Alloplex Biotherapeutics

# Topline safety and efficacy update of SUPLEXA-101, a First-in-Human, Single Agent Study of SUPLEXA Therapeutic Cells in 28 Patients with Metastatic Solid Tumors

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### Background





SLIDI EVA thoropoutio colle are ar	autologous collular thorapy comprised of			_							IABLE	: ZA and ZB – 3	Safety
bighty activated PRMC-derived whi	te blood cells SLIPI EXA cells are broadly	TABLE	1- patie	ent demo	ographics			2A: N	o related SAE				2B: most TEAE were mild to modera
cytolytic against a variety of tumor cell lines <i>in vitro</i> while showing no adverse			As of the data cut off 28 patients were administered three						SAE Verbatim	SAE	SAE Reason	Relationship	
impact on normal resting peripheral	SUPLEXA doses. Patients age median was 64.5 (11SD). Males								Duration				
cells express the hallmark featu	res of antigen presenting cells and are	(43%)	and tema	ales (57%) n of 49 n	(6); all ECO	JU-1. At scree	ning were stage	0104	Bowel obstruction	9 days	Hospitalization	Not Related (NR)	Number of Participants Reporting at least:
immunomodulatory as evidenced k	by dramatic changes in blood composition		a media	11 01 40 11 '20/20\ ;	nontris (60 -	5D) SINCE INITE	a diagnosis with			e daye			Any TEAEs
following administration.		chemo	пегару (	20/20), I	mmunotner	apy (14/20) ai	10  Other  (12/26).	0202	Astrovirus infection	7 days	Hospitalization	NR	Any severe TEAEs (Grade >=3)
This first_in_human (FIH) Phase 1 o	nen-label study is a non-comparative open	Patient	Age/	Tumor	Stage at	Metastasis	Previous Lines		Lower back pain	7 days	Hospitalization	NR	Any treatment related TEAEs
label single-agent survey study de	signed to assess the safety tolerability and	Number	Gender	Туре	Screening	Locations	of Treatment		Perirectal bleeding	25 days	Hospitalization	NR	Any TEAEs leading to withdrawal from study treatm
nreliminary clinical efficacy of rener	ated intravenous (IV) infusions of SLIPI EXA	0101	M / 56	Anal	IV	Luna. Rectum.	Surgery (3)						Any TEAEs leading to discontinuation from study Any TEAEs leading to death
monotherany in subjects with vario	us measurable metastatic solid tumors and					Lymph Node,	Radiation (2)	0203	Ascites worsening	6 days	Hospitalization	NR	Number of Subjects Reporting TEAEs by Severity
homotologic malignancios As a	single agent study no chamatharapoutic					Bone	Anti-tumor (6)	0205	Pulmonary	1 day	Hospitalization (fa	atal) NR	Mild (Grade 1) Moderate (Grade 2)
naemalologic malignancies. As a	single-agent study, no chemotherapeutic	0102	F / 60	Ovarian	IV	Liver, Lymph Node	Surgery (2)		embolism				Severe (Grade 3)
preconditioning, cytokine supportive	or infinute checkpoint infibitors were used.						Anti-tumor (9)	0303	Dyspnoea	38 days	Hospitalization (fa	ital) NR	Life Threatening (Grade 4) Fatal Outcome (Grade 5)
	monufocturing	0104	F / 34	Ovarian	IV	Lung, Ovary,	Surgery (3)						Number of Subjects Reporting TEAEs by Relations
SUPLEAF	Amanufacturing					Rectum, Lymph Node	Anti-tumor (5)						Not Related
		0106	F / 48	Cervical	IV	Lung	• Surgery (1)	FIGU	RE 1 Swimm	ers plot			
SUPLEXA process							Radiation (1)	OKK	was seen in 2	patients	s with CR ar	Id PR IN CRC, V	with majority of the patients attaining
These not engineered, but	ISOLATE WHITE BLOOD CELLS (-50M) CO-INCUBATE WITH	0407	<b>F</b> / <b>C</b> /	Demonstra	N /		Anti-tumor (1)		ı	ATIENT GEND	ER AGE TUMOU	R	
rather reprogrammed to recognize and kill tumor cells.	$\begin{array}{c} \text{Enlist CELLS} \\ (7 \text{ days}) \end{array}$	0107	F / 64	Pancreatic	IV	Lung, Spieen,	Surgery (1)			0110 M	58 Renal	000-	
Simple infusion of less than 60 PATIENT STUDY / min per dose.						Ascites Peritoneum	• Anti-tumor (5)			0112 M	64 Meland 71 Repol	oma 0000-	
		0109	M / 75	Thymic	IV	Lung Pleura	• Surgery (1)	ON	STUDY	0113 M	61 Colore		
	loplex	0100		i i i yi iio		Mediastinum, Lymph	<ul> <li>Radiation (2)</li> </ul>			0111 F	62 Colore	ctal-MSI-H 000	
Biot	therapeutics					Node	Anti-tumor (6)			0115 M	58 Lung	-000	
	A MANUFACTURING	0110	M / 58	Renal	IV	Lymph Node	Anti-tumor (2)			0301 M	63 Meland	oma OOO-	<b>0</b> - <b>0 0 0 0 0 0 0 0</b>
ADMINISTRATION (Repeat)	plex Biotherapeutics ©2023 A universal cellular manufacturing reagent	0111	F / 62	Colorectal-	IV	Peritoneum	• Surgery (1)			0114 F	69 Breast	000-	<u> </u>
	SUPLEXA IN VITRO EXPANSION (9 days)			MSI-H			Anti-tumor (3)			0102 F	60 Ovariar	n <u>000</u> -	$\rightarrow$
CONTROLLED		0112	M / 64	Melanoma	IV	Peritoneum, Lung,	Surgery (1)			0118 M	64 Renal	000-	0-0+0-0 +>
	SHIP STORE CONTROLLED MULTIPLE DOSES					Intramuscular	Radiation (1)						
	DRY ICE) (LIQUID NITROGEN) FREEZE (-50 B) (Cryostorage Stability > 6 months)						Anti-tumor (2)						
		0113	M / 71	Renal	П	Lung, Bone	Surgery (1)			0101 M	56 Apal	0000	
	Alloplex@						Anti-tumor (3)			0215 M	76 Melano		
<b>C</b> 4		0114	F / 69	Breast	IV	Liver, Lymph Node	Radiation (1)			0106 F	48 Cervica		
อเน	ay Design						Anti-tumor (3)			0203 F	70 Ovariar	n 0000	
This restar reports on CUDLEXA		0115	M / 81	Lung	IV		Radiation (1)			0109 M	75 Thymic	000-	○—○—●■
I his poster reports on SUPLEXA-							Anti-tumor (1)			0116 F	76 Liver	000-	
with histologically or cytologically	Pre-dosing period Minimum dosing period Post-dosing period	0116	F / 76	Liver	IV	Liver, Lymph Node	• Surgery (1)	OFF	STUDY	0207 F	47 Cervica		
confirmed measurable solid							Anti-tumor (3)			0303 M	55 Renal	- 000-	
tumors, radiographically	QA/QC 21 -d14 -d7 dQ d7 wk2 wk3 wk4 wk5 wk6 wk7 wk8	0117	F / 61	Colorectal- MSI-H	IV	Lymph Node	• Surgery (1)			0201 F	64 Pancre	atic 0.000	
confirmed as Stage 2 to 4 cancer.		0.44.0			N 7		Anti-tumor (3)			0209 F	69 Colore	ctal-MSS 000	
All eligible subjects received a	Baseline Post	0118	M / 64	Renal	IV	Lung, Bone, Peritoneu	m • Surgery (1)			0202 F	75 Endron	netrial 0-0-00	
minimum of 3 weekly dose of	scan scan	?//L					Radiation (2)			0204 F	58 Ovariar	n <u>0000</u>	
SUPLEXA of approx. 2.5 billion		0201	E / 45	Urotorio		Polvic	Anti-tumor (3)     Surgony (1)			0104 F	34 Ovariar	n <u>000</u> -	— <b>⋇</b> ■
the Investigator Sponsor Medical	Note:	0201	1/43	Oretenic	ĨV		Badiation (3)			0205 M	78 Ureteri		
Monitor and in agreement with	No chemotherapeutic preconditioning						Anti-tumor (5)			0302 F	60 Lung		
the subject, additional SUPLEXA	• No IL-2 cytokine support to be added	0202	F / 75	Endometroi	IV	Luna, Liver.	Surgery (3)			0212 11	70 Colored		1
infusions were administered				d		Lymph Node	Radiation (4)					0	10 20
when available.				carcinoma			Anti-tumor (7)						Time since first SU
Objectives	Endpoints	0203	F / 70	Ovarian	IV	Omentum,	Surgery (5)						
Primary						Peritoneum	Anti-tumor (9)	0	5		10	15 20	25 30/35 40
To assess safety and tolerability of	<ul> <li>Incidence of dose limiting toxicities (DLTs)</li> </ul>	0204	F / 58	Ovarian	IV	Omentum	Surgery (3)	Week					
SUPLEXA in subjects with malignant solid	<ul> <li>Incidence of adverse events (AEs), and serious adverse</li> </ul>						Radiation (1)						
tumor and naematologic malignancies.	events (SAEs) overall, by severity, by relationship to each						Anti-tumor (8)	0111 🔾	<u> </u>		<u> </u>	o(	
	study intervention, and those that led to discontinuation of study intervention	0205	M / 78	Ureteric	IV	Lung, Peritoneum	Anti-tumor (2)	MSI-H 1st	t SUPLEXA batch	O 2nd SU	OOO( IPLEXA batch	0	
Secondary		0207	F / 47	Cervical	IV	Lymph Node	Surgery (1)						
To assess the efficacy of SUPLEXA	Objective response rate (ORR) defined as the proportion						Radiation (4)						
as assessed by the Investigator based on	of subjects with best overall response (BOCR) of either a						Anti-tumor (9)	0117 MSI-H	<u> </u>			<b>—</b>	
response evaluation criteria in solid tumors	Time to Progression (TTP)	0209	F / 69	Colorectal-	IV	Lung, Liver	Surgery (3)			<u> </u>			
Exploratory				NI99			Radiation (1)						Conclusions
Exploratory efficacy outcomes	<ul> <li>Duration of Response (DOR)</li> </ul>						Anti-tumor (4)						
	Time to Response (TTR)	0212	M / 70	Colorectal-	IV	Peritoneum	• Surgery (3)	• P	rimarv endr	oint ac	hieved wit	h no drua rela	ated adverse events.
	<ul> <li>Clinical Benefit Rate (CBR) defined as CR+PR+SD.</li> </ul>		•••				Anti-tumor (6)	• C	econdary o	ndnoint	achieved	with the dar	nonstration of a CR and a DD
	Progression-free Survival (PFS).	0215	M / 76	Melanoma	IV	Lung, Lymph Node	• Surgery (1)	- 3					
	Overall Survival (OS).     Solid turns on bourts Observational Lines International Company in the second seco	0004	N4 / 00	Male	11.7		Anti-tumor (2)	W	iin a treatm	ent nist	ory of prio	r cnemo and	prior ICI.
To evaluate anti-tumor activity of SUPLEYA	<ul> <li>Solid turnours conort: Unange in plasma biomarkers.</li> <li>iORR iPES iDOR iDCR</li> </ul>	0301	IVI / 63	weianoma	IV	Liver, Lymph Node	Surgery (1)	• S	UPLEXA-10	)1 Part	B will expl	ore a combin	ation of SUPLEXA and ICI
by based on modified RECIST v1.1 for		0302	F / 60	Lung	IV/	Lung Lymph Node	Anu-lumor (2)     Surgery (4)						
immune based therapeutics (iRECIST)		0002	1 / 00	Lung		Lang, Lymph Noue	Anti-tumor (1)						Acknowledgements
<b>—</b>	Change from baseline in the following pharmacodynamic	0303	M / 55	Renal	IV	Luna. Lymph Node	Surgery (3)						
To evaluate changes in disease biomarkers	cell phenotyping (e.g. PBMC count and composition and						Radiation (1)	Familie	es and patients a	as well as t	the clinical par	tners Syner-G Bio	Pharma Group (Kirsten Lewus QA-CMC), Q
blood.	select flow cytometric analysis). See Abstract 381						Anti-tumor (2)	Therap	peutics in Brisba	ne AUS), N	Novotech (Syd	ney, AUS) for Tria	l Oversight (Philippa Bendin PM, Florencia F

### Patient Specific Characteristics and Early Outcomes TADLE 2A and 2D Cofety

Jaroty
2B: mos

5)		Number of Participants Reporting at least:				
`)		Any TEAEs				
		Any Dose Limiting Toxicity (DLT) related TEAEs				
		Any severe TEAEs (Grade >=3)				
		Any treatment related TEAEs				
		Any serious TEAEs				
		Any TEAEs leading to withdrawal from study treatme				
		Any TEAEs leading to discontinuation from study				
		Any TEAEs leading to death				
		Number of Subjects Reporting TEAEs by Severity				
		Mild (Grade 1)				
		Moderate (Grade 2)				
		Severe (Grade 3)				
		Life Threatening (Grade 4)				
		Fatal Outcome (Grade 5)				
		Number of Subjects Penerting TEAEs by Polations				



in 2 of 2 mCRC-MSI-H patients, each

IMR Berghofer Medical Research Institute (QGen Cell Falguera DM), and the site teams staff (Kelly Mead, Daniel Clark, Meghan O'Riley, Stephanie Kosmala, Alice Wong).



## ate and only 10% considered related **Solid Tumors** (N=28) n (%) m 20 (71.4%) 111 5 (17.9%) 8 3 (10.7%) 7 5 (17.9%) 7 2 (7.1%) 2 2 (7.1%) 2 2 (7.1%) 2 18 (64.3%) 65 12 (42.9%) 38 3 (10.7%) 5 1 (3.6%) 1 2 (7.1%) 2 ship to Study Treatment 20 (71.4%) 104 3 (10.7%) 7 SD (60%) and an overall CBR of 68% $\rightarrow$ -0 $- \circ - \bullet + >$ ------0↔ -0•→ **──●**◆→ $\leftrightarrow$ 🔵 Dose O Complete Response Partial Response \* Progressive Disease Stable Disease ↔ On Study Off Study

30 40 50 UPLEXA dose (weeks)

> **FIGURE 2 CRC** Patient 0111 was SD on chemo and immunotherapy and became a PR with SUPLEXA Patient 0117 was PD on chemotherapy attaining a PR with PD-1 but a CR with SUPLEXA