EDITORIAL NOTE: This response was updated on June 12, 2017, to reflect the change of the name of the cancer initiative to CANCER BREAKTHROUGHS 2020 as indicated in bracketed language.

RESPONSE TO STAT’S FALSE AND MISLEADING STATEMENTS RELATING TO [CANCER BREAKTHROUGHS 2020]:

We are writing about the inaccuracies and misleading statements in Rebecca Robbins’ STAT article on [Cancer Breakthroughs 2020]. In that article, she states:

“STAT has previously detailed how Soon-Shiong’s high-profile [Cancer Breakthroughs 2020] initiative achieved little scientific progress in its first year, instead functioning primarily as a marketing tool for GPS Cancer. STAT contacted nine health systems said to be using GPS Cancer. None would grant a request for phone interviews.”

Fact:
Rebecca’s assertion that no one would respond to requests for an interview on that topic is false. As indicated by emails pasted below, she not only reached multiple investigators, but these investigators provided glowing reports on the significant progress made during the first year of the [Cancer Breakthroughs 2020], none of which was reflected in her story.

NantHealth provided multiple contacts to the reporter to evaluate the status of the scientific progress of [Cancer Breakthroughs 2020] Initiative. It is not true as she falsely reports that nobody would grant her responses to her requests or inquiries regarding [Cancer Breakthroughs 2020]. The truth is she did in fact reach multiple investigators who provided glowing reports on the significant progress made during the first year of the [Cancer Breakthroughs 2020]. This is evidenced by emails. She failed to report these statements of success and falsely reported that the “initiative achieved little scientific progress serving instead as a marking tool for GPS Cancer.” In addition, Dr. Soon-Shiong’s responses were not accurately reflected in the story.

On February 10, 2017, as seen below in email communications, Dr. Soon-Shiong recommended for Rebecca to speak with Dr. Steve Mamus from the Cancer Center of Sarasota-Manatee. Dr. Mamus, formerly from MD Anderson is one of the busiest oncologists in the state of Florida with regard to his experience with GPS Cancer and [Cancer Breakthroughs 2020]. Rebecca reached out to Dr. Mamus, who then provided written responses to her questions. Similarly, Dr. Azra Raza and Dr. Peter Fasching provided written responses to her questions. Copies of their email communications are appended below. Today, in an email communication from Dr. Mamus to Rebecca at STAT, he stated “Just wanted you to know as a Harvard College graduate with training in molecular biology that it is my view that GPS cancer is the gold standard for molecular testing of tumor specimens GPS is the most important molecular testing platform since oncotype and is an essential routine part of my practice. The proteomics portion of the test is particularly valuable.” It remains to be seen if Rebecca will amend her
Dr. Azra Raza stated, “Through the [Cancer Breakthroughs 2020] Collaboration, I was able to sequence 150 Whole Genomes and measure the expression of every gene (RNA Seq) in 157 bone marrow samples in 2 weeks! We are now obtaining the Proteomics information in these pre-leukemia and leukemia patients. The rigor and velocity with which we are able to home in on novel targets, to monitor the effects of therapy in a dynamic ongoing manner and the ability to combine this form of targeted therapy with immune approaches by deploying immune cells simultaneously in the [Cancer Breakthroughs 2020] trials represent a quantum leap in cancer treatment.”

Despite these enthusiastic responses, Rebecca chose to conclude “[Cancer Breakthroughs 2020] initiative achieved little scientific progress in its first year”, purposefully omitting the written email response to further her inaccurate reporting.

Similarly, Dr. Peter Fasching responded in writing to Rebecca on February 7, 2017:

“For several different cancers a series of trials with cellular and other immunological therapies are on the way. I am leading one of these trials in advanced breast cancer as the principal investigator and expect to include the first patients within the next few months. We are very excited to get these new therapies to the patients.”

Rebecca ignored this written statement and instead attributed the following statement to Dr. Fasching in her inaccurate STAT article saying:

“Fasching said he thinks it’s too early to evaluate the success of the [Cancer Breakthroughs 2020] project, but he likes GPS Cancer and said he’s pleased with how things are going.”

When Dr. Fasching read this statement as reported by Rebecca, he without solicitation called scientists at NantOmsics to state that he did not make such a statement to the reporter and for some reason she completely misrepresented what he said.

The full set of emails from the investigators is appended below:
1. Dr. Mamus Responses

On Fri, Feb 10, 2017 at 1:01 PM, Robbins, Rebecca <rebecca.robbins@statnews.com> wrote:

Hi Dr. Mamus,

My name is Rebecca Robbins, and I'm a Boston-based reporter for STAT, a publication covering health, science, and medicine on a national and global scale.

I'm working on a story about the first year of Dr. Soon-Shiong's [Cancer Breakthroughs 2020], and in our correspondence, Dr. Soon-Shiong suggested I reach out to you to learn more about the collaboration involved in the initiative.

I'm also curious to hear more about your experience using GPS Cancer.

Wondering if you might have some time to talk by phone?

Thanks much,

Rebecca Robbins
Reporter
O: 617 809 2874
C: 714 478 4226
rebecca.robbins@statnews.com
@RebeccaDRobbins

STAT Reporting from the frontiers of health and medicine
@Statnews | Statnews.com | facebook.com/Statnews

Sign up here for free newsletters bringing you the latest in health news, biotech coverage, hospitals reporting and much more.

From: STEVEN MAMUS <stevesarasota@gmail.com>
Date: Fri, Mar 3, 2017 at 12:26 PM
Subject: Re: STAT reporter inquiring about GPS Cancer and Dr. Soon-Shiong's Cancer initiative
To: "Robbins, Rebecca" <rebecca.robbins@statnews.com>

I will respond to written questions only and will give written responses

Steve Mamus, MD
1. How did you first hear about GPS Cancer?

1. I attended a poster session at the ASCO meetings June 2015. I reviewed several hundred posters one day and the poster from Nantomics examining the relationship between quantitative protein expression of Her-2-Neu on in breast cancer and response to Herceptin was the best poster in the session. At that time it struck me that the proteomics story was the most important diagnostic advance for the treatment of solid tumors...in a lot of ways it reminded me of ONCOTYPE DX in that it provided a tool to be more precise in the administration of very expensive and potentially toxic pharmaceuticals.

The major advance of ONCOTYPE Dx among other things is that it identified many patients with early node negative hormone receptor breast cancer that did not require chemotherapy. Prior to development of this assay the overwhelming majority of patients with early breast cancer (LN negative, hormone receptor positive) were advised to have chemotherapy based on existing treatment guidelines. After development of the assay 3/4 patients were advised not to have chemotherapy. Per my recollection as a practicing oncologist there was enormous resistance to this paradigm shift which was resisted by some clinicians for over a decade.

In similar fashion, I believe that GPS cancer is even more important because the number of patients that could have their treatments changed is much larger. With GPS cancer in many cases you are able to get a scorecard which tells you which treatments will NOT work and which treatments are MOST likely to be beneficial.

The proteomics portion of GPS is of particular importance for treatment selection and has been extended beyond Her-2-Neu breast cancer patients (see attachments)

The test is particularly important in patients with advanced non small cell lung cancer where standard guidelines call for in many cases the use of platinum and taxane doublets. Internal data from GPS cancer suggest that the chances are 70% that patients with advanced non small cell lung cancer treated on treatment guidelines using the platinum taxane doublet will have drug resistance to at least the 2 drugs administered.

2. When did you first order GPS cancer?

2. About 18 months ago August 2015

3. Since then, how many GPS cancer tests have you ordered

3. I have sent 152 specimens for either ONCOPLEX and more recently GPS Cancer since August 2015. To be precise the proteomics testing alone was offered until July of 2016. GPS Cancer as a platform containing both Proteomics and Geneomics started in July 2016.

I have gotten all of the results back where the amount of tissue was adequate to do testing. Please understand that there are cases where needle biopsy specimens do not provide enough tissue for testing to be done.

The proteomics portion of the test takes about 2 weeks for results to be available.

For genomics the wait is about 4 weeks.

Steve

Dr Steve Mamus
4. What kinds of cancers/stages of disease are the patients you’re using this for affected by?

4. I have used the assay for solid tumor patients with carcinomas and sarcomas
   I have not been using the assay in patients with melanoma or lymphoma/leukemia

5. What is the reimbursement landscape like?

5. Reimbursement landscape is very complicated. However I feel that GPS cancer is a
   required diagnostic study in any patient I am contemplating systemic therapy i.e. chemotherapy,
   immunotherapy, targeted therapy.

6. Are you choosing it for certain types of cancers/insurance carriers rather than others,
   and if so why?

6. If the patient needs the test I order it. I am insurance blind when ordering the test. As
   indicated above I order the test in patient with carcinoma or sarcomas that may need
   treatment with chemotherapy, hormonal therapy, targeted therapy or immunotherapy.

    Steve
    Dr Steve Mamus

7. How often (approximately) does the GPS cancer result reinforce what you
   would traditionally do? How often does it recommend something different?

    Great question.
    In advanced lung cancer 3/4 patients will have a treatment change if your default
    regimen is a platinum and taxane doublet.

    The question is cancer site specific the big surprise in general is that there is likely
    at least a 1/4 chance in some cases a 3/4 chance that you will change your treatment
    plan depending upon (1) the diagnosis what type of carcinoma, (b) the stage, and (c) what the
    default treatment program an individual oncologist will choose for a particular cancer.

    My general approach to treatment is that all bets are off in terms of a treatment decision until
    we have the results of GPS cancer.

    The specific advantages that I see with the GPS platform for advanced carcinoma among other
    considerations;(I will mention a few here)

    a) Identify patient with platinum resistance (cis-platinum, carboblatinum,oxaliplatinum)

    b) Identify patients with taxane resistance (taxol, taxotere, abraxane, Jevtana)

    c) Verify Her-2-Neu protein expression this is huge...there are patients with IHC and FISH
       positive breast cancers that by proteomics are negative for Her-2-Neu this has large
       implications for both early and advanced breast cancer; clearly there are patient being treated
       for Her-2-Neu breast cancer that are not Her-2-Neu positive.

    d) Identify patients that would be good candidates for treatment with gemzar (gemcitabine)

    e) Identify patients that would be good candidates for treatment with Alimta (pemetrexed)

    f) Identify patients with unexpected protein expression of androgen receptors (particularly in
       triple negative breast cancer patients), ALK, BRAF, Her-2-Neu, EGFR among others

    Steve
    Dr Steve Mamus
Please see attached for publications demonstrating clinical evidence of some of proteomic markers:

1. **TUBB3** (resistance marker for taxanes) – Poster presentation at ASCO GI 2017
2. **ERCC1** (resistance marker for platinums) – Podium presentation at World Lung 2016
3. **ALK** in NSCLC – peer-reviewed publication
4. **HER2** in breast – peer-reviewed publication
5. **HER2** in gastric – peer-reviewed publication

Steve

---

**Steve Mamus, MD**

7. Are any oncologists you know, either in your own clinic or peers in other practices in other health systems using GPS Cancer?

7. I work with 2 other oncologists in my practice that use GPS.

We have a lot of patients in our practice that are snowbirds and spend only part of their year in Florida. When they return to their hometown oncologists up north their have been conversations about GPS Cancer. I also have discussed the test with other oncologists in Florida that I have consulted on.

I should also mention that I have had patients seen in my practice that have gone to academic centers and in some cases the consulting physician has chose to ignore the GPS results. Most recent case involved a patient that I believe was placed on a clinical trial that GPS Cancer suggested would not be a good fit for the patient.

I would look carefully at why some oncologists choose not to do GPS Cancer. In some cases GPS Cancer is a competing platform to an in house inferior outdated technology which is being utilized because the particular institution is at financial risk if GPS is used.

GPS is being used more commonly as I understand it in Phoenix, Philadelphia, some practices in New England and at Indiana University.

That's it done.
Steve
2. Dr. Azra Raza Responses:

From: "Raza, Azra" <ar2017@cunc.columbia.edu>
Date: January 27, 2017 at 1:39:14 PM PST
To: "rebecca.robbins@statnews.com" <rebecca.robbins@statnews.com>
Subject: [Cancer Breakthroughs 2020]

Dear Rebecca,

It was great to speak to you about the [Cancer Breakthroughs 2020]. As I told you, my experience with Patrick has been extremely positive as he is the only one with a vision to help our poor patients in a radically different approach that should abbreviate the time to better solutions. What might have taken ten years to accomplish will now take five. That is the goal and here is how I am involved:

“I want to speak from my personal experience with the [Cancer Breakthroughs 2020] program. It took the Human Genome Project 15 years and a billion dollars to sequence a single genome. Through the [Cancer Breakthroughs 2020] Collaboration, I was able to sequence 150 Whole Genomes and measure the expression of every gene (RNA Seq) in 157 bone marrow samples in 8 weeks! We are now obtaining the Proteomics information in these pre-leukemia and leukemia patients. The rigor and velocity with which we are able to home in on novel targets, to monitor the effects of therapy in a dynamic ongoing manner and the ability to combine this form of targeted therapy with immune approaches by deploying immune cells simultaneously in the [Cancer Breakthroughs 2020] trials represent a quantum leap in cancer treatment.”

Look forward to seeing your piece...

Azra Raza, M.D.
Chan Soon-Shiong Professor of Medicine
Director, MDS Center
Columbia University Medical Center
Milstein Hospital Building, 6GN-435
177 Fort Washington Avenue
New York, NY 10032
3. Dr. Peter Fasching:

From: Fasching, Peter  
Sent: Tuesday, February 7, 2017 1:55 PM  
To: Robbins, Rebecca  
Subject: AW: STAT reporter checking in on Dr. Soon-Shiong's Cancer MoonShot/Breakthroughs 2020

Good Morning,

thank you for your interest in Cancer ... 2020.

I am happy to talk on the phone with you. My number is [REDACTED] If I cannot pick up, please try again. I have some phone conferences today.

Additionally I prepared 3 statements, that could serve as a basis for the conversation.

There are several key points that have come out of [Cancer Breakthroughs 2020] initiative.

- One important step, which is often underestimated, has been fully accomplished: An uncomplicated environment in which doctors, scientists and industry can communicate about next generation trials including immuno-oncology treatments and the complete profiling of tumor and patient genome and the relevant proteome. There have been several very productive large and small scale meetings, with leaders of cancer centers, community oncologists, industry, health insurances, and politicians. This works and is the basis for the next steps.

- For several different cancers a series of trials with cellular and other immunological therapies are on the way. I am leading one of these trials in advanced breast cancer as the principal investigator and expect to include the first patients within the next few months. We are very excited to get these new therapies to the patients.

- Last, over the last year I learnt how to use whole genome and proteome information (GPS Cancer Test) for my patients within a clinical study. You can imagine that having the information about the complete genome of the tumor and the patients comes along with some challenges. It is overwhelming, but good, how fast we are entering this new age of big data and genomic medicine.

Best Regards

Peter
4. Dr. Soon-Shiong’s Responses:

The reporter was provided with a written response with access to multiple publications and hyperlinks demonstrating the progress in year one. Yet she chose to ignore our detailed responses and instead made false statements that Dr. “Soon-Shiong’s high-profile [Cancer Breakthroughs 2020] initiative achieved little scientific progress in its first year, instead functioning primarily as a marketing tool for GPS Cancer.” We responded in writing that the trials initiated and the Pharma collaborations achieved in year one were significant and that GPS Cancer played no role in these initial safety studies of single agent molecules.

Our written responses to Rebecca’s enquires around Feb. 6, 2017, were ignored and is appended below:

1. STAT Question
Hoping to hear from leaders of the coalition about how Year 1 of the [Cancer Breakthroughs 2020] has gone -- what've been the most important tangible accomplishments? how about the biggest challenges? any disappointments?

Dr. Soon-Shiong’s Written Response:

In less than one year there has been remarkable progress on multiple fronts:

- Innovative Clinical Trial designs in collaboration with the FDA
- Positive clinical results with complete responses from [Cancer Breakthroughs 2020] QUILT coalition compounds
- Advanced GMP supply chain of biological protein molecules and off the shelf Natural Killer cells (NK cells)
- Successful scientific collaboration and sharing of data across pharma, biotech and academic centers
- Executed pharma collaboration from biotech companies to share and combine molecules for pre-clinical and phase I clinical testing
- Support of high risk early stage biotech companies in terms of providing
financing for manufacturing and clinical leadership

- Genomic and proteomic breakthroughs in discovery of Neoepitopes
- Multiple clinical and scientific retreats establishing over 3000 oncologists across academia and community with a single central IRB
- Launching of over 20 QUILT trials which are now posted on clinicaltrials.gov

Details regarding these accomplishments in year 1 are described below:

**FDA breakthroughs:**

Dr. Soon-Shiong’s written response:

Several briefings were held with the FDA leadership led by Dr. Soon-Shiong and members of the QUILT coalition (Dec 2015 and Sept 2016). As a result, the QUILT coalition reached agreement and IND approval to combine novel-novel combination immunotherapy agents, one involving infusing an off the shelf therapy (NK cells) and the other involving a fusion protein that upregulates the patient's own endogenous T-cell and NK cell. In less than one year since the announcement of [Cancer Breakthroughs 2020], Dr. Soon-Shiong has led the charge to fund and support of GMP manufacturing and take the regulatory and clinical lead to make T-cell and NK cell combination therapy a reality. The first patient to receive such a combination will be in February for a rare and an aggressive cancer called Merkel Cell carcinoma.

To our knowledge this will be the nation's first effort to harness the immune system to fight cancer by combining an activated NK cell line with a fusion protein to activate NK and T-cells within the patient's own immune system simultaneously.

**Clinical Breakthroughs: Complete Responses**

Dr. Soon-Shiong’s written response:

In less than one year, signals of complete responses have been achieved in multiple cancers including lung cancer (as a consequence of administering the right drug after performing the nation's first whole genome proteomics test ...the GPS test developed by Dr. Soon-Shiong's team (SCENE Magazine, ABC News, GPS Cancer - The Era of Clinical Proteomics is Here, GPS Cancer - Overview by Dr. Patrick Soon-Shiong); complete response in merkel cell cancer patient (after receiving NK cell therapy, data presented at scientific conferences NantKwest Merkel Cell Poster); complete responses in bladder cancer patients (fusion proteins activating NK cells and T cells); and reaffirming complete responses in leukemia
such as non-Hodgkin’s lymphoma and multiple myeloma with Natural Killer cells.

**Scientific Breakthroughs:**

Dr. Soon-Shiong’s written response:

We have accomplished scientific breakthroughs on the proteomics front transcending the world of genomics with dramatic improved outcomes in the clinical setting and affecting the change in therapy as a result of the findings of GPS (GPS Cancer - Overview by Dr. Patrick Soon-Shiong). Through this test and in collaboration with NCI, we have made breakthroughs in identifying neoepitopes in several cancers and most importantly showed that we can establish cancer vaccines using a common cold virus with these neoepitopes in preclinical studies.”

“Finally, we have shown in preclinical models that NK cells can help us establish a cancer vaccine and prevent cancer in a rechallenge… this work was published as well as presented at prestigious cancer conferences (ASH)

2. **STAT Question**
   Where can I find the full list of organizations working on the [Cancer Breakthroughs 2020] as part of the GIC? Is it ONLY the organizations listed [here](#) or is there a fuller list somewhere else?

   Dr. Soon-Shiong’s written response:

   They are listed on the website [here](#).

3. **STAT Question**
   All told, how many [Cancer Breakthroughs 2020] collaborators are there?

   Dr. Soon-Shiong’s written response:

   Currently at the clinical level over 3000 oncologists have been approached and agreed to participate in the QUILT clinical trials under a central IRB ([National Cancer Initiative IRB Established with Schulman IRB to Provide Central Review Services for National Immunotherapy Coalition (NIC) Clinical Trials](#))

4. **STAT Question**
   Beyond the ones listed [here](#). And are the unlisted ones entirely regional cancer centers and academic institutions?

   Dr. Soon-Shiong’s written response:

   They are growing and when made public, they will be listed on the website

5. **STAT Question**
I know Precision Biologics is affiliated with NantWorks, but what exactly does that mean financially? I saw that Dr. Soon-Shiong paid $50 million for majority control of Precision Biologics in 2015. I saw that Jen and others at NantWorks are the media contacts on Precision Biologics press releases.

Dr. Soon-Shiong’s written response:

With regards to high risk early stage companies with promising immunotherapy treatments, vaccines and technology, and for those who have struggled for years to receive funding for manufacturing their product or initiation of their clinical trials, Dr. Soon-Shiong is often approached to fill the gap of this “valley of death”. Precision Biologics, Etubics and Altor were exactly in this situation, and on being approached Dr. Soon-Shiong and his entities made the commitment to accelerate the development of cancer vaccines that would normally take 10 years, to be completed in 5 - the mission of [Cancer Breakthroughs 2020]. Dr. Soon-Shiong has thus provided financial support for high risk early stage technology, and biotechnology companies, to orchestrate the immune system and to enable the rapid development of combination immunotherapy to drive towards a cure and a vaccine in 2020.

6. STAT Question
I saw Dr. Soon-Shiong is on the board of directors of Etubics and then Jen is the media contact for the company -- does Dr. Soon-Shiong have a financial stake in the company, and if so, what is the size of his stake (majority or minority?) and when did he take that position?

Dr. Soon-Shiong’s written response:

See above response

7. STAT Question
I saw Dr. Soon-Shiong was recently named chairman of the board of Altor -- does Dr. Soon-Shiong have a financial stake in the company, and if so, what is the size of his stake (majority or minority?) and when did he take that position?

Dr. Soon-Shiong’s written response:

See above response

8. STAT Question
Are there any other companies on the list of [Cancer Breakthroughs 2020] collaborators -- beyond NantWorks, NantKwest, Precision Biologics, possibly Etubics, and possibly Altor -- in which Dr. Soon-Shiong has a financial stake?

Dr. Soon-Shiong’s written response:
The other companies that are involved with [Cancer Breakthroughs 2020] are Merck KGaA, Amgen, Celgene, Pfizer.

We are presently in discussions with Bristol Meyers Squibb, and Roche and with multiple early stage biotechnology companies. The challenge that [Cancer Breakthroughs 2020] has taken on is to orchestrate and integrate technology that have been developed by these companies because no single company has the solution. And in cases of companies that are highly cash strapped and cannot build manufacturing capacity or scale, Dr. Soon-Shiong steps up.

9. **STAT Question**
   On the flip side, I know Celgene is an investor in Dr. Soon-Shiong's companies -- are any other companies on the list of [Cancer Breakthroughs 2020] collaborators that are, too?

   Dr. Soon-Shiong’s written response:

   Amgen

Rebecca chose to ignore the written email responses from multiple investigators as well as from Dr. Soon-Shiong, and chose to omit the facts to further her false reporting.

We believe a correction and retraction is required.