



## Gastric cancer Global pivotal trial (1st line HER1/HER2)

Global phase 2/3 study underway with phase 2 topline data anticipated Jan 19

- Double-blind randomised placebo controlled
- 32 sites in Asia and Europe
- Phase 2 recruitment completed in August 2018



#### Historical efficacy of 1<sup>st</sup> line GC treatments:

Regimen	ORR	PFS (mon)	Patient subset	Source
FOLFOX	40%	6.2	All	Lee et al, 2010
cis/cap or cis/5FU	35%	5.5	LIED2 ama	TOCA study (Bang et al. 2010)
Herceptin + doublet chemo	47%	6.7	HER2-amp	TOGA study (Bang et al, 2010)

### Biliary tract cancer

#### Promising signs of efficacy in a difficult to treat cancer

40 solid tumour patients (15 BTC patients)

Varlitinib + doublet chemo (18 weeks)

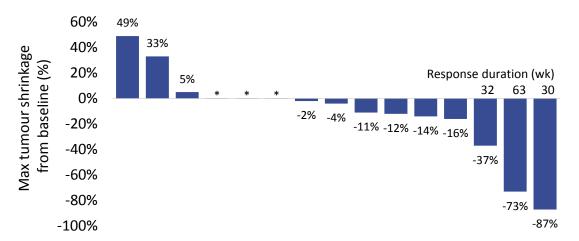
Varlitinib monotherapy

Progression

15 BTC patients were recruited across two phase 1b clinical trials testing *varlitinib* in combination with doublet chemotherapy

- 20% response rate, 87% disease control rate (3 PR, 10 SD, 2 PD)
- Patients had received up to 2 prior treatments
- All responders had a duration of response of at least 30 weeks and were controlled after patients discontinued doublet chemo and continued on *varlitinib* monotherapy

#### Responses in BTC patients (n=15)



#### Responses across all patients (n=40)

Tumour type	N	ORR	DCR
Biliary tract	15	20%	87%
Gastric	5	40%	100%
Colorectal	11	18%	100%
Breast	2	0%	100%
Other	7	0%	86%
Total	40	18%	93%

Data cut-off as of 12 Sep 2017



<sup>\*</sup> These patients did not have measurable lesions, but their disease was declared to be stable by investigator based on non-measurable tumour mass

# Recent data continues to support activity in heavily pretreated BTC and CRC patients

Advanced solid tumour patients

varlitinib + XELOX (oxa / cap)

varlitinib + FOLFOX (oxa / 5-FU)

N = 30

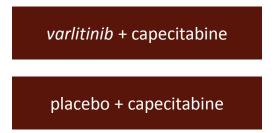
- Phase 1b investigator-initiated trial of *varlitinib* in combination with doublet chemo in solid tumours presented at ESMO 2018
- Patients had a median of 3 lines of prior chemotherapy
- Out of 28 evaluable patients:
  - 3 PR (11%), 16 SD (57%)
  - 36% disease control rate (over 18 wk, after which patients on varlitinib monotherapy)
  - Durable efficacy in BTC and CRC, with 7 patients having PFS over 24 weeks up to 92 weeks
- MTD established at 300mg BID for both regimens
- Study is ongoing testing a further doublet chemo regimen (FOLFIRI)
- Full study results expected in 1H 19

## Biliary tract cancer Pivotal TreeTopp trial (2<sup>nd</sup> line)



- Pivotal "TreeTopp" clinical trial in 2<sup>nd</sup> line BTC
  - 58 sites including US, EU, Japan, China, AsiaPac
  - Led by Dr Milind Javle (MD Anderson)
  - Clinical trial design agreed with US FDA
- Completion of enrolment expected in Jan 2019
- Topline data expected in 2H 19
- Supplemental single-arm China study ongoing in 2<sup>nd</sup> line BTC (68 pts)





Historical efficacy of chemotherapy in 2<sup>nd</sup> line BTC:

ORR	PFS (mon)	OS (mon)	Source
3.4%	3.0	6.6	Fornaro et al, 2015
4%	2.8	7.7	Takahara et al, 2014
7.7%	3.2	7.2	Lamarca et al, 2014

N = 120

Primary endpoints: ORR, PFS

Secondary endpoints: OS, DOR, DCR, tumour size

The trial will meet its primary objective if either endpoint is significant at the one-sided 5% level or if both endpoints are significant at the one-sided 10% significance level

# Varlitinib has the potential to be first targeted therapy approved for BTC and 1<sup>st</sup> line HER1/HER2 coexpressing GC

BTC 2<sup>nd</sup> line

- January 2019 Global pivotal study completion of enrolment
- 2H 19 Topline data readout
- File for approval in major markets

GC 1<sup>st</sup> line (HER1/HER2)

- January 2019 Phase 2 topline data
- Initiate phase 3

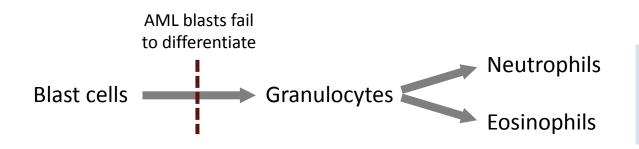
BTC 1st line

- January 2019 Phase 1b data
- Initiate phase 2

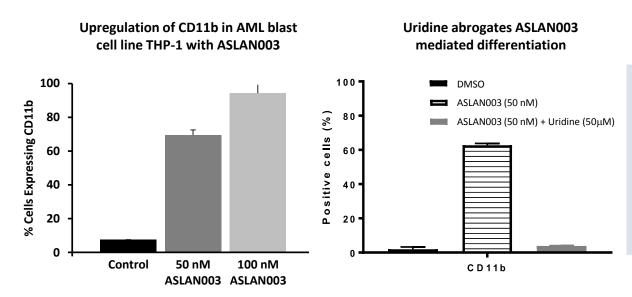
## ASLAN003

### ASLAN003 is an orally active, potent inhibitor of DHODH

DHODH controls the rate-limiting step in the synthesis of pyrimidines and contributes to the production of ATP



ATRA differentiates blasts in up to 15% of AML patients with >90% CR



ASLAN003 promotes differentiation in multiple cell lines that are unresponsive to ATRA. This differentiation is mediated via DHODH.

### Ex-vivo and in-vivo data show promising efficacy in AML

CDX

- ASLAN003 significantly prolonged survival in MOLM-14 (p=0.031) and THP-1 (p<0.001) AML models</li>
- ASLAN003 significantly increased differentiation of AML cells in the bone marrow of xenograft models

**PDX** 

 ASLAN003 significantly prolonged survival in AML patient derived xenografts

Fx-vivo

 ASLAN003 significantly increased differentiation of primary AML cells derived from patients, including one relapsed AML case

### Ongoing phase 2 in R/R AML

#### Study design:

- ASLAN003 monotherapy
- Primary endpoint: CR / CRi rate
- AML mutation analysis and ex-vivo bone marrow differentiation will allow identification of patients that are sensitive to ASLAN003

Relapsed / refractory
AML patients

Cohort 1 – 100mg QD (6 pts)

Cohort 2 – 200mg QD (6 pts)

Cohort 3 – 100mg BID (6 pts)

Cohort 4 – 200mg BID (6 pts)

Dose escalation

N = 24

Expand selected cohort to 20 pts (monotherapy)

Expand selected cohort to 10 pts (combo with azacitidine)

Expansion N = 30

#### ASLAN003 well-tolerated at all dose levels

Adverse event	N=14			
	Any	grade	Grade ≥ 3	
	N	(%)	N	(%)
Leukocytosis	2	14	1	7
Nausea	2	14	0	0
Rash maculo-papular	2	14	0	0
Pleural effusion	1	7	1	7
Abdominal pain	1	7	0	0
Fatigue	1	7	0	0
Conjunctivitis	1	7	0	0
Decreased appetite	1	7	0	0
Hypokalaemia	1	7	0	0
Epistaxis	1	7	0	0
Rash generalised	1	7	0	0

(Data cutoff 16 November 2018, data presented at ASH 2018)

The most commonly occurring related adverse events were leukocytosis, nausea and rash, with grade 3 / 4 leukocytosis in 1 patient

### Early signs of clinical activity in lower dose cohorts

Cohort	100mg QD	200mg QD	100mg BID	Total
Patients treated	6	6	2	14
Patients evaluable for efficacy	2	5	1	8
Patients with signs of efficacy	1	3	0	4

(Data cutoff 16 November 2018, data presented at ASH 2018)

- 14 patients enrolled
- 8 patients received at least 1 post-treatment assessment and evaluable for efficacy
- In the evaluable patients, 4 patients showed clinical signs of efficacy:
  - 1 PR and 1 suspected CR (6% blast cells in peripheral blood, no bone marrow sample)
  - 2 patients exhibited evidence of myeloid differentiation
  - 1 patient developed suspected differentiation syndrome
- Overall
  - 2 suspected Differentiation Syndrome
  - 4 patients had stable disease for more than 3 months

## ASLAN003 has the potential to be first-in-class DHODH inhibitor in oncology

Potent inhibition of DHODH

Binding affinity up to two orders of magnitude stronger than 1<sup>st</sup> generation inhibitors

Potentially differentiated safety profile

Lack of toxicities associated with 1<sup>st</sup> gen inhibitors and other novel AML therapies eg midostaurin, enasidenib

May be applicable in broad range of AML patients

Enables AML blast cells to differentiate into granulocytes in a broad range of AML cell lines

Orphan designation in AML

US orphan drug designation obtained from the FDA

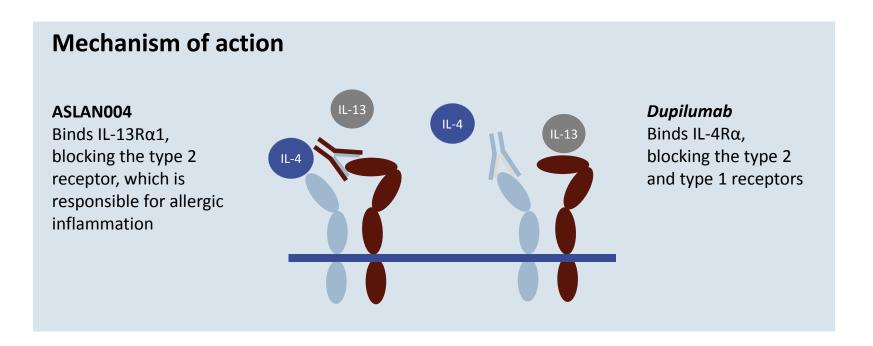
Evidence of activity in TNBC

DHODH inhibition is active in animal models of TNBC and other solid tumours

## ASLAN004

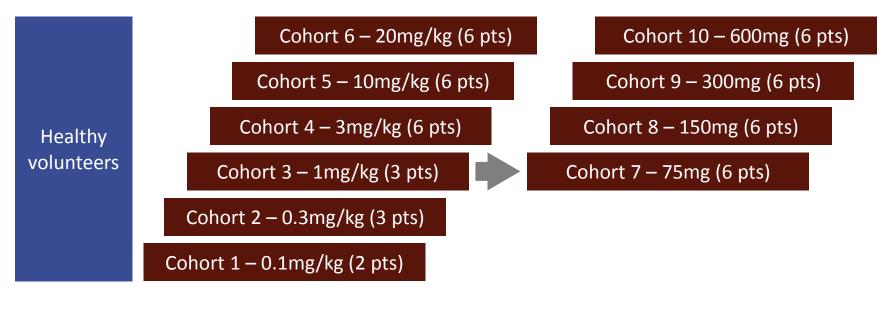
### ASLAN004 blocks signaling through IL-4R / IL-13R

- ASLAN004 targets the IL-13 receptor α1 subunit
- Blocks same pathways responsible for allergic inflammation as dupilumab
  - But ASLAN004 target has narrower cellular distribution than dupilumab target
- Initiated phase 1 in 2H 18



### Phase 1 in atopic dermatitis underway

- Phase 1 single ascending dose recruiting healthy volunteers
- Sites including Singapore, Australia and the US
- Expected to complete in 1H 19



Part A (IV)
60 minute IV infusion via syringe driver

Part B (SC)
Parallel conduct after cohort 3 completed

## ASLAN004 has the potential to be best-in-class therapy

	ASLAN004	Dupilumab
Dosing	<ul> <li>Potential for 4 weekly dosing</li> </ul>	Dosed every 2 weeks
Drug product	<ul> <li>3 months stability 40°C</li> <li>≥6 months stability 25°C</li> <li>Greater storage flexibility</li> </ul>	<ul> <li>14 days max storage at 25°C</li> <li>Cannot be stored above 25°C</li> </ul>
Loading dose	<ul> <li>Not using loading dose</li> </ul>	<ul> <li>Yes (600mg via 2 injections)</li> </ul>
Safety	Type 1 receptor not targeted	<ul> <li>Type 1 receptor potentially implicated in conjunctivitis and herpes infections</li> </ul>

## Summary

### Management team with global development experience

#### **Position Experience** Bank of America AstraZeneca **Merrill Lynch Dr Carl Firth** Head of New Portfolio (China) Head of Asia Healthcare Banking CEO Head of BD (Asia) ( Almirall AstraZeneca **Dr Bertil Lindmark** Head of Development, R&I Global Head of R&D CMO Head of Development, Japan CSO **AstraZeneca** Dr Mark McHale Head of Molecular Sciences, R&I COO Head of Early Asthma Portfolio **Stephen Doyle** Boehringer SANOFI 🧳 Ingelheim **GM** China VP Specialty Care & Diabetes (China) VP Oncology (China) **VP Commercial** Dr Chih-Yi Hsieh NOVARTIS **GM** Taiwan Oncologist, Taipei VGH **VP Medical** Medical Advisor GLOBAL BRANDS **Kiran Asarpota**

**Group Finance Director** 

**VP** Finance



## **Financials**

As of 30 September 2018

Exchange / ticker	US – NASDAQ: ASLN Taiwan – TPEx: 6497
Shares outstanding	160.2M
Cash balance	US\$ 35M
Operating expenses	US\$ 31M (9M 18)
Recent financing	US\$ 42M raised in May 2018 (NASDAQ IPO)

## Anticipated near-term milestones

	Expected timeline	Program	Milestone
$\checkmark$	Complete	ASLAN003	Interim phase 2 data (ASH, Dec 2018)
	January 2019	Varlitinib	GC phase 2 topline data
	January 2019	Varlitinib	1 <sup>st</sup> line BTC phase 1b data
	1Q 19	ASLAN003	Dose optimisation
	1H 19	ASLAN004	Phase 1 SAD completion
	2H 19	Varlitinib	2 <sup>nd</sup> line BTC pivotal topline data

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