SM-88 FIRST HUMAN STUDY (FHS) AND COMPASSIONATE USE PROGRAM CLINICAL ANALYSIS

June 2018

NASDAQ: TYME

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First Human Study (FHS) and Compassionate Use Program

The First Human Study (FHS)

- Conducted with NY Presbyterian Lower Manhattan
- Initially designed as a 6-week monotherapy safety study;
  - Protocol extended following early positive responses to therapy
  - However it was not designed as a treat-to-progression trial
- All patients (n=30) had progressing metastatic disease on entry
  - Failed or refused all available treatments
  - Washout period required before receiving SM-88
  - Referring physicians estimated survival of 3-6 months
- Data submitted to FDA with initial Investigational Drug Application (IND)

Trial initiated in 2012, data cutoff 9/19/17

Compassionate Use Program

- Initially conducted under the same IRB with NY Presbyterian Lower Manhattan
- Expanded to include individual IND patients
- Patients all had progressing metastatic cancers and failed or refused all available treatments
- Combinations with existing therapies were allowed
- 53 patients were deemed evaluable by having a baseline and follow-up scan and have received at least 1 cycle (6 weeks) of therapy

Program began in 2011, data cutoff 2/13/18

Key Takeaways

Through These Two Programs, Confirmed Responses in 15 Different Cancers

- Some patients were on other therapies, however all patients were metastatic and progressing when SM-88 was initiated
- All results confirmed by blinded radiology review

The findings of the Compassionate Use Program Generally Parallel the FHS

- Responses across broad range of cancers
- Comparable response and survival results in both trials
- No reported serious adverse events in either setting

	First Human Study (n=30)	Compassionate Use Program (n=53)	Pooled Data (n=83)
Complete Response Rate	13%	15%	14%
Partial Response Rate	20%	30%	27%
Objective Response Rate (ORR)	**33%**	**45%**	**41%**
Stable Disease	57%	30%	40%
Clinical Benefit Rate (CBR)	**90%**	**75%**	**81%**

FHS data cutoff 9/19/17, Compassionate use program data cutoff 2/13/18

Cancers with Responses to SM-88
Pancreatic
Prostate
Breast
Lung
Ewings Sarcoma
Soft-Tissue Sarcoma
Renal
Ovarian
Colon
Head & Neck (SCCHN)
Thyroid
Glioma/Glioblastoma
Appendix
Hodgkins Lymphoma
Non-Hodgkin's Lymphoma

First Human Study (FHS): Patient Data (30 Patients with Monotherapy SM-88)

AGE	GENDER	METASTATIC CANCER TYPE	PRIOR TRx	# PRIOR SYSTEMIC TRx	ORR ON SM-88	OS	BASELINE ECOG	ECOG AT END OF CYCLE 1
60	F	Breast	N	0	SD	66.2	2	1
54	F	Breast	S,C,R	6	PR	65.1	2	1
50	F	Breast	S,R,H	2	CR	63.6	1	0
51	F	Breast	S	0	CR	63.5	2	1
33	F	Thyroid	N	0	PR	62.8	1	0
60	F	Lung	S,C,R	1	SD	58.9	2	1
58	M	Colon	S,C	1	SD	56.8	1	0
64	F	Breast	H	3	PD	50.6	1	0
53	M	Prostate	H	1	SD	48.5	2	1
57	M	Appendix	S,C	1	CR	47.9	1	0
63	F	Pancreatic	S,C,R	1	SD	44.8	0-1	0
62	F	Breast	N	0	SD	44.7	1	0
43	F	Breast	S,C,H	3	SD	43.0	1	0
67	F	Lung	C,R	1	SD	33.1	0	0
66	M	Prostate	H	1	SD	30.3	1	0

AGE	GENDER	METASTATIC CANCER TYPE	PRIOR TRx	# PRIOR SYSTEMIC TRx	ORR ON SM-88	OS	BASELINE ECOG	ECOG AT END OF CYCLE 1
70	F	Cholangiocarcinoma	C	1	SD	29.2	1	1
51	F	Breast	S,C	5	SD	26.4	1	1
69	M	Lung	S,C,R	1	SD	25.3	0	0
60	F	Pancreatic	S	0	SD	23.8	1	0
64	F	Breast	S,C,R,H	3	PD	23.1	1	0
58	F	Lung	S,C	1	PR	18.9	2	1
70	F	Breast	S,C,R	4	CR	15.1	2	1
49	M	Lung	S,C,R	3	SD	14.1	1	0
53	F	Breast	S,C,H	2	SD	11.0	4	1
48	F	Breast	S,C,R	2	PR	10.7	1	0
63	F	Breast	S,H	1	PD	9.9	2	1
40	F	Breast	S,C,R,H	3	PR	9.3	3	1
55	M	Squamous Cell Throat	N	0	SD	7.4	3	2
81	M	Cholangiocarcinoma	N	0	SD	6.3	3	1
58	M	Pancreatic	C	1	PR	4.1	2-3	1

AGE		ECOG PS		METASTATIC CANCER TYPE			PRIOR TRx	PRIOR LINE OF SYSTEMIC THERAPY		ORR ON SM-88			OS	
Mean	57.7	Mean	1.0	Breast	14	47%	S= Surgery	Median	1	CR	4	13%	Average	33.8
Min	33	Average	1.6	Lung	5	17%	C= Chemotherapy	Average	1.6	PR	6	20%	Median	29.8
Max	81	Min	0	Pancreatic	3	10%	R= Radiation	Min	0	**ORR**	**10**	**33%**		
		Max	4	Prostate	2	7%	H= Hormonal	Max	6	SD	17	57%		
										CBR	**27**	**90%**		
										PD	3	10%		

Select Patient data. ORR- objective response rate, OS- overall survival, ECOG- Eastern Cooperative Oncology Group performance status, CR- complete response, PR- partial response, SD- stable disease, PD- progressive disease, ORR- objective response rate, CBR- clinical benefit rate (CR+PR+SD) ; Data cutoff 9/19/17

FHS Baseline Demographics (n=30)

- Patients were generally heavily pre-treated
- Baseline ECOG Performance Status was 1.6, with 14 (of 30) with a score of 2 or greater
- 33% of patients had documented systemic therapy following SM-88, 47% had any documented treatment including but not limited to radiation and surgery

Summary Patient Overview		
	All (n=30)	Breast (n=14)
Average ECOG PS	**1.6**	**1.8**

PRIOR THERAPIES

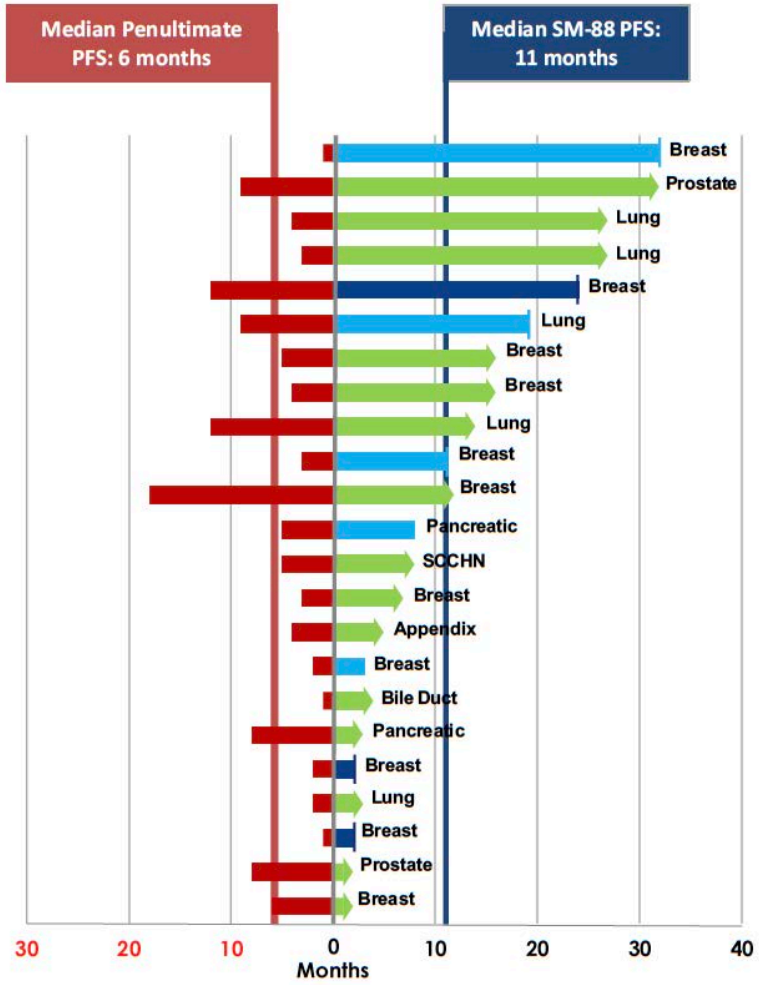
Average Systemic TRx (#)	1.6	2.5
Range	0 to 6	0 to 6
≧2 systemic TRx (%)	37%	71%
Average Total[1] TRx (#)	3.2	4.5
Range	0 to 12	0 to 12
≧2 all TRx (%)	67%	79%

SUBSEQUENT THERAPIES

Systemic (%)	33%	29%
Total[1] (%)	47%	50%

1 Including radiation, surgery or other approved treatments

Penultimate PFS From the First Human Study



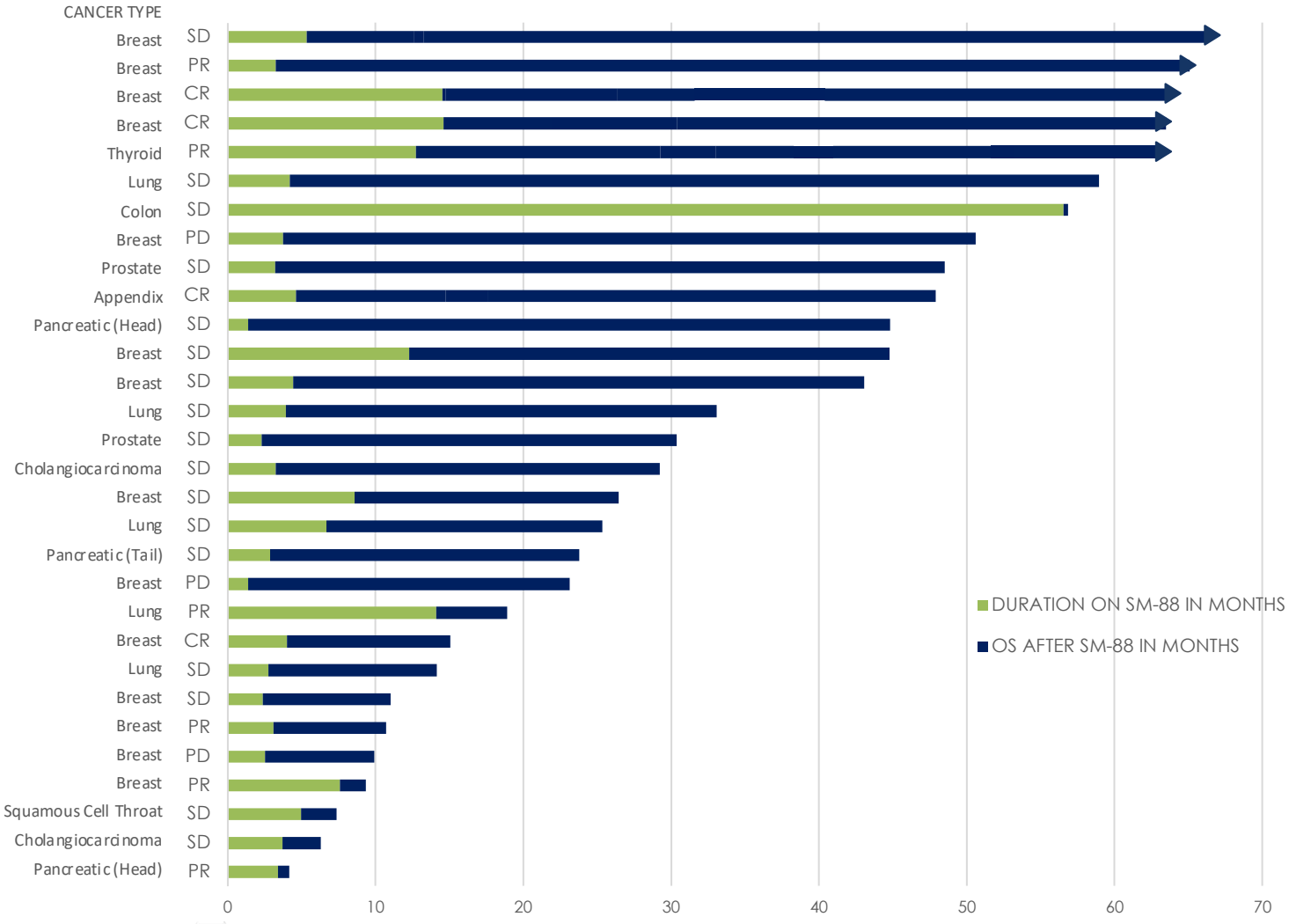
- Penultimate progression-free survival (PFS) is the comparison of PFS on SM-88 to the PFS of the last therapy
- Prior PFS data was available for 23 (of 30) FHS patients
- The PFS with SM-88 was 2.1x longer than the last therapy
- 15 of 23 patients were non-progressive when censored at the end of the study

Study Ended Without Disease Progression	15 / 23
Death Without Disease Progression	5 / 23
Disease Progression	3 / 23
Penultimate PFS Before SM-88	

FHS data cutoff 9/19/17

First in Human Study (FHS): Overall Survival (30 Patients with Monotherapy SM-88)

Data cutoff of 9/19/17



FHS: Segment Analysis

Median survival for patients with ≧2 prior systemic drug therapies was ~2 years

5/11 (45%) of these patients demonstrated RECIST responses (CR=2, PR=3)

Prior Systemic Therapies*	Patients	Average ECOG PS	Median OS (months)	Mean OS (months)
Two or more (median = 3)	11 (37%)	1.7	23	30
One or none (median = 1)	19 (63%)	1.5	33	36

* Systemic therapies include cytotoxic, biologic and/or hormonal drugs

Patients with no subsequent therapy post SM-88 monotherapy demonstrated longer OS than patients who received subsequent therapy

Additional Systemic Treatments*	Patients	Average ECOG PS	Median OS (months)	Mean OS (months)
One or more	14 (47%)	1.6	28	30
None	16 (53%)	1.6	38	37

* Subsequent treatments include cytotoxic/biologic, hormonal agents, local radiation, and/or surgery

43% of breast cancer patients experienced RECIST responses despite 2.5 average prior lines of systemic drug therapy

Responses were seen across multiple genetic profiles, including triple negative

RECIST Response	Patients	Average ECOG PS	Average Prior Lines	Median OS (months)	Mean OS (months)
All	14 (100%)	1.8	2.5	35	36
Complete	3 (21%)	1.7	2.0	64	47
Partial	3 (21%)	2.0	3.7	11	28
Stable Disease	5 (36%)	2.0	2.0	43	38

RECIST -Response Evaluation Criteria In Solid Tumors. Data cutoff 9/19/17

Safety Profile – In First Human Study and Prostate Trial

No grade 2 or higher drug-related adverse events in the Phase Ib/II prostate cancer trial with >85 months of cumulative daily oral dosing experience

Drug-Related Adverse Events Reported in the First Human Study (n=30)[1]

Adverse Event	Grade 1	Grade 2	Grade 3/4	Total
Hyperpigmentation	29 (97%)	1 (3%)	-	**30 (100%)**
Fatigue[2]	13 (43%)	4 (13%)	-	**17 (57%)**
Pain[2]	3 (10%)	1 (3%)	-	**4 (13%)**
Pruritus	1 (3%)	-	-	**1 (3%)**
Burning Sensation	1 (3%)	-	-	**1 (3%)**
TOTAL	**29 (97%)**	**5 (17%)**	-	**30 (100%)**

1. Includes all adverse events deemed as possibly, probably or definitely drug-related.
2. Generally transient

Reported Adverse Event by Grade in the Phase Ib/II Prostate Cancer Trial

	Possibly Related	Total
Grade 1	4/9 patients (44%)[1]	7/9 patients (78%)
Grade 2	0	2/9 patients (22%)[2]
Grade 3	0	1/9 patients (11%)[3]
Grade 4	0	0
Total Patients	4/9 (44%)	7/9 (78%)
Total AEs[4]	5	16

1. "Possibly Related" AEs: vitiligo, hot flashes, bradycardia (observed at baseline), intestinal bloating, flatulence
2. Grade 1 & 2 AEs accounted for 15 of the 16 (94%) AEs reported
3. Hyperkalemia in a subject taking potassium (K+) sparing diuretic
4. Nine of the 16 total AEs reported by two patients. Two patients reported two AEs,and three reported one each

FHS data cutoff 9/19/17, Prostate data cutoff 1/30/18

No drug-related SAEs reported in any patients treated to date, including compassionate use and current Phase II trial

FHS: ECOG Performance Status Improvement

Summary ECOG Performance Status Data for the FHS					
Score	**ECOG Definition[1]**	**Patients**	**Median OS (months)**	**Mean ECOG PS after 6 Weeks**	**Improvement**
0	Asymptomatic	2 (7%)	29	0	-
1	Able to perform light work	14 (47%)	44	0.1	-0.9
2	Unable to perform any work	10 (33%)	38	1.1	-0.9
3	Only limited self-care	3 (10%)	7	1.3	-1.7
4	Bedridden	1 (3%)	11	1	-3.0
1.6	**Average**			**0.6**	**-1.0**

- All patients improved or maintained their ECOG PS within six weeks of starting SM-88 therapy
  - Average ECOG PS improvement of 1.0
  - One patient who was bedridden (PS 4) at baseline was able to return to light work functions (PS 1)
- ECOG PS 2 patients had similar survival PS 1 or PS 0 patients
  - A recent study of 1,655 advanced cancer patients showed survival was approximately halved for each worsening ECOG PS level, with median OS of ~4 months for ECOG PS 2 patients[1]

1.Jang, R.W., et al. 2014: Simple Prognostic Model for Patients With Advanced Cancer Based on Performance Status. Journal of Oncology Practice

Compassionate Use Program: Patient Data (53 Evaluable Patients with at least 6 weeks of SM-88 Treatment)

AGE	GENDER	METASTATIC CANCER TYPE	PRIOR TRx	PRIOR LINES OF SYSTEMIC THERAPY	ORR ON SM-88	OS	MONO OR COMBINATION THERAPY	Baseline ECOG
50	F	Ovarian	S,C	1	PR	74.5	MONOTHERAPY	N/A
51	F	Sarcoma	N/A	N/A	PR	69.8	MONOTHERAPY	N/A
44	F	Breast	S	0	PR	68.5	MONOTHERAPY	0
35	F	Breast	S,H	1	PR	68.5	MONOTHERAPY	0
46	M	Thyroid	N/A	N/A	SD	65.9	MONOTHERAPY	N/A
65	M	Head & Neck (SCCHN)	C, R	1	CR	56.5	MONOTHERAPY	3
46	M	Prostate	R	0	CR	56.0	MONOTHERAPY	0
82	M	Renal	S	N/A	SD	53.4	MONOTHERAPY	N/A
56	M	Prostate	N/A	N/A	CR	52.3	MONOTHERAPY	0
23	M	Hodgkins Lymphoma	C, R	3	CR	49.2	COMBOTHERAPY	2
47	F	Breast	S,H	1	CR	33.8	MONOTHERAPY	1
20	M	Ewings sarcoma	S, C	1	CR	22.5	MONOTHERAPY	3
68	F	Ovarian	S, C	N/A	PR	21.1	MONOTHERAPY	N/A
46	M	Colon	C	1	PR/CR	20.4	MONOTHERAPY	1
53	M	Appendix	S, C	1	SD	19.8	MONOTHERAPY	0
64	M	Prostate	H	1	PR	17.1	MONOTHERAPY	N/A
77	M	Pancreatic	C	1	PR	15.8	COMBOTHERAPY	2
51	M	Pancreatic	S	0	CR	15.3	MONOTHERAPY	2 - 3
65	M	Renal	C	1	SD	12.2	COMBOTHERAPY	1
46	F	Gall Bladder	S, C, R	2	SD	12.1	COMBOTHERAPY	1
73	M	Renal	S, R	N/A	PR	11.7	COMBOTHERAPY	0
39	F	Glioma	C, R	N/A	PR/CR	11.7	COMBOTHERAPY	4
52	F	Breast	S,C,R	1	PR	11.5	COMBOTHERAPY	1
57	M	Colon	S, C	N/A	PD	11.5	COMBOTHERAPY	1
33	F	Soft-Tissue Sarcoma	S, C, R	3	SD	11.2	MONOTHERAPY	N/A
51	M	Glioblastoma	S, C	2	PR	9.6	COMBOTHERAPY	1

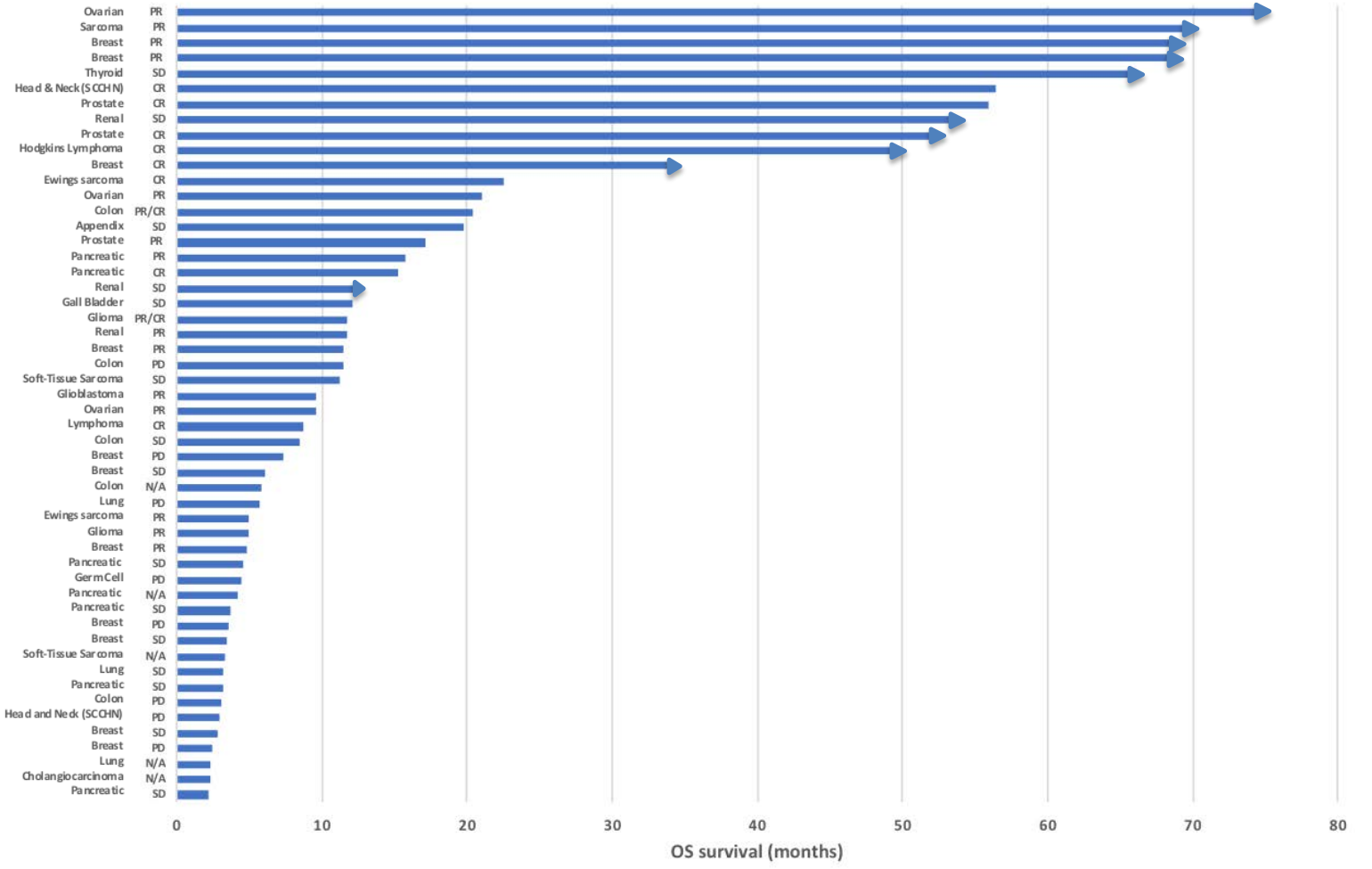
AGE	GENDER	METASTATIC CANCER TYPE	PRIOR TRx	PRIOR LINES OF SYSTEMIC THERAPY	ORR ON SM-88	OS	MONO OR COMBINATION THERAPY	Baseline ECOG
60	F	Ovarian	S, C	1	PR	9.6	COMBOTHERAPY	0
54	M	Lymphoma	S, C	6	CR	8.7	MONOTHERAPY	N/A
71	F	Colon	N/A	N/A	SD	8.5	COMBOTHERAPY	N/A
51	F	Breast	S,C	1	PD	7.4	COMBOTHERAPY	1
58	F	Breast	S,C,R	1	SD	6.0	COMBOTHERAPY	2
46	F	Colon	N/A	N/A	N/A	5.9	MONOTHERAPY	N/A
49	M	Lung	N/A	N/A	PD	5.8	MONOTHERAPY	N/A
8	M	Glioma	N/A	N/A	PR	5.0	MONOTHERAPY	N/A
16	M	Ewings sarcoma	C	3	PR	5.0	COMBOTHERAPY	3
37	F	Breast	S,C,R,H	3	PR	4.8	COMBOTHERAPY	3
43	F	Pancreatic	N/A	N/A	SD	4.6	COMBOTHERAPY	2
27	M	Germ Cell	S, C, R	N/A	PD	4.4	COMBOTHERAPY	3
59	M	Pancreatic	S, C	5	N/A	4.2	MONOTHERAPY	1
70	M	Pancreatic	C	1	SD	3.7	MONOTHERAPY	1
40	F	Breast	S, C, R, H	8	PD	3.6	MONOTHERAPY	1
68	F	Breast	S, C, H	3	SD	3.5	MONOTHERAPY	0
7	M	Soft-Tissue Sarcoma	N/A	N/A	N/A	3.4	N/A	N/A
N/A	F	Lung	N/A	N/A	SD	3.3	MONOTHERAPY	N/A
74	M	Pancreatic	C	3	SD	3.2	COMBOTHERAPY	2
54	M	Colon	N/A	N/A	PD	3.0	COMBOTHERAPY	N/A
60	M	Head and Neck (SCCHN)	C	N/A	PD	2.9	COMBOTHERAPY	2
40	F	Breast	S,C,R	1	SD	2.8	COMBOTHERAPY	2
39	F	Breast	S,C,R,H	6	PD	2.4	MONOTHERAPY	2
52	F	Lung	S, C, R	2	N/A	2.3	COMBOTHERAPY	N/A
54	M	Cholangiocarcinoma	C	1	N/A	2.3	MONOTHERAPY	2
64	M	Pancreatic	N/A	N/A	SD	2.1	MONOTHERAPY	2-3
54	F	Cervical	N/A	N/A	SD	N/A	N/A	N/A

AGE		ECOG PS		METASTATIC CANCER TYPE			PRIOR TRx	PRIOR LINE OF SYSTEMIC THERAPY		ORR ON SM-88			OS	
Mean	50	Mean	1.0	Breast	11	21%	S= Surgery	Median	1	CR	8	15%	Average	19.04
Min	7	Average	1.4	Pancreatic	7	13%	C= Chemotherapy	Average	2	PR	16	30%	Median	9.6
Max	82	Min	0	Lung	3	6	R= Radiation	Min	0	**ORR**	**24**	**45%**		
		Max	4	Prostate	3	6%	H= Hormonal	Max	8	SD	16	30%		
										CBR	**40**	**75%**		
										PD	8	15%		

Select Patient data. ORR- objective response rate, OS- overall survival, ECOG- Eastern Cooperative Oncology Group performance status, CR- complete response, PR- partial response, SD- stable disease, PD- progressive disease, ORR- objective response rate, CBR- clinical benefit rate (CR+PR+SD) ; data cutoff 2/13/18

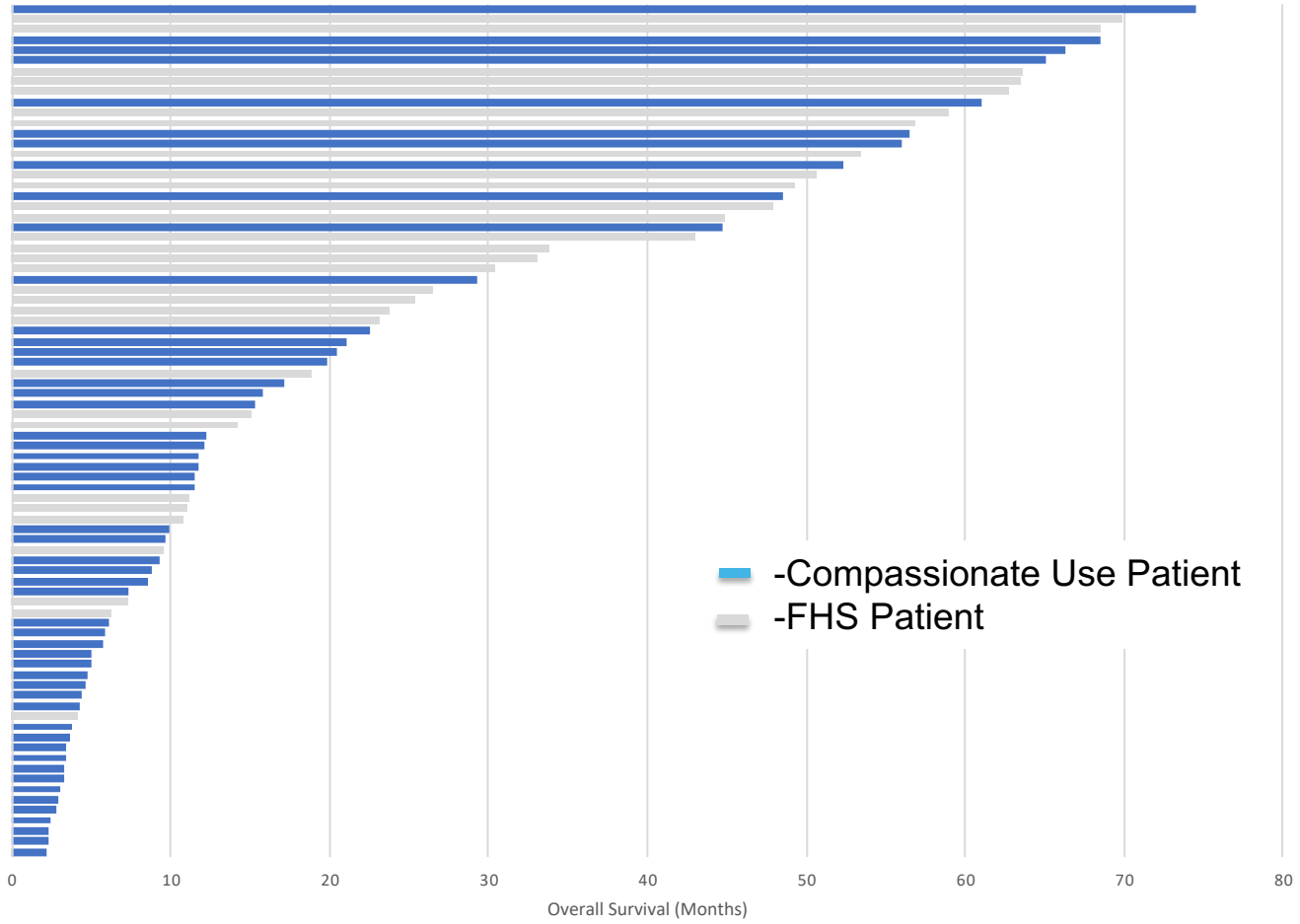
Compassionate Use Program: Overall Survival

(52 Evaluable Patients with at least 6 weeks of SM-88 Treatment and overall survival data)



Data cutoff Feb 13, 2018; 10 patients alive at cutoff

FHS and Compassionate Use Patients: Overall Survival (Pooled data, n=83)

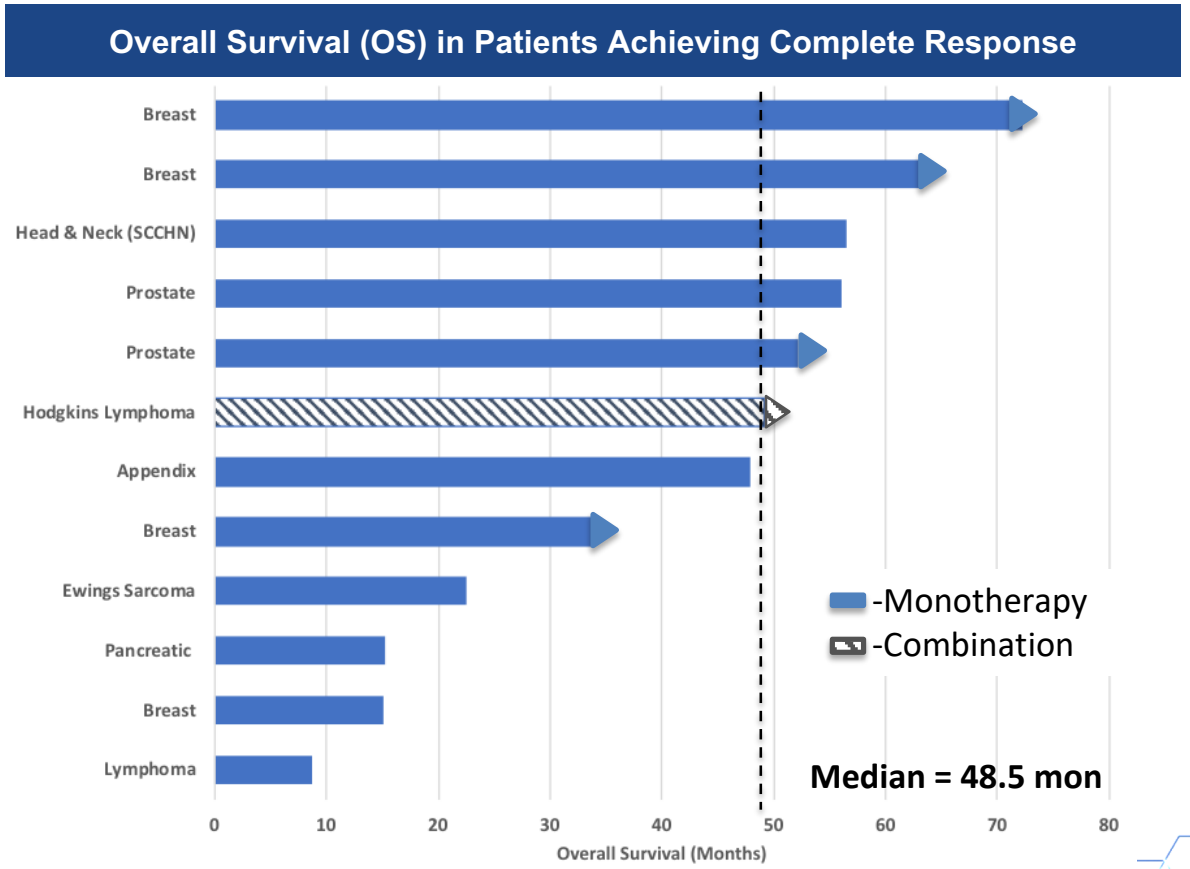


Bars represent individual patients, FHS data cutoff 9/19/17, Compassionate use program data cutoff 2/13/18

Complete Responses with SM-88: Overall Survival (Pooled Data, N=83)

There were twelve (12, 14% of overall) patients, with a range of cancers who achieved a CR with SM-88 treatment

Median survival was 48.5 months

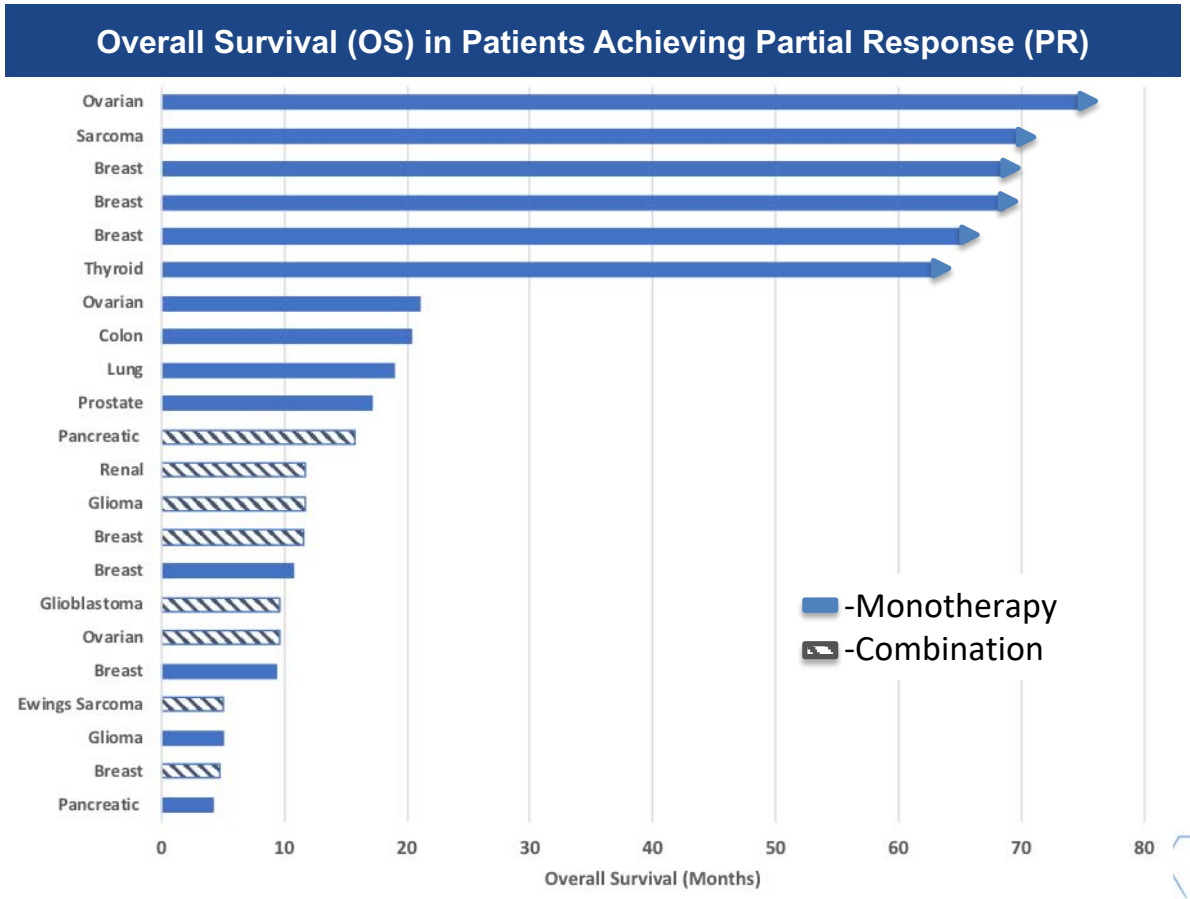


Bars represent individual patients, FHS data cutoff 9/19/17, Compassionate use program data cutoff 2/13/18

Partial Responses with SM-88: Overall Survival (Pooled Data, N=83)

There were twenty-two (22, 27% of overall) patients, with a range of cancer who achieved a PR with SM-88 treatment

Median survival was 13.7 months, 6 patients surviving over 5 years

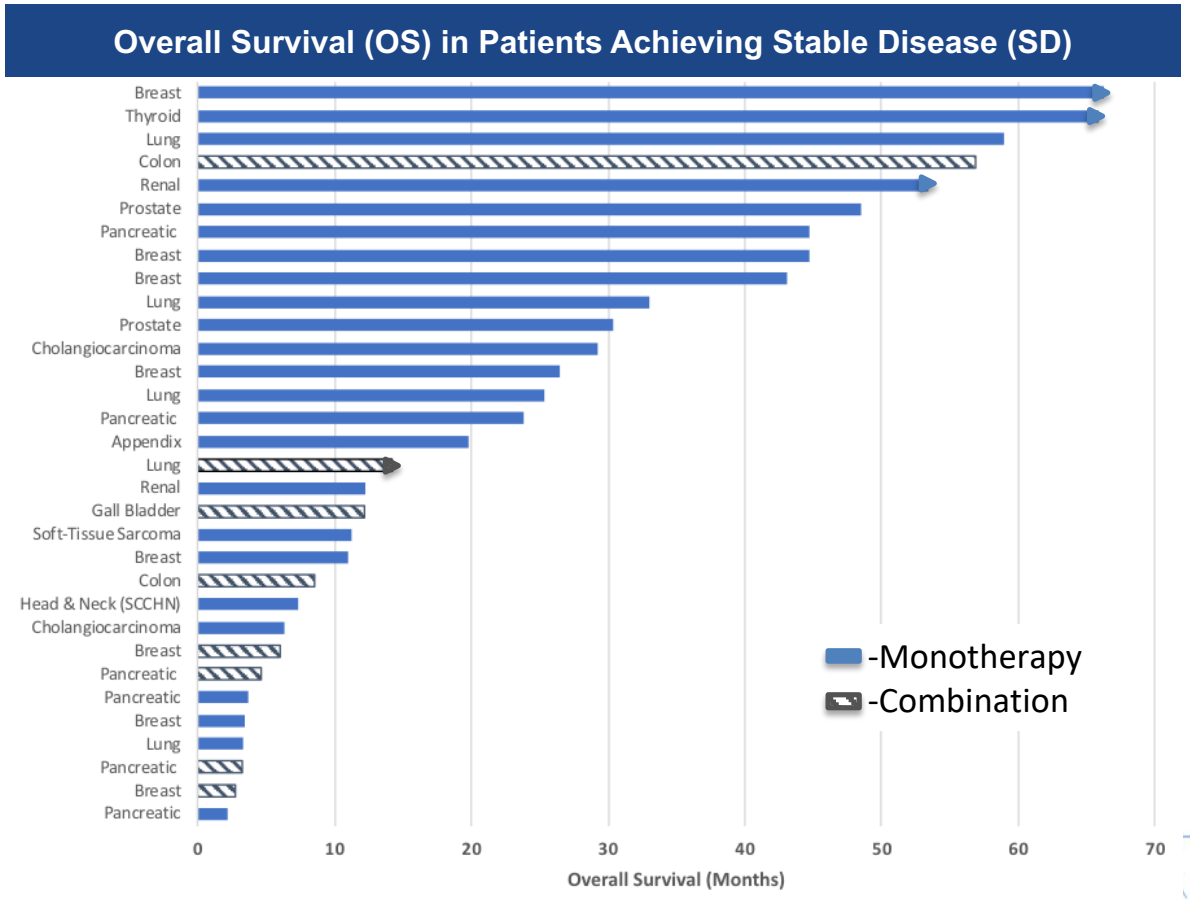


Bars represent individual patients, FHS data cutoff 9/19/17, Compassionate use program data cutoff 2/13/18

Stable Disease with SM-88: Overall Survival (Pooled Data, N=83)

There were thirty-three (33, 40% of overall) patients who achieved stable disease (SD) with SM-88 treatment

Median survival was 17 months, 9 patients surviving over 3 years



Bars represent 32 (of 33) individual patients where survival data was available. FHS data cutoff 9/19/17, Compassionate use program data cutoff 2/13/18.

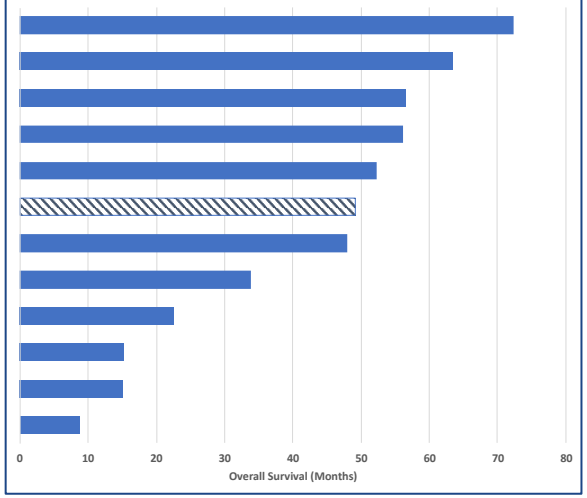
RECIST and Survival with SM-88

Apparently Not the Only Predictor of Overall Survival

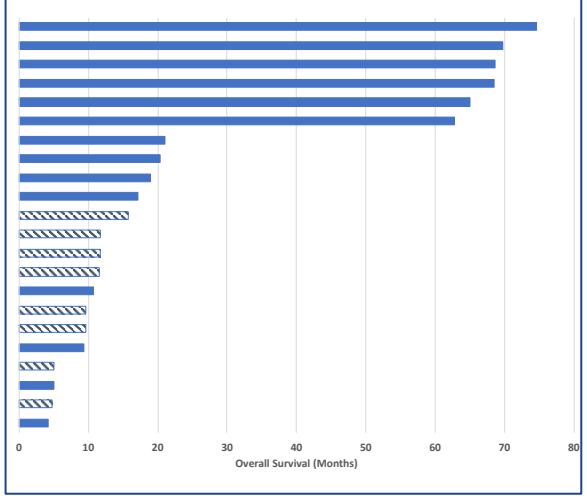
- We believe RECIST criteria alone may not be the optimal assessment of benefit with SM-88
- TYME is incorporating positron emission topography (PET) assessments in all future clinical trials

All Evaluable Patients (n=83)	# of Patients	Median OS (months)	Average OS (months)
Complete Responses	12 (14%)	48.5	41.1
Partial Responses	22 (27%)	13.7	27.1
Objective Response Rate (ORR)	**34 (41%)**	**19.6**	**32.0**
Stable Disease	33 (40%)	17.0	24.4
Clinical Benefit Rate (CBR)	**67 (81%)**	**19.4**	**28.3**

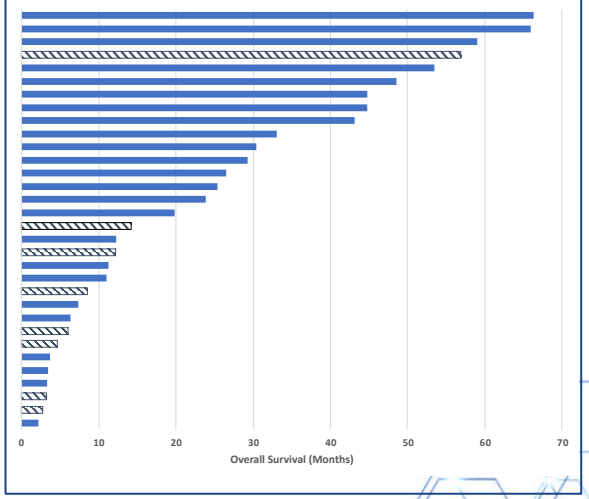
OS in CR Patients



OS in PR Patients



OS in SD Patients



Bars represent individual patients, FHS data cutoff 9/19/17, Compassionate use program data cutoff 2/13/18

Clinical Efficacy Across Different Hormonal Status (Pooled Data, 25 breast cancer patients of 83 evaluable)

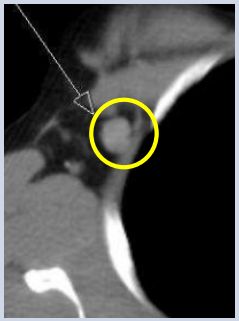
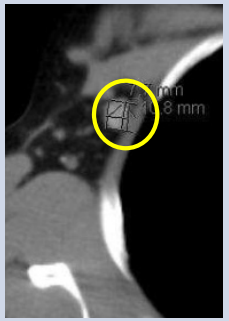
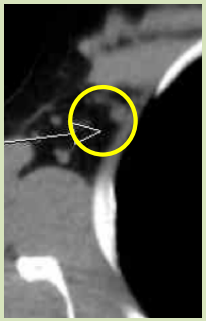
Tumor responses generally consistent across different hormone status'

21 of 25 patients had baseline hormone status available

Hormonal Status	Patients (n)	CR	PR	SD	ORR	CBR	Med OS (months)	Mean OS (months)
ER + and/or PR+, HER2-	12	3 (25%)	2 (17%)	4 (33%)	5 (42%)	9 (75%)	10	22
TNBC (ER-, PR-, HER2-)	5	0 (0%)	2 (40%)	2 (40%)	2 (40%)	4 (80%)	11.5	15
HER2+	4	0 (0%)	2 (50%)	0 (0%)	2 (50%)	2 (50%)	30	35
All Breast Cancer Patients	25	4 (16%)	7 (28%)	8 (32%)	11 (44%)	19 (76%)	15	29

Breast cancer patients achieving stable disease (SD) experienced median and mean survival of 19 and 25.5 months, respectively

Future trials will be exploring alternate surrogates of survival including PET Imaging (PERCIST)

	06/04/2012 Baseline	07/19/2012 6 Weeks	09/03/2013 15 Months
Example lesion (Right axilla lymph node)			
Lesion size	1.5 x 1.5	1.1 x 0.8	Normal Node
SUV Uptake	4.2	None	None

This patient's metastatic breast cancer became metabolically inactive after 6 weeks, but was not determined as a RECIST CR until 15 months later

OS- overall survival, ECOG- Eastern Cooperative Oncology Group performance status, CR- complete response, PR- partial response, SD- stable disease, ORR- objective response rate, CBR- clinical benefit rate (CR+PR+SD); ER – estrogen receptor, PR progesterone receptor, HER2 – breast cancer tumor marker; TNBC triple-negative breast cancer; FHS data cutoff 9/19/17, Compassionate use cutoff 2/13/18

Breast Cancer: Overall Survival

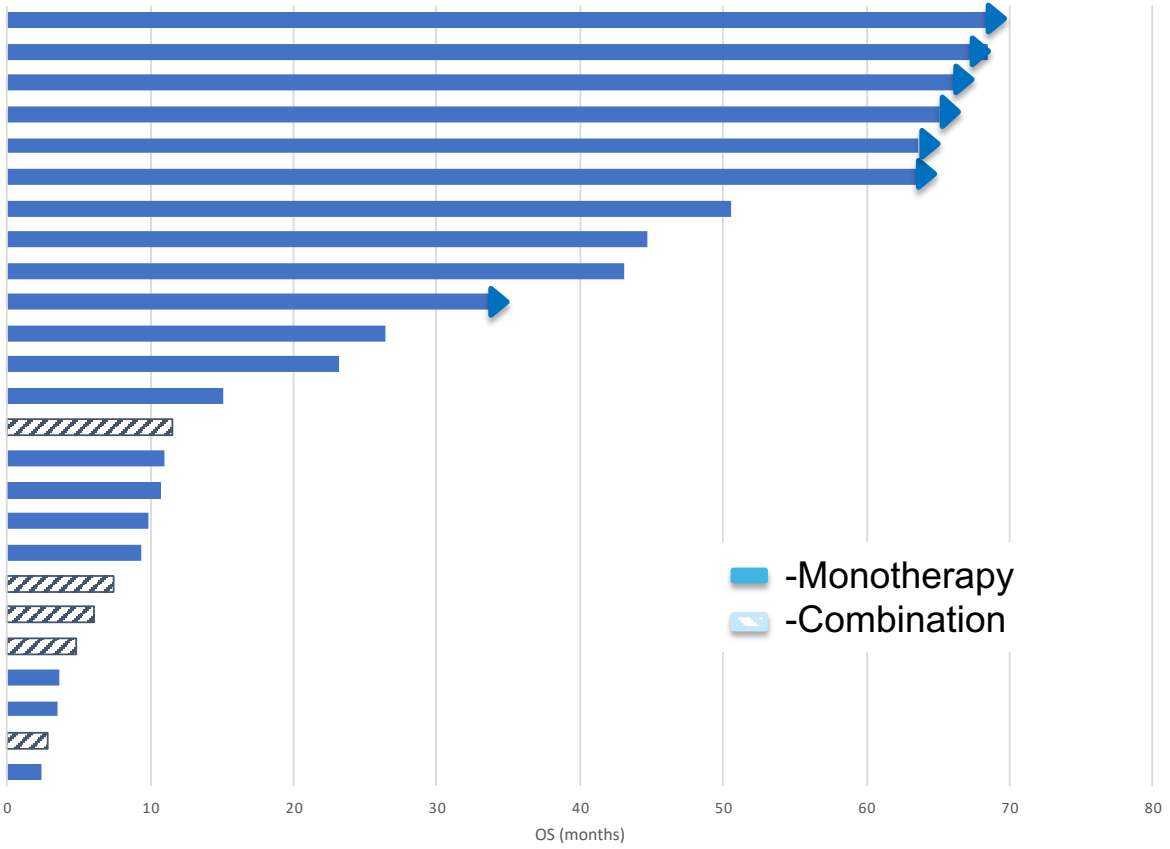
(Pooled Data, N=25 of 83)

Breast cancer was the largest cancer types across programs

Overall Response Rate in this group was 44%

Responses were seen across genetic sub-types and hormonal statuses

Nine patients (36%) survived > than 3 years, Six (24%) survived > than 5 years



Bars represent individual patients, FHS data cutoff 9/19/17, Compassionate use program data cutoff 2/13/18

Triple-Negative Breast Cancer

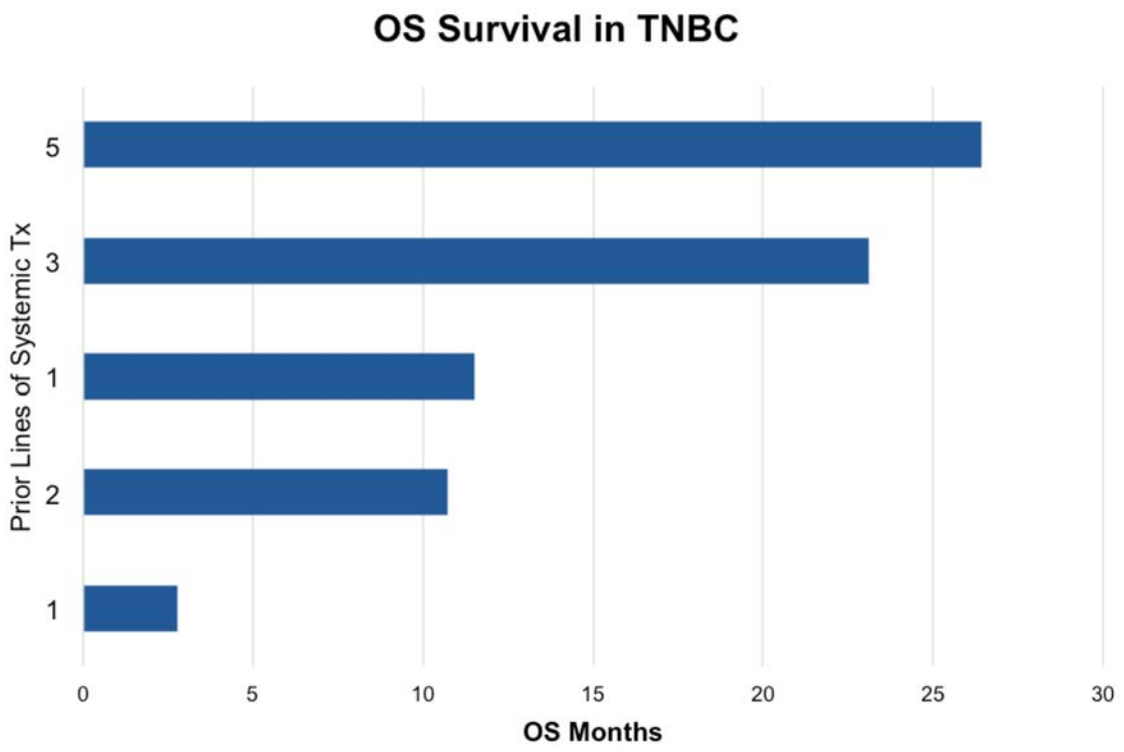
(Pooled Data, N=5 of 83)

Between the FHS and Compassionate Use Program there were five patients with triple-negative breast cancer (TNBC)

Two partial responses (PR) were observed (40%)

Two patients experienced stable disease (SD) (40%)

Median PFS 11.5 months



Bars represent individual patients, FHS data cutoff 9/19/17, Compassionate use program data cutoff 2/13/18

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