

Formation Biologics

A clinical-stage biopharmaceutical company

Lead program projected to achieve clinical validation in 2018



**Formation
Biologics**

formationbiologics.com

Formation Biologics Corporate Summary



- Clinical-stage development company based in Austin
 - Management-led spin-out from YM BioSciences prior to acquisition of YM by Gilead
 - Engineers and develops biotherapeutics for life-threatening cancers and rare diseases
- Lead product:
 - **AVID100**: anti-EGFR antibody-drug conjugate currently in Phase I/II trials;
Designed under leadership of Dr. Walter Blättler, formerly EVP of R&D and scientific founder of ImmunoGen
- Team with track-record of developing drugs, including up to approval
 - Kadcyła®, Tarceva®, momelotinib, as well as hematopoietins, cytokines and interleukins (EPO, GM-CSF, IL-3, IL-6)
 - Nominated as “Best New Drug Developer” by World ADC Summit

Lead Program: AVID100 Mechanism of Action

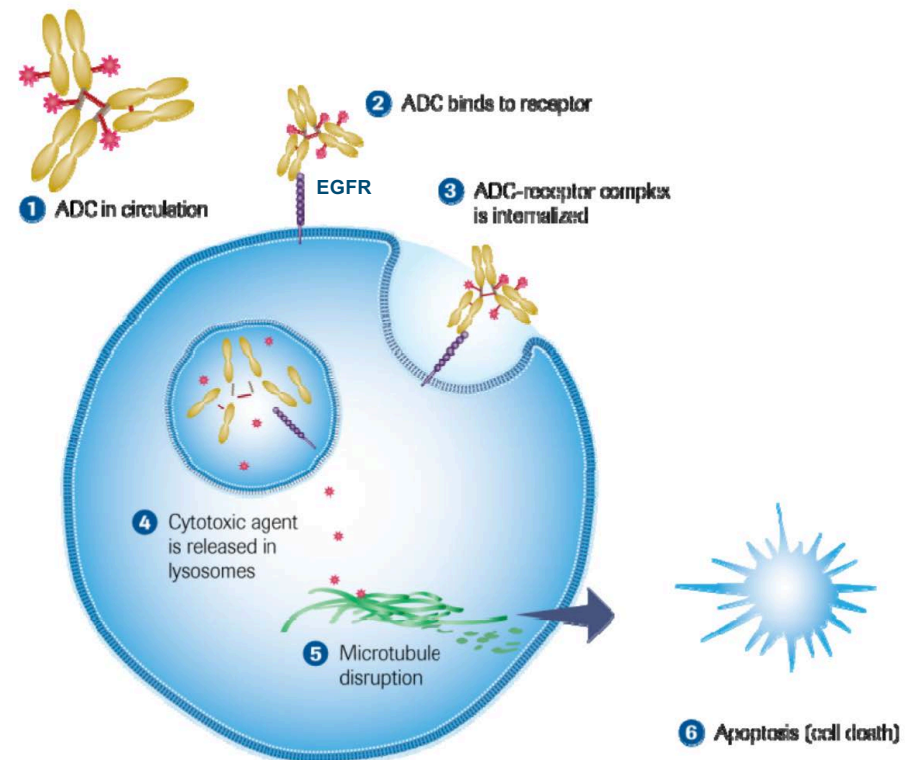
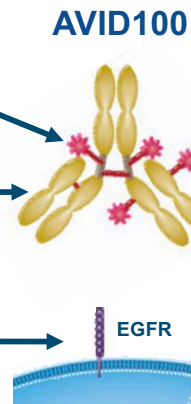
AVID100 targets EGFR and incorporates clinically validated components



anti-microtubule
chemo payload,
clinically validated

anti-EGFR mAb,
clinically
validated class

EGFR, clinically
validated target



AVID100 Market: Select Approved anti-EGFR Therapeutics

Large market and significant unmet medical need



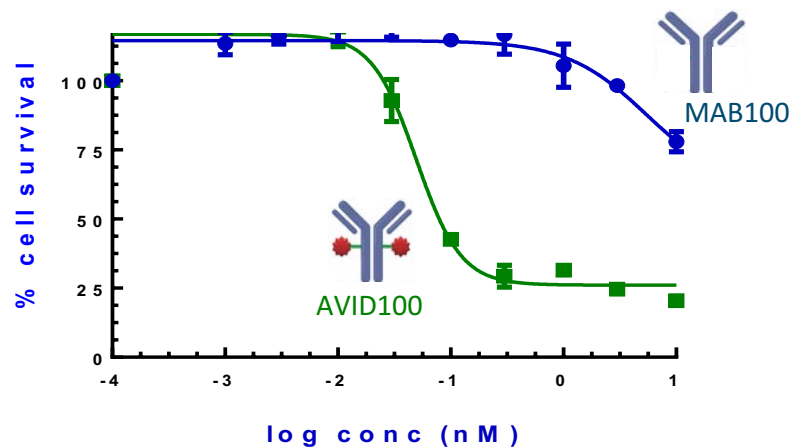
Marketed Anti-EGFR Agent	Approval	Large Market: Approx. Annual Sales	Unmet Need: Single Agent Response Rate
Erbix® (cetuximab) Eli Lilly, Merck KGaA	KRAS-, EGFR+ CRC Head & Neck	\$2 billion	~11%
Vectibix® (panitumumab) Amgen	KRAS- CRC	\$0.5 billion	<10%
Tarceva® (erlotinib) Astellas/OSI, Roche	NSCLC, Pancreatic	\$1.4 billion	<10%
		Total: ~\$4 billion	Average: <10%

AVID100 Discovery:

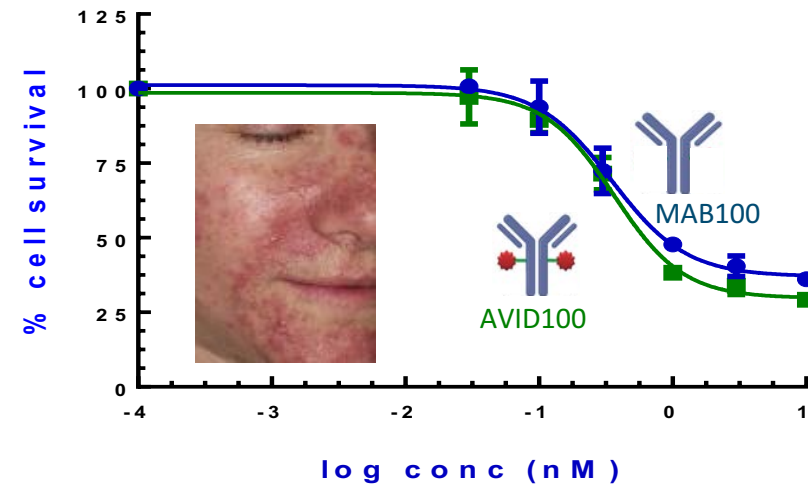
In vitro: AVID100 shows increased cytotoxicity on cancer cells but not enhanced toxicity on normal skin cells when compared to naked anti-EGFR antibody (MAB100 or cetuximab).



Potency: Killing of EGFR+ Cancer Cells*



Toxicity: Killing of EGFR+ Skin Cells*

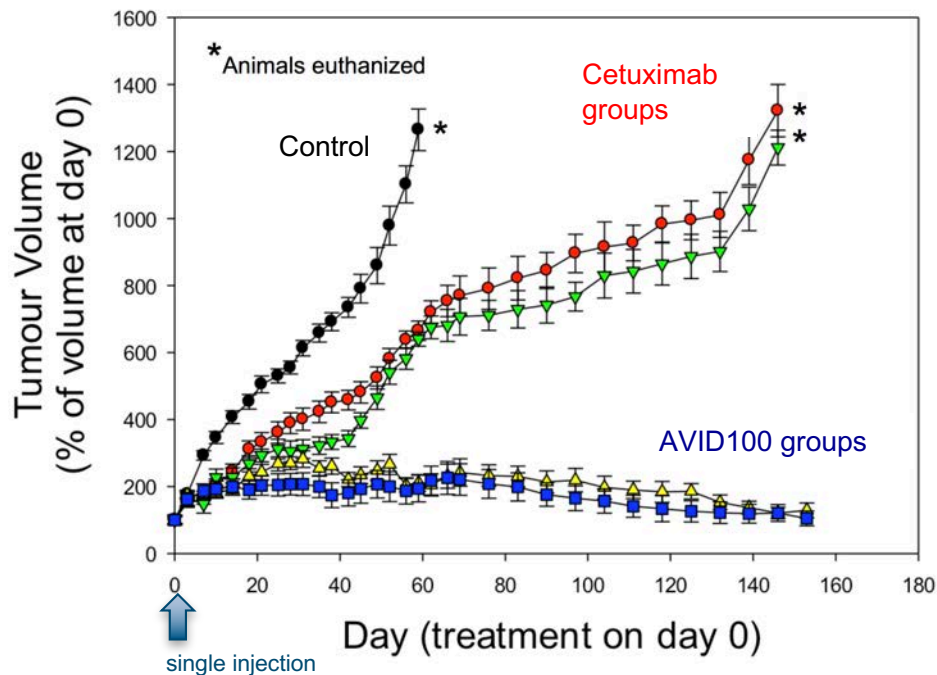


* Data by the National Research Council of Canada

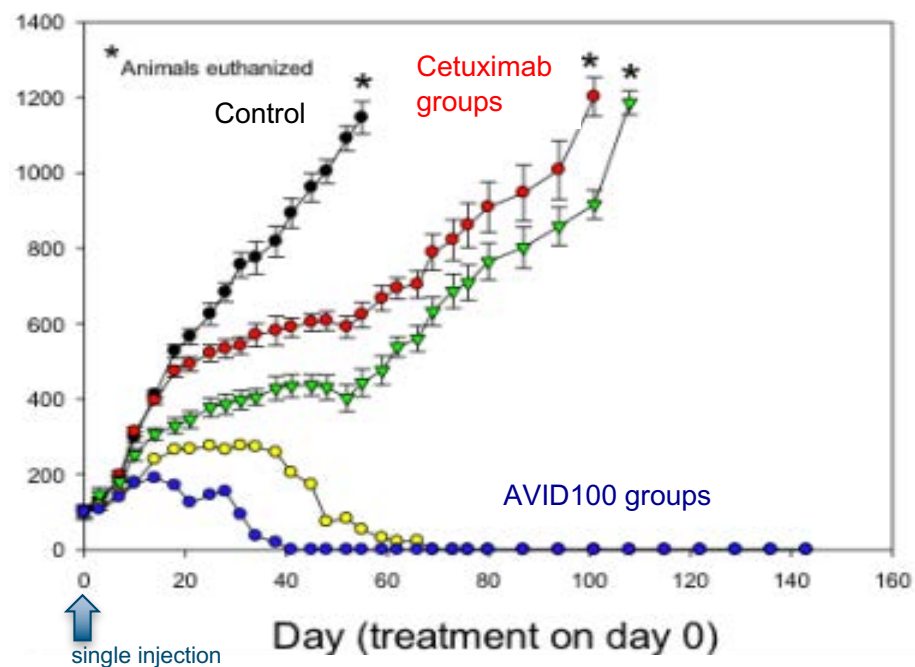
In Vivo: AVID100 is More Efficacious than Cetuximab, the Market-Leading anti-EGFR Agent, in Human Xenograft Tumor Models



Head & Neck Cancer*
25% CR rate in 10mg/kg group



Triple-Negative Breast Cancer*
CR in majority of animals



* Data by Dr. Koropatnick lab, Western University

Primate Studies Confirm *In Vitro* Skin Cell Finding:

AVID100-Induced Rash is Similar to That of Naked Antibody (Cetuximab) Rash



- For anti-EGFR agents, toxicology findings in primates, including rash, are correlated with safety profile in humans (well established with the two approved anti-EGFR mAbs)
- Prior to IND submission, the safety of AVID100 was studied extensively in non-human primates: 5 studies comprising single and repeat-dosing
- **Conclusions from preclinical studies:**
 - AVID100 was well-tolerated with rash similar to that observed with cetuximab
 - AVID100 demonstrated significant anti-cancer activity and potential for a wide therapeutic index

AVID100 Phase I/IIa: Currently Ongoing

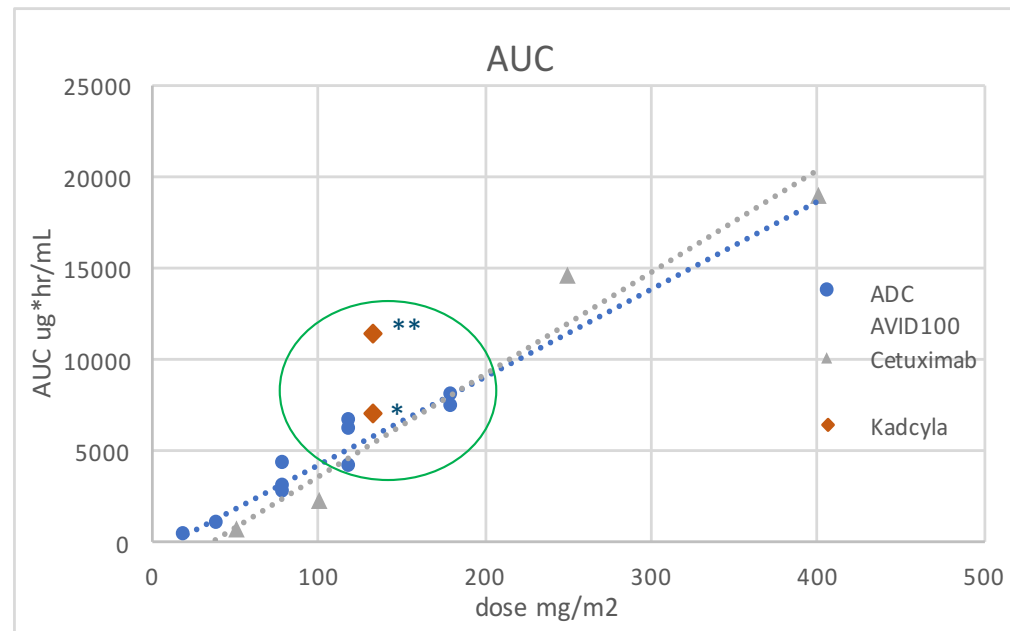
Phase I dose-escalation already achieved AVID100 doses that are expected to be clinically active in Phase IIa trials in patients EGFR IHC3+ tumor types



- Phase I goals: safety assessment and determination of recommended Phase II dose
- Phase I design: Accelerated dose-escalation with single patient cohorts, followed by standard 3+3
 - Patients not selected for EGFR expression during Phase I
- Status: 5th cohort completed (180 mg/m²; ~5 mg/kg) without protocol-defined DLT's in first cycle
 - Currently enrolling 6th cohort (220 mg/m²; ~6 mg/kg administered Q3W)
- Comments: Preclinical data suggest that AVID100 is active at clinical doses >2 mg/kg
 - The marketed ADC, Trastuzumab-DM1 (similar PK and payload technology to that of AVID100) is approved on a 3.6 mg/kg Q3W regimen and demonstrated approx. a 40% response rate

Initial PK Results: AVID100 Comparison with Kadcyła™

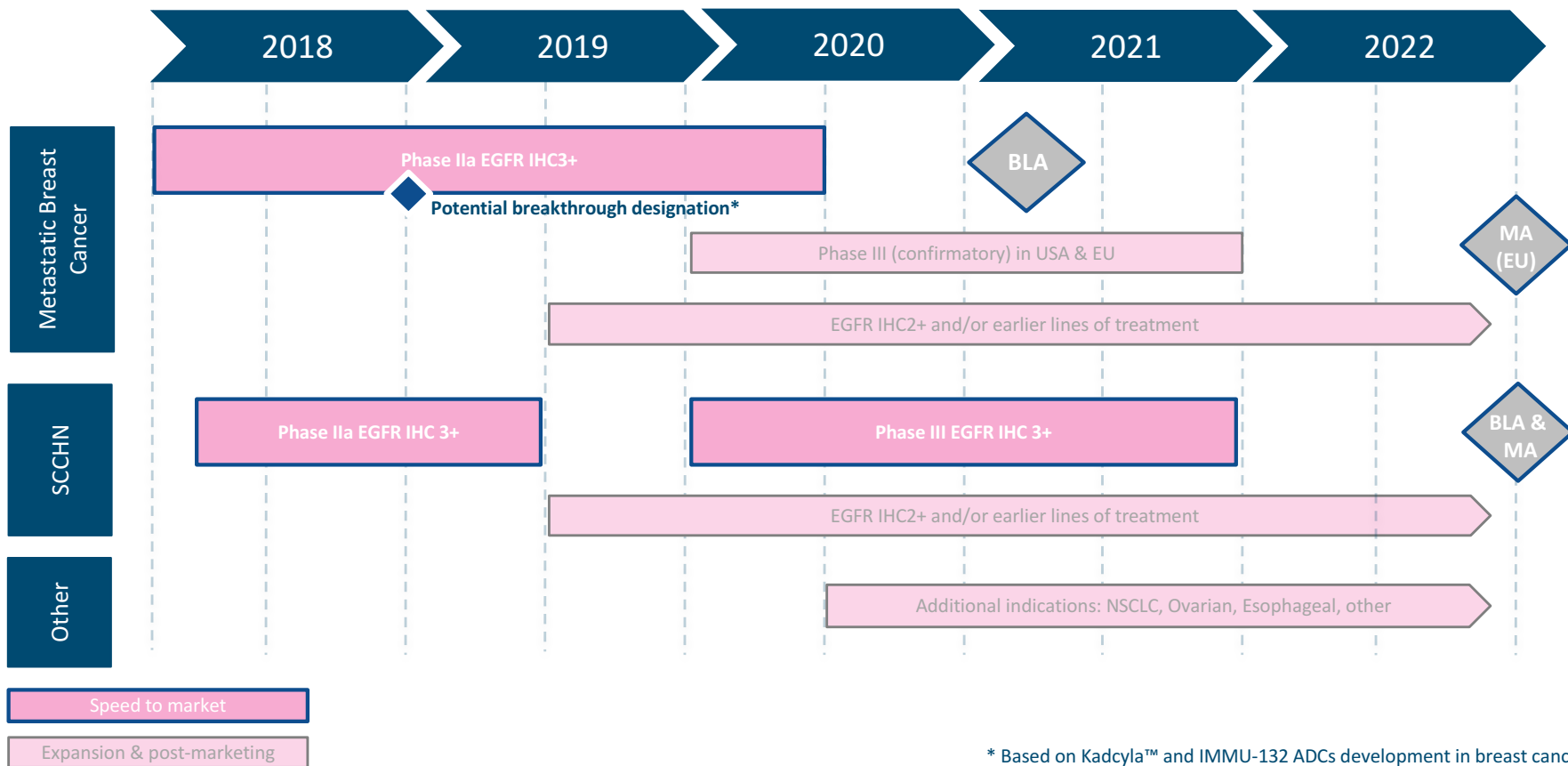
In the ongoing Phase I dose-escalation trial, AVID100 achieved AUC levels similar to that of Kadcyła™, which are associated with significant anti-cancer activity



* Krop et al. 2010 Journal of Clinical Oncology Phase I Study of Trastuzumab-DM1

** Weighted average of all the other studies reported in the BLA (TDM4258g, TDM4374g, TDM4450g, TDM4688g, TDM4370g)

AVID100 Potential Path to Market in Breast Cancer and Squamous Carcinoma of Head and Neck



* Based on Kadcyla™ and IMMU-132 ADCs development in breast cancer

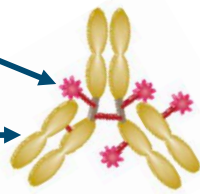
AVID100 Targets a Large Number of Indications: Tumors That Overexpress EGFR and Are Sensitive to Anti-Microtubule Agents



anti-microtubule
chemo payload

anti-EGFR mAb

AVID100



Breast

Head and Neck

Lung

Esophageal

Ovarian

Endometrial

Cervical

Pancreatic

Gastric