# **Company presentation**

September 2018

NASDAQ: ASLN TPEx: 6497



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All statements other than statements of historical fact are forward-looking statements. The words "believe," "may," "might," "could," "will," "aim," "estimate," "continue," "anticipate," "intend," "expect," "plan," or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes are intended to identify estimates, projections and other forward-looking statements. Estimates, projections and other forward-looking statements. Estimates, projections and other forward-looking statements speak only as of the date they were made, and, except to the extent required by law, the Company undertakes no obligation to update or review any estimate, projection or forward-looking statement.



### ASLAN investment highlights

Oncology-focused Deep pipeline	Clinical-stage oncology-focused biopharma company with deep pipeline
Asia-prevalent cancers	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
ASLAN003	Oral DHODH inhibitor with the potential to be first-in-class therapy for AML
Major partnerships	Partnerships with leading pharma and biotechs: Array, BMS, CSL, Almirall
Key milestones in 2018	Value-creating milestones in 2018: topline pivotal data in biliary tract cancer in China, phase 2 gastric cancer, interim phase 2 AML
International presence	International presence with broad experience in Asia, extensive knowledge of target diseases and deep local relationships



### Management team with global development experience



#### Experience

**Dr Carl Firth** CEO



AstraZeneca Head of New Portfolio (China) Head of BD (Asia)

**Dr Bertil Lindmark** CMO



AstraZeneca Head of Development, R&I Head of Development, Japan

**Dr Mark McHale** COO



AstraZeneca Head of Molecular Sciences, R&I Head of Early Asthma Portfolio gsk

CSO

Stephen Doyle GM China VP Commercial



Boehringer Ingelheim VP Specialty Care & Diabetes (China)

SANOFI 🎝

Bank of America 🤎

Almirall

Global Head of R&D

Head of Asia Healthcare Banking

**Merrill Lynch** 

VP Oncology (China)

**Dr Chih-Yi Hsieh** GM Taiwan VP Medical



**U** NOVARTIS Medical Advisor



Oncologist, Taipei VGH





Kiran Asarpota VP Finance

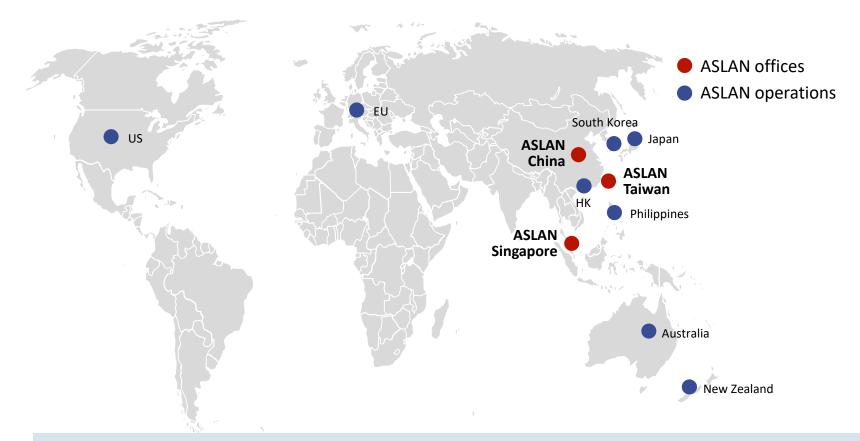


Group Finance Director

GROUP

GLOBAL BRANDS

### 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

1 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.

2 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.

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







### **Development pipeline**

Programs	Discovery	Preclinical	Phase 1	Phase 2	Pivotal	Anticipated milestones		
GLOBAL RIGHTS								
<b>Varlitinib (ASLAN001)</b> Pan-HER inhibitor	Biliary tract cancer					<b>BTC:</b> • Global pivotal topline data (2 <sup>nd</sup> line) 2019		
	Gastric cancer					<ul> <li>China pivotal topline data (2<sup>nd</sup> line) late 2018</li> <li>Interim phase 1/2 data (1<sup>st</sup> line) late 2018</li> <li>GC:</li> <li>Global phase 2 topline data 4Q18</li> </ul>		
	Breast cancer							
	Colorectal can	cer						
<b>ASLAN003</b> DHODH inhibitor	AML					Interim data 2H18		
<b>ASLAN004</b> IL-4/IL-13 <i>Receptor inhibitor</i>	Asthma					IND 3Q18		
	Atopic dermat	itis				IND 3Q18		
PARTNERED PROGRAM	15							
<b>ASLAN002</b> RON/MET inhibitor	Solid tumours							

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 4Q18. (The pale blue shaded section represents the phase 3 portion of this ongoing trial. A separate phase 3 clinical trial is not anticipated.)

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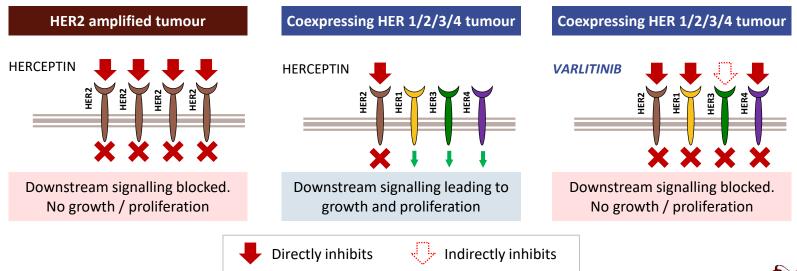
### Overview of *varlitinib* (ASLAN001)

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 400 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.



### Mechanism of action

- Targets the HER family of receptors: HER1, HER2, HER3 and HER4
  - Responsible for driving growth in human epithelial cells
- HER-selective drugs such as Herceptin target only one type of HER receptor (HER2)
  - Established efficacy in tumours driven specifically by HER2
  - Blocking just one receptor type is ineffective for many patients
  - These tumours may be driven by a combination of HER1, HER2, HER3 and HER4
- Varlitinib has the potential to inhibit growth of a much broader range of tumours



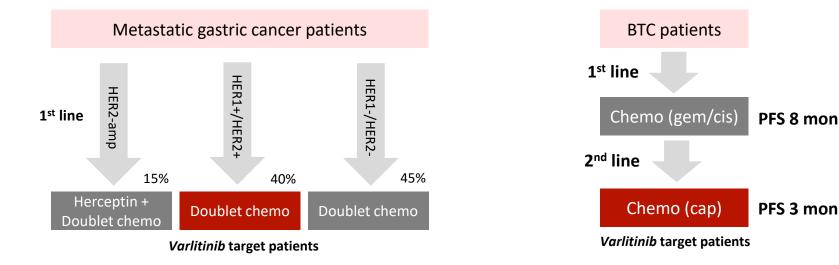
### Opportunities in gastric and biliary tract cancers

#### **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**

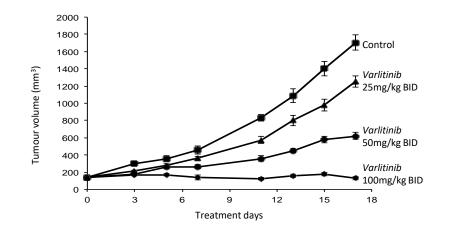
- Often considered as subset of HCC, however drugs approved for HCC are not approved for BTC
- Median OS 11.7 months
- No approved targeted therapies
- Around 70% of BTC express HER-family receptors
- 145,000 patients (China), 13,000 patients (US)



*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 HER1/HER2 drive growth in HER1/HER2 coexpressing disease



Dose dependent tumour growth inhibition in HER1/HER2 coexpressing GC PDX models

Marker	Evaluable HER1/HER2 coexpressing patients	Implications
рМАРК	86% (inhibition)	Reduced tumour proliferation
Ki67	71% (downregulation)	Reduced tumour proliferation
рАКТ	29% (inhibition)	Tumour cell death
TUNEL	60% (upregulation)	Tumour cell death

In a Phase 2 gastric cancer paired biopsy study, varlitinib led to down regulation of proliferation and upregulation of apoptosis in HER1/HER2 coexpressing tumours

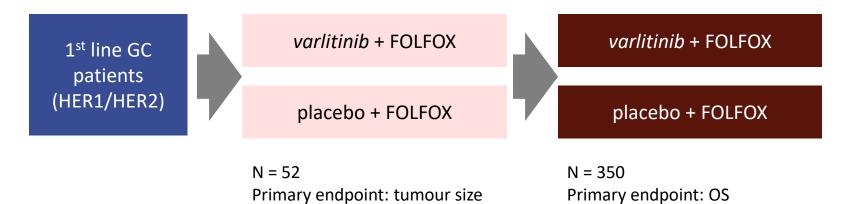
Based on this preclinical and clinical data, we are targeting first-line patients coexpressing HER1 and HER2 that are ineligible for Herceptin



## Gastric cancer

### Global pivotal trial (1<sup>st</sup> line HER1/HER2)

- Global phase 2/3 study underway with phase 2 topline data anticipated in 4Q 2018
  - Double-blind randomised placebo controlled
  - 32 sites in Asia and Europe
  - Phase 2 recruitment completed in August 2018
  - Phase 2 readout expected in 4Q 2018



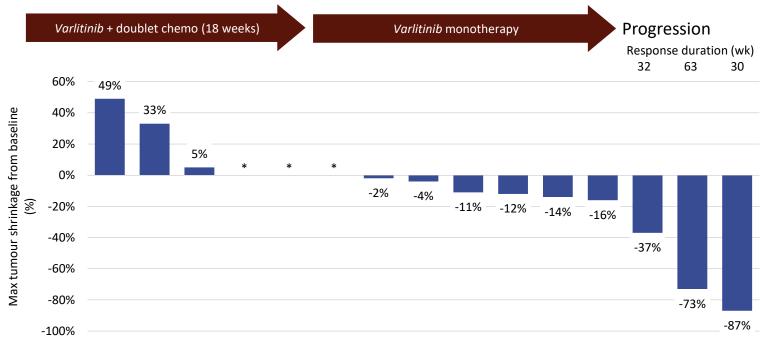


### **Biliary tract cancer**

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

15 BTC patients recruited for phase 1b clinical trials of *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



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



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



- Pivotal "TreeTopp" clinical trial initiated in April 2017 in 2nd line BTC
  - 58 sites including US, EU, Japan, China, AsiaPac
  - Led by Dr Milind Javle (MD Anderson)
  - Clinical trial design agreed with US FDA
- Topline data expected in 2019

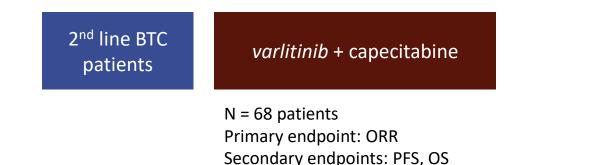


Primary endpoints: ORR, PFS Secondary endpoints: OS, DOR, DCR, tumour size



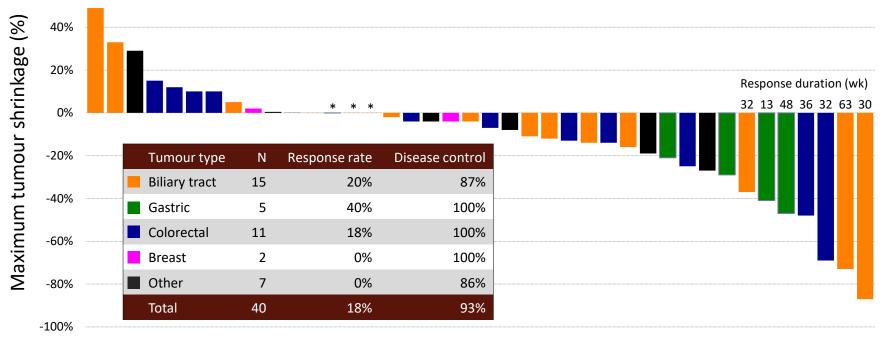
### Biliary tract cancer China pivotal trial (2nd line)

- Varlitinib pivotal trial for BTC underway in China
  - Clinical trial design agreed with China FDA
  - Led by Professor Qin Shukui (Nanjing 81 Hospital and Chair of CSCO)
- Recent Chinese regulatory changes allow for the acceleration of innovative drugs addressing areas of high unmet need
- First patient enrolled in December 2017
- Topline data expected to be reported in late 2018
- We are building our commercial organisation in China





### Safety Doses established with wide range of chemo regimens



Phase 1b combining *varlitinib* with doublet chemotherapy:

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

- All patients received varlitinib and doublet chemo for 6 cycles then monotherapy
- MTD established at 300mg BID with doublet chemotherapy

Across all clinical trials, the most commonly occurring drug-related AEs were fatigue (46% any grade, 6% grade 3/4), nausea (44% any grade, 2% grade 3/4) and diarrhoea (42% any grade, 5% grade 3/4)



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

Potent inhibition of HER1, HER2 and HER4

HER4 inhibition may lead to a more durable response

Low levels of GI toxicity vs other pan-HER inhibitors

Well-tolerated with different chemo regimens

Potentially enables it to be used in broader range of tumours than HER1-selective and HER2-selective agents

HER4 upregulation is an escape mechanism in BC cell lines treated with *lapatinib* - remain sensitive to *varlitinib* 

*Varlitinib* is a reversible inhibitor so only transiently blocks gut epithelia signalling pathways

*Varlitinib* has been combined with 7 different chemo regimens including doublet chemo

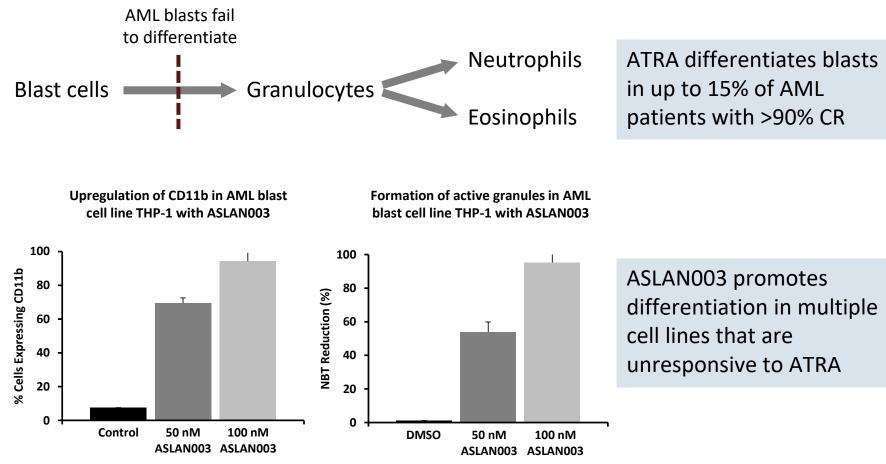






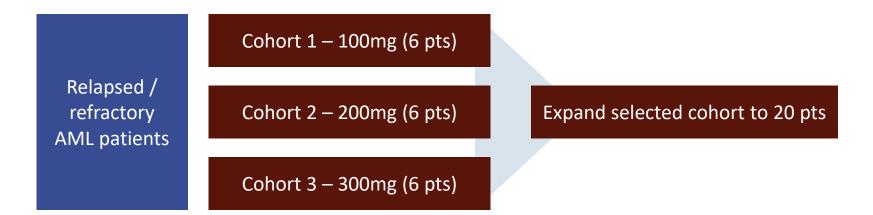
### ASLAN003 is an orally active, potent inhibitor of DHODH

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





### Phase 2 in AML underway



- Patients dosed with ASLAN003 monotherapy for 28 days or until progression
- Primary endpoint: CR / CRi rate
- AML mutation analysis and *ex-vivo* bone marrow differentiation will allow identification of patients that are sensitive to ASLAN003
- Interim data expected 2H 2018



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

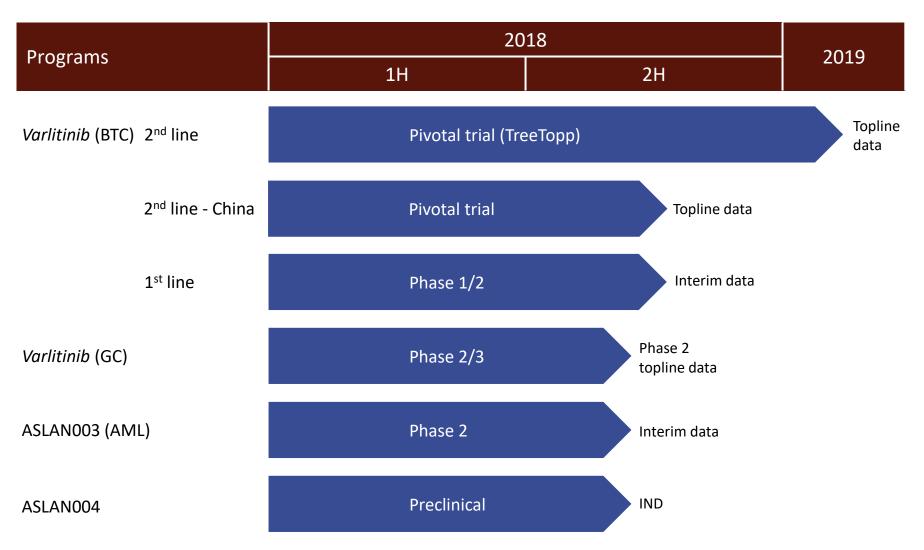
Potent inhibition of DHODH	Binding affinity up to two orders of magnitude stronger than 1 <sup>st</sup> generation inhibitors
Potentially differentiated safety profile	Lack of toxicities associated with 1 <sup>st</sup> gen inhibitors and other novel AML therapies eg midostaurin, enasidenib
May be applicable 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



## Anticipated milestones



### Anticipated milestones





### ASLAN investment highlights



Listed in US (NASDAQ: ASLN) and Taiwan (TPEx: 6497) US\$ 42M raised in NASDAQ IPO in May 2018 (ASLN) Cash balance US\$ 45M (as of 30 June 2018) Operating expenses US\$ 39M (2017)

