



# TCL

THE CANCER LETTER

Inside information on cancer research and drug development

Vol.

44

No.

17

APRIL 27, 2018

[www.cancerletter.com](http://www.cancerletter.com)

## MIAMI'S SYLVESTER USES COOL ART TO BRIDGE DISPARITIES—AND MEET NCI'S NEW REQUIREMENT

In New York City, Peter Tunney's billboard greets you as you enter the Midtown Tunnel: "Welcome to the CITY OF DREAMS" and ushers you out with a "You are now leaving the CITY OF DREAMS."

→ PAGE 3

PETER TUNNEY: HOW THE LARGEST ART MOVEMENT IN HISTORY CAN HELP REDUCE CANCER DISPARITIES

→ PAGE 9

TRIALS & TRIBULATIONS  
LEARNING TO "TALK LESS AND SMILE MORE" WHILE DESIGNING A COE STRATEGY WORTHY OF TRUST

→ PAGE 18

### IN BRIEF

JOHN SAMPSON TO LEAD DUKE'S PHYSICIAN PRACTICE OF OVER 1,500 MEMBERS

→ PAGE 14

### DRUGS AND TARGETS

MYLOTARG APPROVED IN EU FOR PREVIOUSLY UNTREATED, DE NOVO, CD33-POSITIVE AML IN COMBINATION WITH CHEMOTHERAPY

→ PAGE 23

## In this issue

### Editor & Publisher

Paul Goldberg

### Reporter

Matthew Bin Han Ong

### Designer

Jacqueline Ong

### Illustrator

Katherine Goldberg

### Web Developer

David Koh

### Editorial Assistant

Claire Dietz

### Editorial, Subscriptions and Customer Service

PO Box 9905 -  
Washington, DC 20016

**T** 202-362-1809

**F** 202-379-1787

**W** [www.cancerletter.com](http://www.cancerletter.com)

Subscription \$555 per year worldwide. ISSN 0096-3917. Published 46 times a year by The Cancer Letter Inc. Other than "fair use" as specified by U.S. copyright law, none of the content of this publication may be reproduced, stored in a retrieval system, or transmitted in any form (electronic, photocopying, or facsimile) without prior written permission of the publisher. Violators risk criminal penalties and damages. Founded Dec. 21, 1973, by Jerry D. Boyd.

© Copyright 2018  
The Cancer Letter Inc.  
All rights reserved.

® The Cancer Letter is a  
registered trademark.

### THE CLINICAL CANCER LETTER

#### COVER STORY

- 3** Miami's Sylvester uses cool art to bridge disparities—and meet NCI's new requirement

#### CONVERSATION WITH THE CANCER LETTER

- 9** Peter Tunney: How the largest art movement in history can help reduce cancer disparities

#### IN BRIEF

- 14** John Sampson to lead Duke's physician practice of over 1,500 members
- 14** Carl Schmidt joins WVU Cancer Institute
- 14** NCCN publishes translations of guidelines for patients
- 15** Melanoma Research Alliance announces \$11.8 Million in 28 research grants

#### TRIALS & TRIBULATIONS

- 18** Learning to "talk less and smile more" while designing a COE strategy worthy of trust

#### CLINICAL ROUNDUP

- 22** TESARO announces positive top-line results from Quadra trial of Zejula

#### DRUGS & TARGETS

- 23** Mylotarg approved in EU for previously untreated, de novo, CD33-positive AML in combination with Chemotherapy
- 23** Nektar, Takeda to evaluate combining CD122-biased agonist and dual SYK and FLT-3 inhibitor
- 24** Pfizer gets Complete Response Letter for trastuzumab biosimilar



# MIAMI'S SYLVESTER USES COOL ART TO BRIDGE DISPARITIES—AND MEET NCI'S NEW REQUIREMENT

By Paul Goldberg



## In New York City, Peter Tunney's billboard greets you as you enter the Midtown Tunnel: "Welcome to the CITY OF DREAMS" and ushers you out with a "You are now leaving the CITY OF DREAMS."

In Miami, Tunney and business partner Jessica Goldman recently helped transform the gray cement of the Miami Dolphins Hard Rock Stadium into one of the largest street art museums in the world.

Tunney runs two galleries in Wynwood Walls, an urban park devoted to street art, where he and Goldman run two galleries. In one of these galleries, visitors can touch the purportedly \$1 million chandelier Tunney had salvaged from Donald Trump's famously defunct Taj Mahal casino in Atlantic City, NJ.

Brought down to eye level, the thing conjures images of a fallen empire, providing the backdrop for Tunney's collages of playing cards smoothed into an American flag and architects' blueprints peeking out of a comfortingly determinist message: "THE TRUTH ALWAYS HAPPENS."

One day in late February, an RV-sized van wrapped in a painting Tunney created for the University of Miami Sylvester Comprehensive Cancer Center pulled up in front of his gallery in Wynwood Walls, a worldwide destination for admirers of murals and the genre some still call graffiti.

The words "GAME CHANGER" were painted on the RV's side, and if you looked closer, you saw the layering of iconic imagery of all things cancer. The van was a piece of moving art, a gigantic puppet, one artist's contribution to the quest for social justice.

The RV is a part of an experiment conducted by Sylvester. Since human subjects are involved, a green light from the IRB is required, but once

that's done, the behemoth will set out on its appointed rounds, providing information on cancer as well as evidence-based interventions in Liberty City, Little Haiti, Little Havana, and LGBTQ neighborhoods.

If all goes well, Sylvester will be adding vans—bringing the total to as many as four, one per county in the center's catchment area. Tunney says he will be happy to provide the artwork and, if invited, join the RV's crew.

### Why Game Changer?

"I think the game is the accepted-by-default status quo," Tunney said. "Changing the game is literally waking up to a little bit of perspective. The real game changer is when we open our minds, when we can have an open mind to look at things differently."

A conversation with Tunney appears on [page 9](#).

Cancer centers engaged in clinical research and care that are vying to obtain—or retain—the coveted NCI designation have to fulfill the requirement called COE—short for Community Outreach and Engagement. Basic science centers are exempt from having to meet these requirements.

COE became a part of NCI's requirements for designation in December 2017, and now insiders at multiple cancer centers say they are approaching it as one of the most important components of the application, second only to Director's Overview.

"Since the establishment of the NCI Centers Program in the National Can-

cer Act of 1971, NCI-designated cancer centers have been expected to undertake special efforts to reduce the burden of cancer in the communities in which they are located," said Henry Ciolino, director of the NCI Office of Cancer Centers. "To better reflect and further emphasize these efforts, a new component of the Cancer Center Support Grant called 'Community Outreach and Engagement' has been adopted.

"In this, cancer centers describe—and peer-reviewers stringently evaluate—their research on cancers of particular importance to their populations. These include cancers of high incidence, those that result from health disparities in racial and ethnic minorities, rural residents, women, children, the elderly, and those that result from local environmental exposures, behavioral factors, and other issues," Ciolino said to The Cancer Letter. "In order to prevent and treat cancer in the communities they serve, cancer centers form and maintain strong linkages to community partners, including members of underserved and minority populations, which help centers disseminate their knowledge of how to prevent and treat cancer. This is a critical part of the NCI's national mission."

NCI expects cancer centers "to perform research relevant to their catchment area and engage the populations within their catchment area in the research they conduct and other center activities" as part of what appears to be the institute's own game-changing public health strategy.

"To decrease cancer incidence and mortality among populations within its catchment area, including minority and underserved populations, centers also establish partnerships with other healthcare delivery systems and state and community agencies for dissemination of evidence-based findings," NCI's new Cancer Center Support Grant requirements state.





Here is what all cancer centers are expected to show:

- The center's catchment area, including the demographics of its population
- How the catchment area was determined
- The cancer research issues relevant to the catchment area, with particular emphasis on unique or unusual cancer incidence, underserved populations, or cancer health disparities
- How the center engages populations in their catchment area with respect to clinical studies
- The implementation of health policy recommendations, such as tobacco cessation, HPV vaccine uptake, colorectal cancer screening, etc., designed to decrease cancer incidence and mortality rates in the cancer patients they treat and the communities they serve
- How the center addresses cancer health disparities
- As applicable, how the center extends its reach within and beyond its catchment area, through affiliates and other networks that bring the center's expertise to bear on wider populations, rural populations, global cancer research, etc.

"Community engagement is an essential part of advancing cancer research. We must maintain focus on ensuring underrepresented groups are included in research studies," Robert Croyle, director of the NCI Division of Cancer Control and Population Sciences, said to *The Cancer Letter*. "In addition, implementation of evidence-based programs depends heavily on the quality of partnerships with community organizations in both the clinical and public health sectors. So, it's encouraging to see efforts at cancer centers that emphasize this important area of cancer research and care delivery. NCI will continue to collaborate with cancer centers to help raise the bar—im-

proving engagement and the impact of cancer centers in their communities.”

It's unlikely that anyone has approached the COE requirement more artfully than Sylvester. The Miami-based cancer center is scheduled to file an application for the P-30 grant with NCI on Sept. 25.

It's not clear who came up with the name for Sylvester's flotilla. Erin Kobetz, associate director for population science and cancer disparity at Sylvester, says the words popped up in a brainstorming session and had something to do with the cancer center's relationship with the Miami Dolphins football team.

Kobetz's story about evidence-based mobile outreach appears on [page 18](#).

It being South Florida, someone came up with the idea to translate “game changer” into a bunch of languages; not a simple task since idioms are involved. The translations will be posted inside the van.

The next step was obvious—Kobetz wanted to ask Tunney to make the art.

Tunney was a logical choice because of his appreciation for both art and science and his dual role as an artist and an art entrepreneur, Kobetz said. In a previous career, he worked on Wall Street, investing in biotechnology. In 2010, he became the first and only tenant in Wynwood Walls, opening galleries in an area that was being transformed from a shooting alley to one of the world's premier hipster destinations.

“Peter's art speaks to our common humanity,” Kobetz said. “Many of his pieces have a very explicit bent toward the possibility of social action.”

When she went to see Tunney, Kobetz was prepared to deliver a pitch, focus-



ing on the role art can play in overcoming health disparities.

“About a half a sentence into it, I said, ‘Erin, I'm going to save you the whole spiel. I'm in. What do you want me to do? I'll do it.’” Tunney recalled recently.

““

**Community engagement is an essential part of advancing cancer research. We must maintain focus on ensuring underrepresented groups are included in research studies.**

– Robert Croyle

””

South Florida may be one of the world's capitals of health disparities. Among the African American population, you get reverberations from the Tuskegee experiment, where black men with syphilis were left untreated in an observational study even after effective treatments for the disease became available.

The Henrietta Lacks story, too, is still real, a relic of the time when research-

ers could take your cancer cells and commercialize them without consent.

To a public health advocate, an ethical abomination from the past is a barrier. To an artist, it's just more material—and that's the game changer.

South Florida presents challenges you find in few other places.

Among Haitian women, there is reticence to get pelvic exams. The answer: Sylvester dispatches Creole-speaking health workers to convince Haitian women to self-sample. Working with the biochemistry department, Kobetz developed an equivalent of an over-the-counter pregnancy test that detects the DNA of HPV.



Among Afro-Caribbean women, you get a BRCA-1 mutation that confers a high risk of breast or ovarian cancer, but since prevalence of this mutation is unknown, women don't know they are at risk. Sophia George, a Sylvester researcher, recently received a Department of Defense grant to study the ovarian cancer risk in that population.

"First, we need to better understand what these women know about their risk for cancer. How is a family history of breast or ovarian cancer communicated throughout an extended family?" said Stephen Nimer, director of Sylvester Comprehensive Cancer Center. "Also, we can't assume that every woman from the Bahamas or Jamaica knows that if they have a positive family history, they need to get a mammogram starting earlier, or that they may need to undergo a pelvic exam, to reduce their chance of dying from breast or ovarian cancer."

Last year's hurricanes created problems in Sylvester's catchment area as well.

"Monroe County, that includes the Keys, has not recovered, so we want to be out there and to help them with reestablishing the system and making it better," Nimer said to The Cancer Letter. "And we want to have a mammography van to reach that area."

Sylvester's outreach program is also working with the Florida Department of Health to distribute PrEP, pre-exposure prophylaxis, pills that reduce the risk of HIV infection.

Sylvester was one of the first-generation NCI-designated cancer centers in the 1970s, and while the cancer center lost the designation in the mid-1990s, the word "comprehensive" remained as part of its name.

The institution applied to reinstate the designation in 2007, but was unsuccessful.

Five years later, in 2012, the center recruited Nimer, a hematologic malignancies expert at Memorial Sloan Kettering Cancer Center, for the director's job.

"We have been improving our research and educational infrastructure, recruiting dozens of cancer physicians and researchers, and building research programs and multidisciplinary clinical programs, so we can have the greatest impact on our community," Nimer said.

"Through the van, and the efforts of so many, like Peter Tunney, we are bringing clinical cancer care, education and research to communities that have never embraced these missions before," Nimer said.

"Given the diversity of the region that we live and work in, we are thrilled to help change the game."

**"Nou pran devan" is "Game Changer" in Creole. Now try Yiddish...**

English	GAME CHANGER
Spanish	LLEGÓ EL CAMBIO
French	CHANGE LA DONNE
Italian	LA RIVOLUZIONE DELLA RICERCA
German	SPIELVERÄNDERER
Creole	NOU PRAN DEVAN
Portuguese	VIRAR O JOGO
Chinese	游戏规则改变者
Japanese	「ゲームチェンジャー」
Russian	Новый подход
Arabic	بداية جديدة
Yiddish	GANTZE SHEEFT
Hebrew	משמך המשחק
Korean	'게임 체인저'

**FOLLOW US ON LINKED-IN**



[linkedin.com/company/The-Cancer-Letter](https://www.linkedin.com/company/The-Cancer-Letter)

**NEVER MISS AN ISSUE!**

Get e-mail alerts now.



**CLICK HERE**

or sign-up at:  
<https://cancerletter.com/mailling-list/>

Q

&

Tunney spoke with  
Paul Goldberg, editor and  
publisher of The Cancer Letter.

A





CONVERSATION WITH  
THE CANCER LETTER

## Peter Tunney: How the largest art movement in history can help reduce cancer disparities

“

I think the game is the accepted-by-default status quo. Changing the game is literally waking up to a little bit of perspective. The real game changer is when we open our minds, when we can have an open mind to look at things differently.

”



Peter Tunney  
Artist

Recently, Peter Tunney, an artist who runs two galleries in the Wynwood Walls Park in Miami, provided artwork to wrap an RV that Sylvester Comprehensive Cancer Center will use to take cancer interventions to Little Haiti, Liberty City, Little Havana and LGBTQ neighborhoods.

Though one artist can do only so much to confront a social problem as massive as health disparities in the U.S., Tunney is a part of a massive artistic movement.

Call it street art, mural art, untrained art, or graffiti, it's arguably the largest art movement in history.

Social justice isn't an abstract concept to street artists. "I have an army of artists who have participated with us in Wynwood, and many are dispatched on their own projects. Sometimes we ask them to participate in new projects with us," said Tunney, who also runs two galleries in TriBeCa.

"If I asked you to name me ten impressionists—ten—you'd have a hard time. You'd run out at about five or six. If I asked you to give me five big pop artists. Well, Andy Warhol, Roy Lichtenstein, Robert Indiana, then you gotta start thinking. There's usually a few at the forefront of every movement.

"I believe now there's over a million of 'street artists' in the world. They're all coming from a place of social activism. We do all have equal rights, but we're not treated equally."

Tunney spoke with Paul Goldberg, editor and publisher of The Cancer Letter.

**Paul Goldberg: I have a big question, and I might as well start with it. What is the role that you as an artist can play in addressing social problems in today's America?**

**Peter Tunney:** Well, good for you. That is the big question. It's one that I live with.

Every artist can define their role their own way. Most of the "street artists," which is a name I don't love anymore, spend a lot of their time thinking about this question. Their goals are not to become multi-millionaires. Their goals are to change the status quo in certain places on Earth.

I am so grateful just to be here, and breathe the air, and be alive, I'm just compelled to help people who are still suffering. It's not a thankless job, but it's heavy lifting.

You've got to be a lifelong warrior. I consider myself in service for the rest of my life.

**How did the opportunity to help Sylvester with the outreach van project materialize?**

**PT:** I had a meeting with Erin Kobetz. She came here to pitch me, to talk me into lending some of my time and human energy.

About a half a sentence into it, I said, "Erin. I'm going to save you the whole spiel. I'm in. What do you want me to do? I'll do it."

She was kind of taken aback.

I said, "I mean it! What do you want to do? Give me your dream scenario, and then I'll see if I can execute it."

She gave me her scenario, and I said, "I'll do an original painting. We'll sell the painting. That money will go to Sylvester. We'll make prints. The money from the prints go to Sylvester and your projects. Who's going to buy that? A doctor, a lawyer, a philanthropist; right? They will end up hanging it up in their office with pride. It's going to say "Game Changer." They're going to refer to it. It's going to be in the dialogue in that lawyer's office and that philanthropist's kitchen."

In fact, that's exactly what did happen.

They came to me with the words "Game Changer," and the history of Sylvester center, and cancer going back to Nixon, and I gobbled all that stuff up.

When we were done and that van pulled up, that was an exciting moment for me. It was so cool to see the manifestation of that artwork on that van, and it sparked a lot of dialogue from the second it pulled up.

What is this? Who is Sylvester? I got to meet Stephen Nimer. What a guy! Who's going to say no to that guy? We need 10,000 guys like that. We'd change the world. I'll do whatever he says.

In dealing with people like Erin Kobetz and Dr. Nimer, I get leverage. I give them a little bit of my human energy, and they turn it into 100 orders of magnitude more stuff.

My guess is that van's probably going to roll to some neighborhood, and someone that wasn't responding to normal outreach says, "Well, I'll go get tested. That's cool. That looks fun. That looks funny. Everyone's crowding around it."



That's probably going to trickle down, those dominoes will fall, and lives will be changed for the better.

What's better than that?

**What does "Game Changer" mean here? Is it your word? Is it their word?**

**PT:** They came to me with "Game Changer." I'm going to steal it, co-opt it, and do other works that say "Game Changer," because I just love it.

**It's interesting, because they were also playing with translations, which is a thankless task. It's so Anglo, the concept.**

**PT:** It's a real Americanized thing, "Game Changer." We had to translate it into many languages, which was also their idea, which I thought was genius. They may not have a perfect translation, but nothing's perfect. Who cares?

**What's the game? How do you change it?**

**PT:** I think the game is the accepted-by-default status quo. Changing the game is literally waking up to a little bit of perspective. The real game changer is when we open our minds, when we can have an open mind to look at things differently.

Your mind will get opened when it happens to you; right? When your aunt that you loved, or your mom, or your

brother, or your son gets diagnosed with cancer, and your life changes on that phone call—never to be the same again—your game is changed.

You're going to go through what everyone goes through, which is grief, anger, denial, and then—helping others. That's the path we take. We're just people. We get sick, and we've got to take care of each other.

It's so easy; right? It's so easy.

**Cancer is a political problem, though, which is why I've been covering this for so long and not getting tired. The Game Changer van is going to communities that were badly served by science, or what passed for science. Think of Henrietta Lacks, or Tuskegee. How do you overcome the distrust? I think that's where the artist has to come in.**

**PT:** Well, it's where we would hope the artists come in, and we would like them to come in harder. Remember, the role of the artist, for me, is not to solve the problem. The role of the artist, specifically, is to articulate the problem and bring it to your attention.

I'm not going to solve cancer, but I may be able to get people to think about something differently, whether it's mental health, wrongful incarceration, or cancer, which are the areas I'm involved in.

We just want to get a little dialogue in front of your face, let you think about this for one minute of your busy day. There's people around you that are suffering from something you don't

have to suffer from, because you're in a more privileged position.

**There's a political aspect to art, or can be—and should be. Think, for example, of Bread and Puppet Theater and their buses. At political protests, Bread and Puppet uses buses as puppets. And here you are with this Game Changer van, and you are using it as a puppet.**

**PT:** The van is a puppet. That's right. It's an extension... I can't go drive the van every day. I'm just one guy. I'm always looking for leverage.

**You are addressing the Tuskegees and so forth, and the mistrust towards science, because how can anyone not trust a puppet? Tell me if this is a crazy question.**

**PT:** Well, we trusted Sesame Street puppets; right?

**Yeah.**

**PT:** Listen, a puppet is a vehicle. A billboard is a vehicle. A giant mural is a vehicle.

I know that you use the New York Post in your collages a lot, but Miami is really different. There are so many languages used, and everyone's speaking at the same time. Is there a common language of art that enables you and your puppet to communicate within, say, Little Haiti, or Liberty City? Is it the same language or is it a different language?

**PT:** I use text a lot; right? I just got back from Dubai, and this artist eL Seed uses Arabic text. He studied Arabic. He didn't know it. He started studying it when he was, like, 20. He loves the calligraphy, and the beauty of this text.

He was doing this big wall right at the base of the Burj Khalifa, in the center of Dubai, just the most massive construction site on the planet. I think about this one little human being pulling it all together, adding the human element to this incomprehensible construction site. He is adding the soul to the sea of glass, steel and concrete.

I said, "Why are you starting over there?"

He said, "I write right to left." I didn't even think of that. It was so beautiful, I was forgetting there was a message in there. I don't know how many people are going to be able to read that message. I could not read that message. It had to be read for me.

When you're using text, there's always a level of translation.

Right.

**PT:** The Wynwood Walls—there's very little text in here. One guy, Pixel Pancho, has robots and foliage that he mixes into his art. He is really against deforestation on the planet. That's what he does, that's his flag.

A lot of people come here and do a selfie in front of it, because they like pink or whatever. That's going to happen, too.

On the whole, I think art, like music, is the universal language.

Are you going to be on the Game Changer bus at some point?

**PT:** At some point, I'd be happy to go there and be on it, if they feel that is a productive thing for me to do.

I will go spend a day with them on the van, sign stuff, give stuff away. My role, normally, is I'm a funny eccentric person, and that's just the way of engaging people. It's better than being a stiff, dry person.

Right.

**PT:** I don't like to add to the negativity. I could put up billboards that say the world is going to hell in a hand basket, but they've already got that covered. I'm just on the positive side.

A lot of time people get it wrong. I put up a New York City billboard that says, "Welcome to the CITY OF DREAMS." That's where I live.

I just want to show you the other side.

I'm going to have an opportunity to do a big show in Washington, D.C., that I can't tell you about. Very visible and

very public. Everyone thinks I'm going to go down there and do this big anti-Donald Trump thing, which is way too obvious for me. Here's a quote for you, "Art is never obvious."

My show's going to be called something like, "Beautiful, Beautiful World." I'm going the other way, man!

What are you going to do with the next several puppets? Because the folks at Sylvester say they're going to have some more.

**PT:** I don't know anything about the future, but I'll do whatever they ask me to, and then try to add my own unique kind of mojo into it.

Just in defense of what we did here, we did this little event in my gallery in Wynwood Walls, about 100 people for cocktails, the unveiling of the van. Their whole team, by the way, is just aces. No clunkers in the crew, from the guy taping the thing on the van to the smartest doctor there, they were all rowing the same boat.

There was dialogue. There was money raised. There was awareness. There were questions. "Peter, why would you be involved in this cancer thing? Do you have cancer?" You know, all this kind of stuff.

Oh, absolutely.

**PT:** It was in the context of the Wynwood Walls, with the truck parked outside.



### Where was it?

**PT:** There was nothing here.

Right in front of the Wynwood Walls—that street was one of the most blighted streets in the middle of the worst neighborhood in Florida. There was nothing here but despair and violence.

And now we have the Game Changer van and Dr. Stephen Nimer here, and Erin Kobetz talking about cancer treatment.

The amount of people that they've been able to attract to Sylvester, I read somewhere, 140 doctors or something. That's a lot of talent. You can't do any of these things by yourself. You need Dr. Steven Nimer to be compassionate and smart with his patients. You need Erin Kobetz. You need the guy who cleans the floors at the hospital. Without the janitors, you cannot operate your hospital. Period.

**Well, you're working with Sylvester, but other cancer centers could probably use some of this experience. What would be your advice to Steve Nimer's counterparts at other cancer centers?**

**PT:** Send me an email.

**You would work with others as well?**

**PT:** I have an army of artists who have participated with us in Wynwood, and many are dispatched on their own projects.

Sometimes we ask them to participate in new projects with us.

I'm doing a project now for the Innocence Project and the Sunny Center, which take care of wrongly incarcerated people after they finally get out.

Only about 6 percent of exonerees get money. Most just get, like, a bus ticket and \$20, and they've been in jail for 29 years under horrible conditions. I feel it must be our responsibility to take care of the exonerees.

**Well, how about art for health disparities?**

**PT:** For sure. I can't do every program. I can't do everything that they ask, but I pick my spots. I picked Game Changer. I picked Sylvester. They asked me. I was their first choice. I was impressed.

They walked into the door of my gallery. I give a lot of credit for showing up. They showed up, and I'm like, "What can I do for you?"

**I've been saying since November 2016 that this is actually a good time for American artists.**

**PT:** I think so.

**Because they're giving us material.**

**PT:** Yeah. Martha Cooper, who's been photographing street art for a long time, said, "Little did I know when we were running from the police after tagging something, and I was photographing them, that I would be photographing the beginning of the largest art movement in the history of mankind."

Those words really struck me, and I've co-opted those words often. I believe that the street art, mural art, untrained art, whatever category you'd like to call it, is, in fact, the largest art movement in the history of mankind.

If I asked you to name me ten impressionists—ten—you'd have a hard time," Tunney said in a recent conversation. "You'd run out at about five or six. If I asked you to give me five big pop artists. Well, Andy Warhol, Roy Lichtenstein, Robert Indiana, then you gotta start thinking. There are usually a few at the forefront of every movement.

I believe now there's over a million of these street artists in the world.

They're all coming from a place of social activism. We do all have equal rights, but we're not treated equally. That's the basis, that's the big movement. I think you're exactly on point.

That doesn't mean that they're having a great time. Many of these artists I know have lost friends and family members to everything you can imagine. In the street art community, I bet we know a lot of people that have overdosed, that have killed themselves.

It's really a difficult road to be an artist, but I think you're right. It is a good time to be an artist.

## IN BRIEF



## John Sampson to lead Duke's physician practice of over 1,500 members



John Sampson was elected president of the Private Diagnostic Clinic, the physician practice of Duke Health, with 1,650 members practicing in Duke hospitals and more than 100 clinics in North Carolina.

Sampson will continue to serve as chair of the Duke Department of Neurosurgery. The PDC is one of the first and the largest academic multi-specialty group practices in the U.S., with 1.7 million patient visits in FY18 and \$850 million in total revenue.

In addition to patient care, PDC members conduct research and serve as faculty in the Duke University School of Medicine. The PDC collaborates with other entities within the Duke University Health System to expand opportunities and advance Duke's clinical, research, and academic missions.

In this role, Sampson will provide strategic direction and oversight of the financial and management aspects of the physician organization. This includes implementing initiatives to best position the PDC for continued growth and success, and leading, on behalf of PDC members, the due diligence and negotiations of the potential integration of the PDC and Duke University Health System.

Sampson is the Robert H. and Gloria Wilkins Distinguished Professor and co-leader of the Duke Cancer Institute Neuro-Oncology program. He is a recognized leader in the surgical resection and experimental treatment of complex brain tumors.

He currently focuses his clinical practice on treating patients with benign and malignant brain tumors and divides his time between his clinical practice and an active research laboratory investigating new modalities of direct brain tumor infusion and immunotherapy.

## Carl Schmidt joins WVU Cancer Institute



Carl Schmidt, a surgical oncologist specializing in cancers of the liver, pancreas, and stomach, will join the West Virginia University Cancer Institute in July.

Schmidt will serve chief of surgical oncology and surgeon in chief of the WVU Cancer Institute. He plans to grow the program's capacity to serve a larger number of patients and offer more innovative surgeries through fostering relationships across the state.

Schmidt comes to WVU from the Ohio State University College of Medicine Wexner Medical Center, where he served as associate professor of surgery. At Ohio State, he also served as vice chair of quality and patient safety and program director for surgical oncology fellowships.

Schmidt's scholarly work focuses on outcomes for patients with gastrointestinal cancers and quality of care for cancer patients.

## NCCN publishes translations of guidelines for patients

The National Comprehensive Cancer Network has published a newly-translated Italian version of the NCCN Guidelines for Patients for stomach cancer, funded by the NCCN Foundation thanks to No Stomach for Cancer.

Over the past year, the NCCN Foundation also worked with the Kidney Cancer Association to translate patient guidelines for kidney cancer into Chinese, Czech, German, and Spanish.

The guidelines are available free-of-charge at NCCN's website or via through their app. Print copies of the NCCN Guidelines for Patients are available on Amazon.com for a nominal fee.

In 2017 alone, the NCCN Guidelines for Patients were viewed more than



eight million times by nearly 400,000 individuals, worldwide. The library currently contains 39 different guidelines, including breast, colon, lung, and prostate cancers.

## Melanoma Research Alliance announces \$11.8 Million in 28 research grants

The Melanoma Research Alliance has announced funding for 28 research grants totaling \$11.8 million.

The awards will fund researchers at 23 institutions from across the United States, Australia, and Belgium to accelerate research and advance the prevention, diagnosis and treatment of melanoma.

This year's grant awards will support 13 Team Science Awards and 15 Young Investigator Awards. Together, these awards represent the single largest grant year ever by the Melanoma Research Alliance and brings the total invested by the organization to over \$100 million.

These 28 research projects will accelerate research addressing critical issues in melanoma, including identifying novel drug targets, treatments and biomarkers, as well as studies aimed at preventing melanoma or improving methods of early detection.

Several research projects will provide critical advancements in the understanding of rare and difficult-to-treat melanoma subtypes. Six awards will examine new therapeutic interventions to determine how specific genetic alterations contribute to the development and progression to acral lentiginous melanoma.

MRA's 2018 grants are made possible through the significant contributions

of individuals, families, institutions and corporate allies. Donors and partners providing financial support for 75% or more of an award are listed below within the award naming.

## 2018 Awards

### Team Science Awards

#### Targeting BAP1-dependent alterations in metastatic uveal melanoma

*The Helman Family-MRA Team Science Award, 2018-2021*

- Andrew Aplin, Thomas Jefferson University
- Emily Bernstein, Icahn School of Medicine at Mount Sinai
- J. William Harbour, Sylvester Comprehensive Cancer Center/University of Miami Health Systems
- Young Investigator: Marlana Orloff, Thomas Jefferson University

#### Diet, mental health, and the microbiome in response to immunotherapy

*MRA Team Science Award, collaboratively funded by University of Texas MD Anderson Cancer Center, 2018-2021*

- Lorenzo Cohen, University of Texas MD Anderson Cancer Center
- Jennifer Wargo, University of Texas MD Anderson Cancer Center
- Young Investigator: Jennifer McQuade, University of Texas MD Anderson Cancer Center

#### Autophagy in the tumor microenvironment as a target for drug development

*The Anna-Maria and Stephen Kellen Foundation-MRA Team Science Award, 2018-2021*

- Hilary Collier, University of California, Los Angeles
- Beatrice Knudsen, Cedars-Sinai Medical Center
- Lili Yang, University of California, Los Angeles
- Young Investigator: Claudio Scafoglio, University of California, Los Angeles

#### Telomere crisis in acral melanoma: Diagnostic and prognostic potentials

*The Black Family-MRA Team Science Award, 2018-2021*

- Titia de Lange, The Rockefeller University
- Marcin Imielinski, Joan & Sanford I. Weill Medical College of Cornell University
- Young Investigator: John Maciejowski, Memorial Sloan Kettering Cancer Center

#### Commensal microbiota and anti-PD-1 efficacy

*MRA Team Science Award, collaboratively funded by The University of Chicago, 2018-2021*

- Thomas Gajewski, The University of Chicago
- Jason Luke, The University of Chicago
- Cathryn Nagler, The University of Chicago
- Young Investigator: Riyue Bao, The University of Chicago

#### Patient focused therapy for acral melanoma

*The Sokoloff Family-MRA Team Science Award, with collaborative funding from Memorial Sloan Kettering Cancer Center, 2018-2021*

- Ruth Halaban, Yale University
- Charlotte Ariyan, Memorial Sloan Kettering Cancer Center
- Alfred Bothwell, Yale University
- Jian Cao, Yale University
- Neal Rosen, Memorial Sloan Kettering Cancer Center
- Richard White, Memorial Sloan Kettering Cancer Center
- Jedd Wolchok, Memorial Sloan Kettering Cancer Center
- Qin Yan, Yale University
- Young Investigator: Gauri Panse, Yale University

### Identifying genetic dependencies in rare forms of melanoma

*MRA Team Science Award, 2018-2021*

- Nicholas Hayward, Queensland Institute of Medical Research
- Francisca Vazquez, Broad Institute
- Young Investigator: Ken Dutton-Regester, Queensland Institute of Medical Research

### Prognostic and functional role of altered circular RNAs in melanoma

*Leveraged Finance Fights Melanoma-MRA Team Science Award, 2018-2021*

- Eva Hernando, New York University School of Medicine
- Ernesto Guccione, Icahn School of Medicine at Mount Sinai
- Edward and Julie Minskoff – Young Investigator: Melissa Wilson, New York University School of Medicine

### Next-generation neoantigen-targeting peptide vaccines for melanoma patients

*BJ's Wholesale Club-MRA Team Science Award, 2018-2021*

- Patrick Ott, Dana-Farber Cancer Institute
- Bradley Pentelute, Massachusetts Institute of Technology
- Catherine Wu, Dana-Farber Cancer Institute
- Young Investigator: Osama Rahma, Dana-Farber Cancer Institute

### Regulating telomerase & telomere homeostasis in acral melanoma development

*MRA Team Science Award, collaboratively funded by the research institutions, 2018-2021*

- Gavin Robertson, The Pennsylvania State University College of Medicine
- Jiyue Zhu, Washington State University
- Young Investigator: De Cheng, Washington State University
- Young Investigator: Shobhan Gaddameedhi, Washington State University
- Young Investigator: Raghavendra Gowda, The Pennsylvania State University College of Medicine

### Defining and targeting driver events in acral melanoma

*U.S. Trust-MRA Team Science Award, 2018-2021*

- Keiran Smalley, H. Lee Moffitt Cancer Center & Research Institute
- Yian Chen, H. Lee Moffitt Cancer Center & Research Institute
- John Koomen, H. Lee Moffitt Cancer Center & Research Institute
- Jane Messina, H. Lee Moffitt Cancer Center & Research Institute
- Jamie Teer, H. Lee Moffitt Cancer Center & Research Institute

- Young Investigator, Florian Karreth, H. Lee Moffitt Cancer Center & Research Institute

### Directing adaptive immune responses to non-polymorphic MHCs in melanoma

*MRA Team Science Award, collaboratively funded by Massachusetts Institute of Technology, 2018-2021*

- Forest White, Massachusetts Institute of Technology-Koch Institute for Integrative Cancer Research
- Dane Wittrup, Massachusetts Institute of Technology
- Young Investigator: Michael Birnbaum, Massachusetts Institute of Technology-Koch Institute for Integrative Cancer Research
- Young Investigator: Stefani Spranger, Massachusetts Institute of Technology-Koch Institute for Integrative Cancer Research

### DAMPening immunotherapy adverse events in melanoma

*MRA Team Science Award, collaboratively funded by the research institutions, 2018-2021*

- Pan Zheng, University of Maryland, Baltimore
- Yang Liu, University of Maryland, Baltimore
- Young Investigator: Siwen Hu-Lieskovan, The University of California, Los Angeles

## Young Investigator Awards

### Molecular and immune profiling of acral melanoma from various ethnicities



*MRA Young Investigator Award, collaboratively funded by University of Texas MD Anderson Cancer Center, 2018-2021*

- Phyu Aung, University of Texas MD Anderson Cancer Center

### **Building a predictive framework for vaccine design against melanoma**

*Elliott and Ruth Sigal-MRA Young Investigator Award, 2018-2021*

- Nicolas Chevrier, The University of Chicago

### **Manipulating cellular metabolism to promote cancer immunity in melanoma**

*The Robbins Family-MRA Young Investigator Award, 2018-2021*

- Ku-Lung Hsu, The University of Virginia

### **Investigating the mechanistic basis for tumor immunogenicity in melanoma**

*The Sokoloff Family-MRA Young Investigator Award, 2018-2021*

- Nikhil Joshi, Yale University

### **LncRNAs as modulators of protein synthesis rewiring in melanoma**

*Amanda and Jonathan Eilian-MRA Young Investigator Award, 2018-2021*

- Eleonora Leucci, Katholieke Universiteit Leuven

### **Primary anogenital melanoma: Comprehensive molecular and immune analysis**

*MRA Young Investigator Award, collaboratively funded by University of Texas MD Anderson Cancer Center, 2018-2021*

- Priyadharsini Nagarajan, University of Texas MD Anderson Cancer Center

### **Isoform-specific targeting of the PI3Ks to overcome cancer immunoresistance**

*MRA Young Investigator Award, collaboratively funded by University of Texas MD Anderson Cancer Center, 2018-2021*

- Weiyi Peng, University of Texas MD Anderson Cancer Center

### **Dependence of melanoma metastasis on AMPK-mediated metabolic switch**

*Ellen and Gary Davis Foundation-MRA Young Investigator Award, collaboratively funded by Joan & Sanford I. Weill Medical College of Cornell University, 2018-2021*

- Elena Piskounova, Joan & Sanford I. Weill Medical College of Cornell University

### **The genomic landscape of individual melanocytes from human skin**

*Tara Miller Melanoma Foundation-MRA Young Investigator Award, 2018-2021*

- A. Hunter Shain, The University of California, San Francisco

### **A novel approach for NF1 mutant melanoma sub-classification**

*MRA Young Investigator Award, 2018-2021*

- Edward Stites, The Salk Institute for Biological Studies

### **Targeting PSGL-1 inhibitory pathways to promote anti-tumor T cell immunity**

*The Denise and Michael Kellen Foundation-MRA Young Investigator Award, 2018-2021*

- Roberto Tinoco, Sanford Burnham Prebys Medical Discovery Institute

### **Pilot study of intervention to reduce sunburns in melanoma survivors**

*The Wayne Stinchcomb Big Orange Foundation-MRA Young Investigator Award for Women in Scientific Research, 2018-2021*

- Rachel Vogel, The University of Minnesota – Twin Cities

### **Targeting the JNK-ITCH signaling pathway in melanoma**

*Mary Jo and Brian Rogers-MRA Young Investigator Award, 2018-2021*

- Lixin Wan, H. Lee Moffitt Cancer Center & Research Institute

### **Developing advanced non-invasive histology techniques**

*Brownstein, Hyatt, Farber & Schreck-MRA Young Investigator Award, 2018-2021*

- Jesse Wilson, Colorado State University

### **Targeting BRAF/NRAS wildtype melanoma with ERBB3 and MEK Inhibition**

*Julie and Edward J. Minskoff-MRA Young Investigator Award, collaboratively funded by New York University School of Medicine, 2018-2021*

- Melissa Wilson, New York University School of Medicine

# THE CLINICAL CANCER LETTER



## TRIALS & TRIBULATIONS

# Learning to “talk less and smile more” while designing a COE strategy worthy of trust



**By Erin Kobetz**

*Associate Director for Population Science and Cancer Disparity  
Sylvester Comprehensive Cancer Center*

Fourteen years ago, I was recruited to the University of Miami to develop a program in cancer disparities.

Despite being a Miami native, I knew very little about the local cancer landscape, so spent my first few months analyzing registry data to identify trends in disease burden.

That accomplished, I engaged local community stakeholders to help me make sense of what the data revealed and orient me to tangible research opportunity. I will never forget the lesson imparted in an early community meeting. A leader from Little Haiti, the largest enclave of Haitian settlement in the

United States, said, “Mohammed isn’t going to the mountain. Honey, you better bring that mountain to us.”

This statement was, in many ways, my light bulb moment. It forced me to revisit my assumptions about research and identify a strategy, or compromise, that gave equal priority to my academic interests and community need. Now, many years later, I am still challenged to maintain that compromise and to ensure that my research and, more importantly, Sylvester’s strategy for com-

munity outreach and engagement successfully aligns catchment area need and the center's scientific priorities. It is within this unlikely marriage between academic and community benefit that the idea for the Sylvester outreach vehicle was born.

An outreach vehicle isn't an inherently unique idea. Many NCI-designated cancer centers and community hospitals have them and employ them as a way to bridge well-documented gaps in access to cancer education and screening. What may be distinct about Sylvester's Game Changer vehicle, art aside, is that it is a physical manifestation of our Center's commitment to the notion of translational research as service.

Certainly, the vehicle's utmost goal is to fill gaps in local capacity for cancer prevention and early detection. However, it is also a mobile laboratory of sorts, critical in helping further contextualize Sylvester's catchment area. All individuals who interact with the vehicle will be consented to research and asked to provide survey and biological data, which will offer de-novo insight into the distribution of cancer risk occurring within smaller, more meaningful geographic areas, such as neighborhoods. Sylvester's catchment area, South Florida, is neighborhood-based, and it is within this geography that actual heterogeneity in ancestry, behavior, and environmental exposure can be observed and measured.

As a point of reference, South Florida is a four-county region that is home to nearly six million individuals. The area is broadly characterized by cancer disparity and lack of access to the formal healthcare system. Access to healthcare is challenged, in part, by the unparalleled diversity in race/ethnicity, ancestry, and culture that is the hallmark of South Florida. Nearly half of all persons living in this region were born outside the United States (mostly Latin America and the Caribbean), and more

than a third speak a language other than English at home.

As the gateway to Latin America and the Caribbean, South Florida is easily accessible to immigrants, encompassing the full continuum of the wealthy elite to the most impoverished. Collectively, they seek safe harbor from natural disaster political oppression, or both, and settling in South Florida's ethnic enclaves, such as Little Haiti and Little Havana.

“

The community remains our inspiration. Through ongoing collaboration, we are poised to nominate other innovative outreach strategies that 'bring the mountain' to people and places, disenfranchised by healthcare and research opportunity.

”

In such places, the culture, language, even dietary preferences of one's country of origin are reproduced and must be accounted for when entertaining the possibility of research and intervention.

I learned this lesson early on when trying to engage leaders from Little Haiti in a conversation about the community's excess burden of cervical cancer. My analysis of registry data had identified that disease incidence among Haitian women was four times higher than the rate observed for other women. I assumed that we (Sylvester) should staff a clinic in Little Haiti, which offered free Pap smears as a way to increase screening uptake and had figured out the institutional logistics and politics for getting this done.

When I proudly presented this idea to community leaders, they were not

impressed. In fact, they sent me back to Sylvester with very bruised ego, admonishing me to "do better" and "think smarter." In retrospect, I understand their reaction. I had presented myself that day in Little Haiti like an unwelcome dinner guest who has many, unsolicited opinions that are typically better left unshared. I never asked the community leaders about their perspectives on the data or to nominate potential solutions to address it. Rather, I naively thought I had all the

answers. I had spent the bulk of my life pursuing formal education in science and didn't yet realize that my many hours of coursework translated to a specific type of knowledge that had real, tangible boundaries.

Over the years, I have come to accept this limitation and approach community interactions from a place of humility, where I "talk less and smile more."

Community members' expertise, while often not cultivated by institutions of higher learning, is essential and must be married to academic knowledge for research to translate to actionable opportunity. This participatory approach to science is not always an easy pill to swallow. It adds significant time to an already laborious process, and for me, incites an internal conflict about how to best strike compromise between



what is scientifically ideal and what is feasible for a community, given cultural, political, and economic factors that shape perceptions of research and its relative benefit for health.

Early on in my career, we tried to conduct a mail-based survey with a random sample of Miami residents to estimate the prevalence of local cancer screening practices. I had been taught that this approach was the gold standard for a population assessment of behavioral risk. I mailed over 4,000 surveys, and only two percent of potential respondents returned one.

Despondent, I asked one of my community partners to make sense of my experience after the fact. Laughing, he told me that if he had opened a letter from the University of Miami, he would have burned it as quickly as he could for fear that it was a trick from the Immigration and Naturalization Service, now Immigration and Customs Enforcement. Others that I asked voiced a similar concern as well as a skepticism about research, broadly.

I have come to learn that research is still a dirty word for many South Florida communities. In Little Haiti, many community members vividly recall the early days of the AIDS epidemic when Haitian ancestry was erroneously labeled as a risk factor, or one of the four H's, for transmission.

Though the research documenting the increased prevalence of this then mysterious disease among Haitian immigrants was not inherently bad, the way it was manipulated by the media and others led to the legitimized discrimination of a group of people already very much living on the margins.

Other underrepresented communities also readily point to examples of so-called "parachute researchers," who collected data with the sole intent of

advancing their career sometimes at the expense of community benefit. I'll never forget when a community member, now colleague, from Liberty City, a historical African American neighborhood, infamous for race riots in 1980, said, "We've seen your likes before. You tell us what we want to hear, so we give you what you need, and then you disappear as soon as you have it. We will not be your guinea pigs, too."

Given this historical perspective and more recent concerns about immigration status, Sylvester has formalized a Community Advisory Committee that gives individuals traditionally disenfranchised from research a forum for ongoing dialogue about collaborative science. The CAC is comprised of diverse stakeholders, including patient advocates, civic activists as well as representatives from social service organizations, religious institutions, and local Federally Qualified Health Centers.

CAC members work closely with Sylvester leadership and members on various initiatives including, though certainly not limited to, our Game Changer vehicle.

In fact, Sylvester purchased the vehicle based on CAC feedback and designed it collaboratively with select CAC members.

Based on their input, the vehicle's interior is divided into two areas.

The front, designed in collaboration with the University of Miami School of Communications, serves as a mobile, multimedia center to support interactive education about various cancer-related topics. It also includes a clinical trial search tool, developed by the UM SOC and our University's Clinical Translational Science Institute that enables individuals to search for open research opportunities for which they may be eligible, as well as, participate in a "con-

sent to re-contact" program for future research opportunity.

The back has two private rooms for consultation and cancer c screening. Screening tests and interventions will be selected based on scientific evidence, documented need (e.g., secondary data), and obviously, significant community input.

Remember my free Pap clinic idea?

Had I built that, no one would have come.

Despite my good intention, routine Pap smear screening runs counter to widespread, pluralistic interpretations of disease etiology in Little Haiti and other Afro Caribbean enclaves in Miami and elsewhere throughout the US. Many individuals in such communities hold views that simultaneously value the dogma of Western medicine and something like humoral theory, which dates back to Hippocrates. Prevention, according to humoral theory, necessitates achieving balance in bodily humors through teas and ritual baths, rather than an invasive physical exam. When my community partners suggested I "think smarter," they expected me to recognize that my truth, or perspective, about health was not absolute.

Taking this lesson to heart, I am staffing the vehicle with four rotating certified Community Health Workers who are bi- or tri-lingual, indigenous to our target communities, and well versed in local norms and nuances surrounding the discussion of sensitive topics such as cancer and clinical research.

They have undergone extensive training on human subjects' research, data collection, cancer screening, and how to successfully navigate individuals to local resources, as needed. Appointments for the vehicle can be made using an online calendar and/or by phone in English, Spanish, French, and/or

Haitian Creole to accommodate South Florida's linguistic diversity.

In its initial year, the vehicle will largely focus on four medically underserved communities throughout Miami-Dade County (Little Haiti, Liberty City, South Dade/migrant farm workers, and LB-GTQ). In each community, we have identified a CAC partner to host the vehicle on a weekly basis.

Most partners are local organizations with deep roots in their community and an ability to mobilize their large social networks to capitalize on the vehicle's services. The host site will help promote the vehicle through culturally appropriate communication channels and extend Sylvester's ability to link participants to other local resources and follow up, when needed. They also serve as the vehicle's "community home," which helps further dissuade persistent suspicion about research intent.

We don't yet know how our outreach efforts, or the vehicle specifically, will impact cancer outcomes in our catchment area. This is one of our institutional goals and was a promise made to our CAC early on in the vehicle's conceptualization. They demanded measurement as a way to document progress and further community buy-in for vehicle participation and Sylvester's research mission, more broadly.

We are still figuring out how to be wholly responsive to this request and find creative metrics like growing social media presence (e.g., number of Instagram followers and/or re-tweets) that can serve as a marker of impact for diverse audiences.

The community remains our inspiration. Through ongoing collaboration, we are poised to nominate other innovative outreach strategies that "bring the mountain" to people and

places, disenfranchised by healthcare and research opportunity. I'm convinced—based on my experience thus far—that the real solutions for equity exist in the communities whose reality is characterized by the very disparity that we seek to change.

I am forever grateful to that community partner who spoke boldly and candidly when she challenged my ideas about science. In suggesting that I leave my privileged perch at the Cancer Center and engage the community in a community-centric manner, she reset my professional map and perhaps that of Sylvester.

Within the next month, pending IRB approval, we will literally be on the road, following this map, to realize the opportunity that her comments inspired and to bring cancer outreach and research to South Florida in an artful, unexpected manner. It is our hope that this will be one of many Game Changers.

We believe that this approach is innately scalable for Sylvester's broader catchment area and potentially a global audience.

During a recent visit to Haiti, I was stuck in bottleneck traffic next to a brightly colored tap tap, or share taxi, that immediately made me think of the Game Changer vehicle and what it could mean in the context of a Low and Middle Income Country.

I then laughed aloud, after recognizing the obvious, aesthetic similarity between the tap tap and Sylvester's Game Changer vehicle. My community partner's ideas are increasingly the lens through which I see the world and the potential of what research can and should be.

We can only achieve the potential to move mountains, together.

“

I'm convinced—based on my experience thus far—that the real solutions for equity exist in the communities whose reality is characterized by the very disparity that we seek to change.

”

## CLINICAL ROUNDUP



## TESARO announces positive top-line results from Quadra trial of Zejula

TESARO Inc. said the QUADRA study of Zejula treatment in heavily pre-treated patients with ovarian cancer achieved the pre-specified primary endpoint and demonstrated Zejula monotherapy activity in a biomarker-selected patient population.

Previous studies have shown PARP inhibitor activity in the late-line treatment of patients with BRCA mutations.

QUADRA, a single arm study (n=461), was conducted to assess the activity of Zejula monotherapy in the fourth-line plus treatment of specific ovarian cancer patient populations. Of the 92% of QUADRA participants who were PARP inhibitor naïve, 15% had a BRCA mutation, over two-thirds were platinum resistant/refractory and 63% had received prior bevacizumab.

Zejula demonstrated activity in the primary efficacy population of fourth and fifth-line HRD positive patients

who were PARP inhibitor naïve, and platinum sensitive (n=45), with an objective response rate of 29%, and duration of response of 9.2 months. In patients who were fourth line or greater with BRCA mutations, including platinum-sensitive, resistant and refractory, (n=55), the ORR was 31% and the median DOR was 9.4 months.

At a starting dose of 300 milligrams of Zejula, the most commonly observed adverse events were consistent with prior clinical experience and included myelosuppression, which was generally managed via dose modifications. TESARO intends to discuss a biomarker focused regulatory submission with the FDA for a potential supplemental New Drug Application in the second half of 2018.

Beyond QUADRA, clinical trials of niraparib in ovarian cancer include:

### First Line:

- PRIMA: Monotherapy phase III trial for patients with first-line ovarian cancer regardless of biomarker status expected to complete enrollment in Q2 2018; data anticipated in 2019
- OVARIO: Combination phase II trial assessing Zejula with bevacizumab for patients with newly diagnosed ovarian cancer
- FIRST: Combination phase III clinical trial of chemotherapy ± TSR-042, and Zejula in first-line ovarian cancer to be initiated in 1H 2018

### Recurrent:

- NOVA: Monotherapy phase III trial for patients with platinum sensitive, recurrent ovarian cancer, regardless of biomarker status (complete; patients being followed for overall survival)

- AVANOVA: Combination phase II trial with bevacizumab for patients with recurrent ovarian cancer; anticipate data to be available in 2H 2018 to support data submission for a meeting held in 2019

### Platinum-Resistant:

- TOPACIO: Combination phase II trial with anti-PD-1 for patients with platinum-resistant ovarian cancer or triple negative breast cancer (abstracts accepted for presentation at ASCO)

**FOLLOW US  
ON  
TWITTER**



@TheCancerLetter



## DRUGS &amp; TARGETS



## Mylotarg approved in EU for previously untreated, de novo, CD33-positive AML in combination with Chemotherapy

The European Commission approved Mylotarg (gemtuzumab ozogamicin) in combination with daunorubicin and cytarabine for the treatment of patients age 15 years and above with previously untreated, de novo, CD33-positive acute myeloid leukemia, except acute promyelocytic leukemia.

The drug is sponsored by Pfizer Inc.

Mylotarg is the first and only AML therapy approved in the European Union that targets CD33, an antigen expressed on AML cells in up to 90% of patients.

The European Commission's approval of Mylotarg was based on data from an investigator-led, phase III randomized, open-label study (ALFA-0701) in previously untreated, de novo patients. Mylotarg received approval by the FDA in September 2017 for adults with

newly diagnosed CD33-positive acute myeloid leukemia, and adults and children 2 years and older with relapsed or refractory CD33-positive AML.

Hepatotoxicity, including life-threatening and sometimes fatal hepatic failure and VOD/SOS, have been reported in patients treated with MYLOTARG. Other special warnings and precautions include myelosuppression and infusion-related reactions.

In the combination therapy study ALFA-0701, clinically relevant serious adverse reactions were hepatotoxicity, including VOD/SOS (3.8%), hemorrhage (9.9%), severe infection (41.2%), and tumour lysis syndrome (1.5%). In monotherapy studies, clinically relevant serious adverse reactions also included infusion related reactions (2.5%), thrombocytopenia (21.7%), and neutropenia (34.3%).

The most common adverse reactions (> 30%) in the combination therapy study were hemorrhage and infection. In monotherapy studies the most common adverse reactions (> 30%) included pyrexia, nausea, infection, chills, hemorrhage, vomiting, thrombocytopenia, fatigue, headache, stomatitis, diarrhea, abdominal pain, and neutropenia.

Mylotarg is an antibody-drug conjugate composed of the cytotoxic agent calicheamicin, attached to a monoclonal antibody targeting CD33, an antigen expressed on the surface of myeloblasts in up to 90 percent of AML patients. When MYLOTARG binds to the CD33 antigen on the cell surface it is absorbed into the cell and calicheamicin is released causing cell death.

Mylotarg was approved by the FDA in September 2017 for adults with newly diagnosed CD33-positive acute myeloid leukemia, and adults and children 2 years and older with relapsed or refractory CD33-positive AML.

## Nektar, Takeda to evaluate combining CD122-biased agonist and dual SYK and FLT-3 inhibitor

Nektar Therapeutics and Takeda Pharmaceutical Co. Ltd. join a clinical collaboration to evaluate Nektar's investigational medicine, NKTR-214, with Takeda's investigational medicine, TAK-659, as a potential combination treatment regimen in multiple cancer settings.

NKTR-214 is an investigational immunostimulatory therapy designed to expand specific cancer-fighting T cells and natural killer cells directly in the tumor micro-environment and increase expression of PD-1 on these immune cells. TAK-659 is a dual inhibitor of both spleen tyrosine kinase, a kinase involved in cell proliferation and FLT-3, a cytokine receptor in the receptor tyrosine kinase class III.

Under the agreement, Nektar and Takeda will each maintain global commercial rights to their respective investigational medicines. Nektar and Takeda will split the costs related to the clinical trial and each company will contribute their respective compounds to the clinical collaboration.

The first trial is expected to start in the second half of 2018 and will evaluate the combination of an every three-week schedule of NKTR-214 with oral daily doses of TAK-659 in patients with Non-Hodgkin Lymphoma.

NKTR-214 is an investigational immunostimulatory therapy designed to expand specific cancer-fighting CD8+ effector T cells and natural killer cells directly in the tumor micro-environment and increase expression of PD-1 on these immune cells.

NKTR-214 targets CD122 specific receptors found on the surface of these cancer-fighting immune cells in order to stimulate their proliferation. NKTR-214 is being evaluated in multiple clinical trials in cancer patients. It has an antibody-like dosing regimen similar to the existing checkpoint inhibitor class of approved medicines.

TAK-659 is an orally-available investigational reversible dual SYK/FLT-3 inhibitor. SYK is a non-receptor cytoplasmic kinase that binds to phosphorylated immuno-receptor tyrosine-based activating motifs and mediates cellular proliferation and survival.

Mutations in FLT-3 genes can result in the constitutive activation of the FLT-3 receptor and result in acute myeloid leukemia and acute lymphoblastic leukemia. TAK-659 demonstrates both direct- and immune-mediated tumor cell kill mechanisms. It is currently being explored in clinical studies as a single agent and in combination in solid and hematological malignancies.

## **Pfizer gets Complete Response Letter for trastuzumab biosimilar**

Pfizer Inc. announced it has received a Complete Response Letter from FDA in response to the Biologics License Application for the company's proposed trastuzumab biosimilar. In the CRL, FDA highlighted the need for additional technical information.

The additional requested information does not relate to safety or clinical data submitted in the application, the company said. Pfizer said it's working closely with FDA to address the contents of the letter.

## **REACH PEOPLE WHO MATTER IN ONCOLOGY**

Advertise your meetings and recruitments in The Cancer Letter and The Clinical Cancer Letter

Find more information

**HERE**

or visit:

<http://cancerletter.com/advertise/>

## **INSTITUTIONAL PLANS**

Allow everyone in your organization to read The Cancer Letter and The Clinical Cancer Letter.

Find subscription plans

**HERE**

or visit:

<http://cancerletter.com/subscribe/>