# **BIOTHERAPEUTICS**

Iovance Investor Event & KOL Roundtable

Society for Immunotherapy of Cancer (SITC) Annual Meeting November 10, 2022

#SITC22

# ADVANCING IMMUNO-ONCOLOGY

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Introduction

- Friedrich Graf Finckenstein, M.D., Chief Medical Officer, Iovance

#### **Presentation Summary**

– Amod Sarnaik, M.D., H. Lee Moffitt Cancer Center

C-144-01 Study in Advanced Melanoma

#### **KOL Panel**

Multi-Disciplinary Perspectives on TIL Therapy

- Madan Jagasia, M.D., M.S., M.M.H.C, EVP, Medical Affairs, Iovance (Moderator)
- Allison Betof Warner, M.D., Ph.D., Memorial Sloan Kettering Cancer Center
- Miguel Perales, M.D., Memorial Sloan Kettering Cancer Center
- Martin McCarter, M.D., University of Colorado Cancer Center

#### Q&A



# **Forward-Looking Statements**

Certain matters discussed in this presentation are "forward-looking statements" of lovance Biotherapeutics, Inc. (hereinafter referred to as the "Company," "we," "us," or "our") within the meaning of the Private Securities Litigation Reform Act of 1995 (the "PSLRA"). All such written or oral statements made in this presentation, other than statements of historical fact, are forward-looking statements and are intended to be covered by the safe harbor for forward-looking statements provided by the PSLRA. Without limiting the foregoing, we may, in some cases, use terms such as "predicts," "believes," "potential," "continue," "estimates," "anticipates," "expects," "plans," "intends," "forecast," "'guidance," "outlook," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes and are intended to identify forward-looking statements. Forward-looking statements are based on assumptions and assessments made in light of management's experience and perception of historical trends, current conditions, expected future developments and other factors believed to be appropriate. Forward-looking statements in this press release are made as of the date of this press release, and we undertake no duty to update or revise any such statements, whether as a result of new information, future events or otherwise. Forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties and other factors, many of which are outside of our control, that may cause actual results, levels of activity, performance, achievements and developments to be materially different from those expressed in or implied by these forward-looking statements. Important factors that could cause actual results, developments and business decisions to differ materially from forward-looking statements are described in the sections titled "Risk Factors" in our filings with the Securities and Exchange Commission, including our most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, and include, but are not limited to, the following substantial known and unknown risks and uncertainties inherent in our business: the effects of the COVID-19 pandemic; risks related to the timing of and our ability to successfully develop, submit, obtain and maintain U.S. Food and Drug Administration ("FDA") or other regulatory authority approval of, or other action with respect to, our product candidates, and our ability to successfully commercialize any product candidates for which we obtain FDA approval; whether clinical trial results from our pivotal studies and cohorts may support registration and approval by the FDA; preliminary and interim clinical results, which may include efficacy and safety results, from ongoing clinical trials or cohorts may not be reflected in the final analyses of our ongoing clinical trials or subgroups within these trials or in other prior trials or cohorts; the risk that enrollment may need to be adjusted for our trials and cohorts within those trials based on FDA and other regulatory agency input; the changing landscape of care for cervical cancer patients may impact our clinical trials in this indication; the risk that we may be required to conduct additional clinical trials or modify ongoing or future clinical trials based on feedback from the FDA or other regulatory authorities; the risk that our interpretation of the results of our clinical trials or communications with the FDA may differ from the interpretation of such results or communications by the FDA (including from the recent pre-BLA meeting with the FDA); the risk that the rolling BLA submission for lifileucel in metastatic melanoma may take longer than expected; the acceptance by the market of our product candidates and their potential reimbursement by payors, if approved; our ability or inability to manufacture our therapies using third party manufacturers or our own facility may adversely affect our potential commercial launch; our manufacturing capacity plans may not be successful; the results of clinical trials with collaborators using different manufacturing processes may not be reflected in our sponsored trials; the risk that unanticipated expenses may decrease our estimated cash balances and forecasts and increase our estimated capital requirements; and other factors, including general economic conditions and regulatory developments, not within our control.

# **Unmet Medical Need for Metastatic Melanoma Therapy**

No FDA Approved Treatment Options After Progression on Checkpoint (Anti-PD-1) Therapy and BRAF/MEK inhibitors



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- 5. Keytruda USPI accessed Mar 2022 (4%) and Weber et al., Lancet Oncol 2015 (ICC 10%)
- 6. Kirchburger et al., Eur J Cancer 2016 and Goldinger et al., J Clin Oncol 2018

Abbreviations: EU5=France, Germany, Italy, Spain and United Kingdom, 1L=first line therapy, 2L=second line therapy, 3L=third line therapy, ORR, objective response rate; mOS, median overall survival; PD-1, programmed cell death protein-1

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# Amod Sarnaik, M.D.

Professor of Cutaneous Oncology and Immunology at H. Lee Moffitt Cancer Center Presenting Author and Lead C-144-01 Investigator

- Surgical oncologist in Department of Cutaneous Oncology, Immunology Program and Melanoma Center of
  Excellence at Moffitt Cancer Center
- Professor of Oncology and Surgery at University of South Florida
- **Primary research interest**: Novel immunotherapeutic treatments for melanoma
- **Clinical interests**: Surgical treatment of melanoma and other cutaneous-based skin cancers, sentinel lymph node biopsy techniques, and minimizing surgically-related morbidities
- Education: Undergraduate degree from Harvard University and medical degree from University of Michigan School of Medicine
- **Postgraduate training**: University of Cincinnati, OH; Howard Hughes investigational postdoctoral fellowship in molecular genetics; surgical oncology fellowship at Moffitt Cancer Center
- >90 publications in peer-reviewed literature



# **KOL Panelists**

**Multi-Disciplinary Perspectives on TIL Therapy** 

#### Medical Oncology



Allison Betof Warner, M.D., Ph.D.

Assistant Attending Physician and Melanoma Medical Oncologist, Memorial Sloan Kettering Cancer Center

#### **Cell Therapy**



#### Surgery



Martin McCarter, M.D. Surgical Director for the Esophageal and Gastric
Multidisciplinary Clinic, Vice Chair for Strategy and
Program Development Department of Surgery, UCHealth
Cancer Care - Anschutz Medical Campus - University of
Colorado Cancer Center



# Lifileucel TIL Cell Monotherapy in Patients With Advanced Melanoma After Progression on Immune Checkpoint Inhibitors and Targeted Therapy: Pooled Analysis of Consecutive Cohorts (C-144-01 Study)

**Amod Sarnaik,**<sup>1</sup> Karl D. Lewis,<sup>2</sup> Harriet Kluger,<sup>3</sup> Omid Hamid,<sup>4</sup> Eric Whitman,<sup>5</sup> Sajeve Thomas,<sup>6</sup> Martin Wermke,<sup>7</sup> Mike Cusnir,<sup>8</sup> Evidio Domingo-Musibay,<sup>9</sup> Giao Q. Phan,<sup>10</sup> John M. Kirkwood,<sup>11</sup> Jessica C. Hassel,<sup>12</sup> Marlana Orloff,<sup>13</sup> James Larkin,<sup>14</sup> Jeffrey Weber,<sup>15</sup> Andrew J. S. Furness,<sup>14</sup> Nikhil I. Khushalani,<sup>1</sup> Theresa Medina,<sup>2</sup> Friedrich Graf Finckenstein,<sup>16</sup> Madan Jagasia,<sup>16</sup> Parameswaran Hari,<sup>16</sup> Giri Sulur,<sup>16</sup> Wen Shi,<sup>16</sup> Xiao Wu,<sup>16</sup> Jason Chesney<sup>17</sup>

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# C-144-01 Phase 2 Study Design

Phase 2, multicenter study to assess the efficacy and safety of autologous TIL (lifileucel) for treatment of patients with metastatic melanoma (NCT02360579



Abbreviations: ORR, objective response rate; DOR, duration of response; PD-1, programmed cell death protein-1; IRC, independent review committee

DOR, duration of response; ECOG, Eastern Cooperative Oncology Group; IL-2, interleukin 2; IRC, Independent Review Committee; NMA-LD, nonmyeloablative lymphodepletion; ORR, objective response rate; OS, overall survival; PD-1, programmed cell death protein 1; RECIST, Response evaluation Criteria in Solid Tumors; TEAE, treatment-emergent adverse events; TIL, tumor-infiltrating lymphocytes.

# **Patient Disposition**



\*AEs included: gastrointestinal bleeding, septic shock, and pleural effusion. IL-2, interleukin 2; TIL, tumor-infiltrating lymphocytes.

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## **Baseline Patient and Disease Characteristics**

Cohorts 2 and 4 Heavily Pre-Treated and Mostly Similar; Cohort 4 had both Higher Disease Burden and Elevated LDH

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Characteristic	Cohort 2 (n=66)	Cohort 4 (n=87)	Cohort 2+4 (N=153)
Median age (range), years	55.0 (20, 79)	58.0 (25, 74)	56.0 (20, 79)
Sex, n (%)			
Male	39 (59.1)	44 (50.6)	83 (54.2)
Female	27 (40.9)	43 (49.4)	70 (45.8)
Screening ECOG perform	ance status, n (%)		
0	42 (63.6)	62 (71.3)	104 (68.0)
1	24 (36.4)	25 (28.7)	49 (32.0)
Melanoma subtype,* n (%	b)		
Cutaneous	39 (59.1)	44 (50.6)	83 (54.2)
Mucosal	4 (6.1)	8 (9.2)	12 (7.8)
Acral	4 (6.1)	6 (6.9)	10 (6.5)
<i>BRAF</i> V600-mutated, n (%)	17 (25.8)	24 (27.6)	41 (26.8)
PD-L1 status, <sup>†</sup> n (%)			
TPS ≥1%	37 (56.1)	39 (44.8)	76 (49.7)
TPS <1%	12 (18.2)	20 (23.0)	32 (20.9)
Liver and/or brain lesions by IRC, n (%)	28 (42.4)	44 (50.6)	72 (47.1)
Median target lesion SOD (range), mm	95.8 (13.5, 271.3)	99.5 (15.7, 552.9)	97.8 (13.5, 552.9)

Characteristic	Cohort 2 (n=66)	Cohort 4 (n=87)	Cohort 2+4 (N=153)
Baseline lesions in ≥3 anatomic sites, n (%)	44 (66.7)	65 (74.7)	109 (71.2)
Baseline target and nontarget l	lesions,‡ n (%)		
>3	43 (65.2)	73 (83.9)	116 (75.8)
.DH, n (%)			
≤ULN	39 (59.1)	31 (35.6)	70 (45.8)
>1–2 × ULN	19 (28.8)	35 (40.2)	54 (35.3)
>2 × ULN	8 (12.1)	21 (24.1)	29 (19.0)
Aedian number of prior herapies (range)	3.0 (1, 9)	3.0 (1, 8)	3.0 (1, 9)
Prior therapy			
Anti–CTLA-4, n (%)	53 (80.3)	72 (82.8)	125 (81.7)
Anti–PD-1 + anti–CTLA-4 combination, n (%)	34 (51.5)	48 (55.2)	82 (53.6)
Primary resistance to anti–PD-1/PD-L1 per SITC criteria, <sup>1</sup> n (%)	52 (78.8)	57 (65.5)	109 (71.2)
Median lines of ICI (range)	2.0 (1, 5)	2.0 (1, 7)	2.0 (1, 7)
Retreated with ICI, n (%)	48 (72.7)	65 (74.7)	113 (73.9)

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\*47 patients (31%) had melanoma of other subtype (including unknown primary subtype or insufficient information).

<sup>†</sup>45 patients in the Cohorts 2+4 had missing PD-L1 status.

<sup>‡</sup>One patient in Cohort 2 had missing data on number of baseline target and nontarget lesions.

1. Kluger HM et al. J Immunother Cancer. 2020;8:e000398.

BOR, best overall response; ECOG, Eastern Cooperative Oncology Group; IRC, independent review committee; LDH, lactate dehydrogenase; PD-1, programmed cell death protein 1; PD-L1, programmed death ligand 1; SITC, Society for Immunotherapy of Cancer; SOD, sum of diameters; TIL, tumor-infiltrating lymphocytes; TPS, tumor proportion score; ULN, upper limit of normal.

# **Patient Treatment Patterns**

Patients Heavily Pre-Treated (1-9 Prior Lines of Therapy)



- 17 (11.1%) received only 1 line of prior therapy
- 125 (81.7%) received anti–CTLA-4
- 82 (53.6%) received anti–PD-1 + anti–CTLA-4 combination
- Median of 2 lines (range, 1-7) of ICI-containing therapy

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• 113 (73.9%) retreated with ICIcontaining therapy prior to lifileucel

The R package networkD3 was used to generate the Sankey plot. ICI, immune checkpoint inhibitors; L, line of therapy.

# Safety



#### Non-Hematologic TEAEs in ≥30% of Patients\*<sup>†</sup>

Preferred Term,n (%)	Any Grade	Grade 3/4
Chills	117 (75.0)	8 (5.1)
Pyrexia	81 (51.9)	17 (10.9)
Febrile neutropenia	65 (41.7)	65 (41.7)
Hypophosphatemia	58 (37.2)	41 (26.3)
Hypotension	52 (33.3)	17 (10.9)
Fatigue	51 (32.7)	6 (3.8)
Diarrhea	48 (30.8)	2 (1.3)

#### Grade 3/4 Hematologic Lab Abnormalities\*

Preferred Term,n (%)	Grade 3/4
Leukopenia	156 (100.0)
Lymphopenia	156 (100.0)
Neutropenia	156 (100.0)
Thrombocytopenia	147 (94.2)
Anemia	111 (71.2)

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Median number of IL-2 doses administered was 6

M5

M6

**Time Since Lifileucel Infusion** 

- All patients experienced ≥1 TEAE (any grade); 94.9% experienced ≥1 Grade 3/4 TEAE
- TEAEs were consistent with known safety profiles of NMA-LD and IL-2 and in line with previous reports
- Incidence of TEAEs decreased rapidly within the first 2 weeks after lifileucel infusion

M7

**M8** 

M9

M10

\*Per CTCAE v4.03; Safety Analysis Set (N=156).

<sup>†</sup>Grade 5 TEAEs included pneumonia (n=1), acute respiratory failure (n=1), arrhythmia (n=1), and intra-abdominal hemorrhage (n=1).

All occurrences of AEs were counted if a patient experienced a new onset of the same AE at different timepoints. If multiple records were reported on the electronic case report

M4

M3

form because of toxicity grade decrease of the same AE that had not resolved, then the event was counted once with the highest grade reported.

15 events were reported after Month 12 (Grade 1, n=7; Grade 2, n=6; Grade 3, n=1; Grade 5, n=1).

AE, adverse event; D, day; IL-2, interleukin 2; M, month; NMA-LD, nonmyeloablative lymphodepletion;

TEAE, treatment-emergent adverse event

# **Objective Response Rate (ORR)**

	Cohort 2 (n=66)	Cohort 4 (n=87)	Cohort 2+4 (N=153)
ORR, n (%)	23 (34.8)	25 (28.7)	48 (31.4)
(95% CI)	(23.5, 47.6)	(19.5, 39.4)	(24.1, 39.4)
Best overall respons	se, n (%)		
CR	5 (7.6)	4 (4.6)	9 (5.9)
PR	18 (27.3)	21 (24.1)	39 (25.5)
SD	24 (36.4)	47 (54.0)	71 (46.4)
Non-CR/Non-PD*	1 (1.5)	0	1 (0.7)
PD	15 (22.7)	12 (13.8)	27 (17.6)
Nonevaluable <sup>†</sup>	3 (4.5)	3 (3.4)	6 (3.9)

# 31.4% IRC-assessed ORR

- 91% concordance rate between IRC- and investigator-assessed ORR
- Median time from resection to lifileucel infusion was 33 days

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\*Patient did not have acceptable target lesions and had best overall response of non-CR/non-PD per IRC assessment. †Six patients were nonevaluable for response (5 due to early death; 1 due to new anticancer therapy).

CR, complete response; IRC, independent review committee; ORR, objective response rate;

PD, progressive disease; PR, partial response; SD, stable disease

## **Tumor Burden Reduction and Best Response to Lifileucel**

Reduction of Tumor Burden in 79.3% (111/140) of Patients



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target lesions by IRC).

\*-100% change from baseline is presented for CR assessment that includes lymph node lesions.

CR, complete response; PD, progressive disease; PR, partial response; SD, stable disease; SOD, sum of diameters

# **Univariable and Multivariable Analyses of ORR**

Response to Lifileucel Observed Across All Subgroups Analyzed

#### **ORR by Patient and Disease Characteristics**

Subgroup	n/N	ORR	95% CI	
Overall	48/153	31.4	(24.1, 39.4)	<b>⊢∳</b> −1
Age Group, years				
<65	39/117	33.3	(24.9, 42.6)	<b>⊢</b> ∎−1
≥65	9/36	25.0	(12.1, 42.2)	
Baseline ECOG Performance Status				
0	32/84	38.1	(27.7, 49.3)	<b>⊢</b> ⊷−1
≥1	16/69	23.2	(13.9, 34.9)	<b>⊢</b> ●∔I
BRAF Mutation Status				
V600E or V600K Mutated	13/41	31.7	(18.1, 48.1)	<b>⊢</b>
Non-Mutated	35/112	31.3	(22.8, 40.7)	<b>⊢</b> ••−•
PD-L1 Status				
TPS ≥1%	28/76	36.8	(26.1, 48.7)	<b>⊢</b> •••••
TPS <1%	11/32	34.4	(18.6, 53.2)	<b>⊢</b>
Patients with Baseline Liver Lesions	17/59	28.8	(17.8, 42.1)	<b>⊢−</b> ● <mark> −− </mark>
Patients with Baseline Liver and/or Brain Lesions	19/72	26.4	(16.7, 38.1)	⊢ ● ¦ · I
Baseline Target Lesion Sum of Diameters				
<median (98="" mm)<="" td=""><td>34/74</td><td>45.9</td><td>(34.3, 57.9)</td><td><b>⊢</b>−−1</td></median>	34/74	45.9	(34.3, 57.9)	<b>⊢</b> −−1
≥Median (98 mm)	14/75	18.7	(10.6, 29.3)	⊢●I

#### ORR (95% CI)

#### **ORR** by Disease and Prior Therapy Characteristics

Subgroup	n/N	ORR	95% CI	
Baseline LDH				
≤ULN	27/70	38.6	(27.2, 51.0)	li∎ I I I I I I I I I I I I I I I I I I I
>ULN	21/83	25.3	(16.4, 36.0)	
>2×ULN	3/29	10.3	(2.2, 27.4)	
Prior Lines of Therapy				
1-3	32/99	32.3	(23.3, 42.5)	<b>⊢●</b> −1
≥4	16/54	29.6	(18.0, 43.6)	<b>⊢</b>
Prior Anti–CTLA-4 Use				
Yes	41/125	32.8	(24.7, 41.8)	H-BI
No	7/28	25.0	(10.7, 44.9)	
Prior Anti–PD-1 + Anti–CTLA-4 Combination Use				
Yes	22/82	26.8	(17.6, 37.8)	
No	26/71	36.6	(25.5, 48.9)	
Primary Resistance to Prior Anti–PD-1 or PD-L1 by SITC Definition <sup>1</sup>	36/109	33.0	(24.3, 42.7)	
1. Kluger HM et al. <i>J Immunother Cancer</i> . 2020;8:e000	398.			0 20 40 60 80 100
95% CI is calculated using the Clopper-Pearson Exact	test.			ORR (95% CI)
Vertical dotted line represents overall ORR (31.4%).				

 In adjusted (ECOG PS) multivariable analyses, LDH and target lesion sum of diameters (SOD; tumor mass across locations) were correlated with ORR (P=0.008)

- Patients with normal LDH and SOD < median had greater odds of response than patients with either (odds ratio (OR): 2.08) or both (OR: 4.42) risk factor(s)
- Higher odds of response with lower tumor burden suggest that early intervention with lifileucel after ICI may maximize benefit

CTLA-4, cytotoxic T lymphocyte-associated protein 4; ECOG, Eastern Cooperative Oncology Group; LDH, lactate dehydrogenase; OR, odds ratio; ORR, objective response rate; PD-1, programmed cell death protein 1; PD-L1, programmed death-ligand 1; PS, performance score; SOD, sum of diameters; TPS, tumor proportion score; ULN, upper limit of normal.

# Time to Response, Duration of Response, and Time on Efficacy Assessment for Confirmed Responders (PR or Better)

- Median time from lifileucel infusion to best response was 1.5 months
- Responses deepened over time
  - 7 patients (14.6%) initially assessed as PR were later confirmed CR
  - 4 patients (8.3%) converted to CR
    1 year post-lifileucel infusion;
    2 (4.2%) of these 4 patients
    converted after 2 years
  - Best response of 10 patients
     (20.8%) improved from SD to PR
- 35.4% of responses ongoing as of data cutoff



CR, complete response; PD, progressive disease; PR, partial response; SD, stable disease

## **Duration of Response\***

Median DOR Not Reached at Median Study Follow Up of 36.5 Months



	Cohort 2 (n=23)	Cohort 4 (n=25)	Cohort 2+4 (N=48)
Median follow- up, months	45.1	33.0	36.5
95% CI	(44.2, 51.4)	(30.4, 35.2)	(34.7, 44.2)
Median DOR <sup>†</sup> , months	NR	10.4	NR
95% CI	(NR, NR)	(4.1, NR)	(8.3, NR)
Min, max (months)	1.4+, 54.1+	1.4+, 34.3+	1.4+, 54.1+
DOR ≥12 months, n (%)	15 (65.2)	11 (44.0)	26 (54.2)
DOR ≥24 months, n (%)	11 (47.8)	9 (36.0)	20 (41.7)

\*Patients not experiencing PD or who did not die prior to the time of data cut had their event times censored at the last adequate tumor assessment. For patients who received new anticancer therapies, DOR was censored at the date of last tumor response assessment prior to the start of new anticancer therapies. For patients with PD or death immediately after >2 consecutive missing tumor assessment visits, DOR was censored at the last adequate tumor assessments. \*Based on Kaplan-Meier estimate.

Shaded area indicates 95% CI

DOR, duration of response; NR, not reached; PD, progressive disease.

# **Overall Survival by Response at 6 Weeks After Lifileucel Infusion**

mOS Not Reached in Patients Who Achieved Response at First Assessment



Buyse M, Piedbois P. On the relationship between response to treatment and survival. *Stat Med.* 1996;15:2797-2812.
 \*Based on Kaplan-Meier estimate.
 NR, not reached; OS, overall survival.

	Median OS* (months), by response at 6 weeks <sup>1</sup>	95% CI
Responders	NR	30.4, NR
Non- responders	10.3	6.8, 13.1
Log-rank <i>p-</i> value	<0.0001	

mOS not reached in a landmark analysis in patients who achieved response at first assessment (6 weeks post-lifileucel infusion)

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# **Overall Survival**

mOS was 13.9 Months and 12-Month OS Rate was 54.0% (95% CI: 45.6%, 61.6%)







# Multi-Disciplinary Perspectives on TIL Therapy

- Madan Jagasia, M.D., M.S., M.M.H.C, Executive Vice President, Medical Affairs (Moderator)
- Allison Betof Warner, M.D., Ph.D., Assistant Attending Physician at Memorial Sloan Kettering Cancer Center, Melanoma Medical Oncologist, Memorial Sloan Kettering Cancer Center
- Miguel Perales, M.D., Chief, Adult Bone Marrow Transplant Service, Memorial Sloan Kettering Cancer Center
- Martin McCarter, M.D., Surgical Director for the Esophageal and Gastric Multidisciplinary Clinic, Vice Chair for Strategy and Program Development Department of Surgery, UCHealth Cancer Care - Anschutz Medical Campus - University of Colorado Cancer Center



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