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Welcome to NET Wise. This is a podcast for neuroendocrine cancer patients and caregivers that presents expert information and patient perspectives. My name is Laran Hyder, from the Neuroendocrine Tumor Research Foundation.

In previous episodes, we spoke about direct treatments for NETs – surgery and interventional radiology – which are ways of finding a specific tumor and physically destroying it. These are effective treatments, except when they aren't. As good as these treatments are at knocking out some tumors completely, they are only effective against tumors that we know about, are big enough to see and feel, and are in a place that can be accessed and operated on safely. They're also only good for patients who are healthy enough to receive them.

We also discussed nuclear medicine, specifically PRRT, and how it offers promising results in many patients, but also how it isn't effective in all cases of NETs, and how the long-term results aren't fully clear yet.

But there are many other ways of treating NETs, including many systemic treatments, which introduce anti-cancer medicines into the bloodstream. In many cases, these are the best and most effective treatment available, and they are what we are going to focus on today.

When we think about using medicines to treat cancer, we generally think about chemotherapy, which has come to mean using a type of drug that attacks tumor cells in a very aggressive way. These are medicines whose side effects can be even more uncomfortable than the direct symptoms of the disease, and so they're best used in fast-moving cancers where other options are limited. Here's Dr. George Fisher, a medical oncologist from Stanford University:

Fisher: *"It's inelegant. Chemotherapy tends to target DNA and cause DNA damage and causes cell death. Well, that's fine if it's only to the tumor cell, but many of our chemotherapy drugs have collateral damage by causing cell death in hair follicles and people can lose their hair; or if it damages the gut, you can have diarrhea; or if it causes problems in the bone marrow, you can have low blood counts. That's what standard chemotherapy is all about."*

Here's Dr. Ed Wolin, Director of the Center for Carcinoid and Neuroendocrine Tumors at Mt. Sinai in New York:

Wolin: *"Chemotherapy has always had a bad name for neuroendocrine tumors because it doesn't work and causes a*

lot of side effects. The major exception has been people that have really, really aggressive neuroendocrine tumors, high grade neuroendocrine tumors like small cell differentiated neuroendocrine carcinoma of the lung, or other types of high-grade neuroendocrine tumors. It's very effective. It doesn't cure the cancer in most cases, but it can sure shrink it up fast. But in most neuroendocrine tumors that we see, the so-called well-differentiated neuroendocrine tumors, carcinoids, it doesn't work so well."

Instead, the first choice with NETs is generally a medication that works on tumors differently than traditional chemotherapies, and often by targeting a mechanism that is specific to NETs. Think of a commando raid instead of a bombing – it takes longer to get the job done but does a much better job of hitting a specific target without also destroying everything else that surrounds it.

Perhaps the most popular medical treatment for NETs are a class of drugs called somatostatin analogs.

Fisher: *"I usually start with the mildest treatments, and the mildest treatment that we have for neuroendocrine tumors is something called somatostatin analogs. That's a mouthful, but the most common one is called octreotide, or the trade name's called Sandostatin. So octreotide or lanreotide, which is the newer, a more recent edition of the somatostatin analog."*

Here's Dr. Aman Chauhan, an oncologist at the Markey Cancer Center at the University of Kentucky:

Chauhan: *"Somatostatin analogs are one of the oldest and most studied treatments for neuroendocrine tumor. And I would say even today arguably forms the backbone of the treatment, or the mainstay of the treatment, for neuroendocrine tumor."*

Fisher: *"They get absorbed through the fat or the muscle and they get in the bloodstream. They go through blood and they bind to wherever there's a somatostatin receptor. It's a hormone that binds specifically to receptors on the neuroendocrine cell."*

This is exactly the same mechanism we heard about in episodes two and four of the series when we talked about gallium 68-dotatate PET-CT scanning, and also PRRT treatments. Both of these use somatostatin analogs to seek out the neuroendocrine tumors in your body and lock onto them, ignoring almost all other types of cells. In those cases, they do this to deliver radioactive material to those tumor locations. So you can find and see them in the case of gallium scans, or attack them with radiation in the case of PRRT.

Interestingly though, in addition to just acting as a guide to help a radioactive element find its way, the somatostatin analog itself has a therapeutic effect. It was originally used to treat some of the symptoms of NETs, specifically the hormonal effects of carcinoid syndrome, but then two studies, a smaller one

called PROMID, and then a larger one called CLARINET showed conclusively that these drugs can also slow or even halt the growth of NETs, sometimes for years.

Fisher: *"The somatostatin receptors on the tumor cells, if they bound by the octreotide or lanreotide, then that will turn off the secretion of any endocrine hormones that are being produced, and oftentimes will also slow the growth – the actual proliferation of those cells – so that the tumor stops growing, or it grows more slowly."*

Here's Dr. Pam Kunz, Director of the Neuroendocrine Tumor Program at Stanford:

Kunz: *"The purpose, or the goal, of using a somatostatin analog is to slow down the growth of the cancer. It is not likely that those medications will shrink the tumor, but they have a very good chance at controlling the cancer."*

Wolin: *"For people with intestinal neuroendocrine tumors, 61 and a half months average cancer control just with Lanreotide alone. It's remarkable. That means half the patients were controlled a lot longer than that, some people more than 10 years. In the overall population, including pancreatic neuroendocrine tumors, other neuroendocrine tumors, the average control time was about 38 and a half months, still a long period of cancer control. We've seen individuals who have been on it literally for decades."*

And so there are two somatostatin analogs currently being used for NETs: Octreotide, which comes in two formulas – short-acting and long-acting – and Lanreotide, which only comes in a long-acting version.

Chauhan: *"So they've both at present used interchangeably for either carcinoid syndrome control or tumor growth control as a front line, or the first line, agent of choice."*

Here's Carolina Creamer, a Physician's Assistant who works with NET patients at the University of Pennsylvania.

Creamer: *"The short acting is subcutaneous, so, it's one – it's an injection that's more along the lines of insulin. It can be given multiple times a day, depending on how the physician prescribes it, but it's something that the patient can give themselves. And then the long-acting ones, they're either intramuscular or deep subcutaneous – It goes in the buttock and it has to be given by another person typically, so that's why we have them come to the infusion center, or have a home nurse give it. So, the old paradigm was to give the short-acting Octreotide for a few weeks to see if the patient tolerated it. But now, we jump right to the long-acting, either Octreotide or Lanreotide, and now the short-acting is more used for what we call rescue injections. So oftentimes, it's patients with carcinoid syndrome, and if they're having really severe attacks of diarrhea or flushing, they can use the short-acting in*

addition to the long-acting once a month to control symptoms."

These long-acting somatostatin analogs are very often the first medication prescribed for NET patients. They can be very effective; they're easy to administer, and with a low incidence of side effects. Of course, low side effects doesn't mean no side effects, and because somatostatin is a hormone, these medications can have some hormonal effects.

Creamer: *"So the idea is that it will hopefully help diarrhea if it's someone with carcinoid syndrome. But sometimes they can... they can actually make the diarrhea worse."*

Wolin: *"Because one of the side effects of somatostatin analogs like Octreotide or Lanreotide is it stops the production of digestive enzymes by the pancreas. As a result, undigested food goes all the way to the colon without being digested, and bacteria in the colon will ferment it and make lots of gas. So a lot of people who complain of diarrhea, fatty bowel movements, floating bowel movements, greasy bowel movements, urgent bowel movements, all this kind of bowel movement stuff – it's related to not having enough pancreatic enzymes. And once you recognize this, it's easily treated by a nutritional supplement called pancreatic enzymes."*

Creamer: *"Sometimes they can cause abdominal pain, fatigue. It can affect blood sugars – so it can actually make them go up or down. We have to educate on hypoglycemic and hyperglycemic symptoms. And it does have cardiovascular effects, it can slow the heart rate a little bit, but it's not something... it's something that, you know, is monitored every time they have vital signs, but it's not something we see all that commonly.*

It obviously has an injection site pain. The two different injections have different size needles. I've had patients that have had both and they say, you know, it's the same, and it does hurt. Some people tolerate it better than others. So I think some patients say it depends on whoever's administering it. I have patients that have their favorite nurse. They will only let this one nurse give it to them because they insist that it's less painful. And you know, I think there's a lot to be said for that. But it's... we've had patients on these, these medications for many, many years. It's typically a well-tolerated medication."

Perhaps the most important side effect of long-term use of these drugs is gallstones, painful lumps of solid fat that form in the gallbladder, a small sack-like organ that help the liver distribute bile. The good news is that this can be solved by removing the gallbladder, a common surgery that has few long-term effects.

Here's Dr. Eric Nakakura, a surgeon at the University of California, San Francisco:

Nakakura: *"A gallbladder is basically a sack. It holds the bile that's made in the liver. And when you eat certain types of foods, especially foods high in fat, it causes the gallbladder to contract and empty that tank of bile, because the bile helps absorb your fat."*

The gallbladder's most common organ removed for patients in surgery, and it's typically removed for patients that have symptomatic gallstones. Now if you look at thousands of patients that have either had or have not had their gallbladder removed, there's really no difference in their digestion, their bowel movements, and things like that. Now there are always patients that have noticed that they have more diarrhea or digestive issues after the gall bladder is removed. But if you look at an equal population of patients that have never had the gall bladder removed, you'll see the same sort of symptoms. So we really don't feel removing the gallbladder affects patients in any way."

Because somatostatin analogs are used in so many different NET treatments, surgeons often remove a patient's gallbladder proactively while they're doing another kind of surgery, to prevent these problems from developing later on.

Wolin: *"However, if you still have a gallbladder and your somatostatin analogs, don't worry about it. Just leave your gallbladder alone and if you need to have it taken out one day, and usually it can be done with a laparoscope and can be done later on."*

As effective as these medicines can be, they aren't always effective.

Zweig: *"Steven Zweig, I'm a radiologist. About 10 years ago or so, I began to suffer from intermittent abdominal pain that nobody could explain. I would go into the emergency room on several occasions for pain, and all of my labs, my physical exam – everything came back negative, negative, negative. So one of the ER docs decided to do a CT scan of my abdomen and pelvis, and a very small tumor was found in the pancreas. I went to Chicago and I was told that it was neuroendocrine tumor.*

They got me a GI surgeon who specialized in the pancreas, and she did a distal pancreatectomy. Put me back together again... it was pretty rocky course postoperatively, but then slowly I began to recover. March 2016 was the date of the surgery.

I went back to work in Michigan part time, and then eventually full time. And I was fine. And pretty much, that's it. It was just surveillance. And then when small metastatic lesions show their face, she put me on the Lanreotide. The shot itself takes, you know, minute and a half. It does hurt a little bit, nothing to complain about. And I don't really think I had much in the way of any complications because of it. It's very, very easy. Walk in, they say "hi", sit down, take your blood pressure, give you the shot, outside you go, gone. Takes two minutes. So I did

that for four months. Did an MRI - really did not see it to be working all that well, or at all.

I want to say about three weeks ago, I underwent a chemo embolization of the right lobe of the liver, which is making things very difficult."

Fisher: *"So we know the drugs can slow the growth of these tumors, but they don't always work. And even they work, they don't always work forever. Tumors can eventually become resistant to them."*

And in most patients, these are just the first of several different kinds of medical treatments that are used to discourage the growth of NET cells. Some of these block the signals telling cancer cells to grow, and others prevent the formation of blood vessels that feed cancerous cells.

Here's Dr. Jennifer Chan, and oncologist at the Dana Farber Cancer Institute in Boston:

Chan: *"The cancer cell has various receptors, and some of these receptors are involved in the signaling that drives cell growth and cell proliferation. And there are agents that can bind to those receptors to block that signaling pathway to then block these processes that are responsible for the growth and spread of disease, and also the growth of blood vessels that support this process of growth and spread."*

And while these target therapies technically fall under the category of chemotherapy, they're quite different from the kinds of chemotherapy drugs more traditionally used.

Fisher: *"So we usually reserve the term chemotherapy for drugs that are intended to kill cells, and that's cytotoxic chemotherapy that has a lot in common with the other drugs that we use for other types of cancers. The targeted therapies are not so great at killing cells, so they don't shrink tumors as often as we'd like, but they can stall the growth."*

mTOR inhibitors work by blocking signaling pathways that tell cancer cells to grow.

Fisher: *"Afinitor or Everolimus is a drug which binds to a specific molecule, an enzyme within the cell called mTOR. And when you bind to that mTOR, you can slow the growth of cells and sometimes even shrink them."*

Chan: *"And Everolimus, by blocking this pathway has been shown to slow growth pancreatic neuroendocrine tumors, as well as non-functional gastrointestinal and lung neuroendocrine tumors, so this is also an option that we will consider for patients."*

These were derived from an antibiotic called Rapamycin, which has kind of an incredible backstory. It's called that because it was discovered on the island of Rapa Nui, also known as Easter

Island, the place with those famous ancient statues of giant heads.

Wolin: *"In the middle of nowhere in the Pacific, it's one of the most isolated places in the world, and sitting here on the grass are these things that probably weight 120 tons. They're probably a hundred feet high, and they've been there for hundreds and hundreds and hundreds of years and have never blown away in the big storms. Nobody knows how they got stood up there, a solid piece of stone, and how the ancient engineers did it. But they clearly had some pretty sophisticated engineering in this island. So somebody went to look at these stones, whatever, and while he was there, he got this brilliant idea: 'Why don't I take some dirt from the Easter Islands back to America and analyze it, and maybe in this dirt there will be a fungus that's making an antibiotic, and maybe that antibiotic will be something that's never been discovered before, and I'll hit the jackpot like Streptomyces?' Okay, what are the chances of this happening? This is like, unbelievable, right? People have look everywhere in China and Africa and America, all over the world looking for antibiotics coming from microorganisms. But who would think that there would be something special?*

Well, believe it or not, he hit the jackpot. They found a fungus that had never been discovered in the world. And this made an antibiotic that was never discovered in the world, so they named the antibiotic Rapamycin, because the island is Rapa Nui island. It turned out it not only killed

microorganisms like fungi, but it also turned out that it had anti-cancer properties.

At that time, they were taking every molecule that anybody ever discovered and doing these large-scale tests – just testing every random molecule that ever happened to see if it had anti-cancer properties in the laboratory. The NIH was funding this. They discovered that, just for no real scientific reason, this stuff had anticancer properties, and then they started researching what happened.

So it turned out this enzyme that was being inhibited they didn't have a clue what it was, so they called it 'mTOR' – that means 'Mammalian Target of Rapamycin'. So it sounds really scientific when you don't know what you're talking about to say, 'well, what is rapamycin? It's an mTOR inhibitor. And what does it do? It inhibits mTOR', you see.

So people started studying this and they realized that mTOR was a central regulator of cell growth metabolism – determines how long the cells live, when they die – and that neuroendocrine cancers have all kinds of mutations that have a big defect in this mTOR pathway, so that they have lots of mTOR, and by inhibiting the mTOR you preferentially will inhibit the growth of neuroendocrine cells compared to other cells."

And stalling the growth of a tumor can make a huge difference in prognosis.

Wolin: "They did a randomized trial. It was the largest study ever done in pancreatic neuroendocrine tumors. Four hundred and ten patients were randomly assigned to placebo with the understanding they will get Everolimus if the cancer grows, and the other people got Everolimus. The difference between the two groups was astounding – the average cancer control time was 14.4 months, versus 5.4 with placebo. It's not as long as we see with PRRT, it's not as long as we see in somebody who's never been treated before who gets Lanreotide, but it's a major advance in the field. And we're now working on ways of making it even better.

It was also proven by the RADIANT-4 trial to be an effective treatment for lung carcinoids, and it's been FDA approved for lung carcinoids. The average time for cancer control was close to 14 months. And that was average – there are patients who have been controlled for years. So that's a wonderful drug."

Other targeted therapies block the growth of blood vessels to the tumor. This cuts off the supply of resources the tumor needs to live and grow.

Fisher: "And these are called angiogenesis inhibitors. It's another mouthful, but the one that's approved for pancreatic neuroendocrine tumors is called sunitinib. And the trade name for it, which is always easier to pronounce, is called Sutent. So Sutent is a pill that you take that

among other things target the blood vessels that feed the tumor. If you were to imagine that tumor can't grow without blood vessels feeding it, and if you crippled the growth of blood vessels, then the tumor would have trouble growing. It might even shrink a little bit.

Wolin: *"It turned out that in pancreatic neuroendocrine tumors, it was highly effective. Progression free survival, which means how long patients can go with no sign of cancer growing was 11.4 months – it's just virtually identical to what we saw with everolimus. Works completely differently, but it's another type of pill. It is effective. It's most effective in pancreatic neuroendocrine tumors."*

Chan: *"And there also have been some recent clinical trials that have shown that another tyrosine kinase inhibitor, pazopanib, can slow growth of non-pancreatic neuroendocrine tumors. Another trial, another phase-three trial that was conducted in China, of a tyrosine kinase inhibitor called surufatinib also slowed growth of non-pancreatic neuroendocrine tumors. There are other trials that are going on evaluating other tyrosine kinase inhibitors called cabozantinib and axitinib. So you may hear about these agents also in the future."*

In spite of what we said at the beginning of the episode, there are actually a couple of traditional chemotherapy approaches that do work well with some nets.

Fisher: "So if I had a tumor that was growing at a pretty good clip, or a pancreatic neuroendocrine tumor that was bulky and needed to be smaller, I needed to make it smaller so that the person would feel better, I might give them a combination of two drugs. One is called temozolomide, or sometimes abbreviated Temodar, and the other is called capecitabine, and sometimes known as Xeloda. And so the Tem/Cape combination, temozolomide and capecitabine, is a treatment that is very effective for pancreatic neuroendocrine tumors and can shrink the tumor, or keep it from growing, for many months and even for years.

It can be a very effective treatment and they're pills. Even though their chemotherapy pills, people don't lose their hair. They might have a few days of nausea. The blood counts are usually just fine. Sometimes they go down, but they can adjust the dose. Sometimes one of the drugs will cause a little bit of diarrhea or some dry skin, but otherwise these are very well tolerated treatments that can have profound effect on pancreatic neuroendocrine tumors.

Wolin: "With lung carcinoids it does have activity. The data's a little bit sparse, but you can see that it does have significant activity, can stop the disease from growing in many people, typically for less than a year. But it's a well-tolerated oral chemotherapy, in general, for most people, and is another type of effective chemotherapy."

So with all of these options, these different kinds of medicines plus the surgeries and interventional radiology procedures, PRRT, and other interesting options we'll be discussing in the future, like immunotherapies – what should you be doing, and when, and in what order? That's a complicated question and one that you and your doctors need to weigh carefully.

Here's Dr. Blaise Polite, an oncologist at the University of Chicago:

Polite: *"We have a lot of things in our armamentarium now that we didn't have five years ago or 10 years ago, and it now becomes the job of all the researchers here that that you've heard, and many others, to figure out how do we put this all together? How do we sequence it? And also how do we personalize it for each and every one of you?"*

Here's Dr. David Metz, a gastroenterologist who specializes a NET treatment at the University of Pennsylvania:

Metz: *So you've got surgery, you've got liver-directed therapies, we've got small molecules, we've got chemotherapies, we've got the targeted radiation therapies, and with some luck we'll be getting more and more as treatment goes. So each patient can go through a whole lot of these treatments in various different sequences or combinations, and that's what a tumor board is all about.*

Since there is no defined algorithm for neuroendocrine tumors, we feel it's really important for people to sit around a room and everybody claims what they think they can offer this particular patient – so the surgeons can cut, and the radiologists can burn, and the x-ray technicians can radiate, and the nuclear medicine people can give PRRT, and the oncologists can give chemo or small molecules, and the gastroenterologists can inject things... So in essence what a tumor board is, is 'here's Mrs. Jones, this is her history, this is what she's had before, this is the extent of disease, here are images for us all to look at, here is the pathology report: aggressive, not aggressive, you know... where it is. All right, what's the next best step for this lady? Because we want to keep her going for the next 10,15,20 years.'"

And the truth is all these different tools overlap in terms of what they can do. What the best course of action might be for particular patient can often be a matter of opinion, with different equally knowledgeable doctors making very different recommendations.

Nakakura: *"Yeah... I think that drives patients crazy, especially patients that come to a doctor thinking that we all have the same answer, right? In fact, I have some patients that say, 'I don't understand it – you're a doctor, you went to medical school. This guy went to medical school. Didn't you guys study the same stuff? And here you guys are saying completely different things.'*
(laughs)

But I think that's the reality of complex diseases, and neuroendocrine tumors is probably one of the most complex, is that there is no one right answer. There will be maybe multiple treatment options that are very reasonable."

So choosing the best course of treatment is often not a question of what is the most effective way to destroy the tumor, but rather what's the treatment that will make you feel the best for the longest period of time.

Fisher: *"If I gave you a drug that has no side effects and it keeps the disease in check for six months or a year, that's great. If it has an impact on quality of life that makes you think twice about taking a pill every day, then maybe it's not so good. Maybe I should try to strive to do better or find a less toxic way of treating you."*

Nakakura: *"Well, I think the number one thing is the risks. So if you're... if one of the recommendations is some very, say, complex surgery, and you're told that there is high risk of side effects, significant complications, even potential death, you have to really think about that option before signing on; versus if one of the recommendations is observation or a somatostatin analog – a hormone shot – I think you're going to have fewer reservations accepting that. Or I should say, there's less immediate risk of those interventions, but you might say there are some significant risks that... what if it doesn't work? What if the disease progresses? So I think those are the sort of things you've got to think about."*

Karen Grace is a Registered Nurse and cCoordinator of the Interventional Oncology Program at Northwestern Memorial Hospital in Chicago:

Grace: *"Well, are you symptomatic? That's the first question. Because if you're symptomatic then we tend to want to treat that or tend to want to look at that and see what can be done. A mild progression in a tumor that's small is different than a mild progression in tumor that's really big, and it changes your mind, really, on how your approach is going to be for that patient, because you don't want to waste a therapy on something so tiny. Maybe it just needs an ablation, versus a larger tumor that might need another treatment, depending on your symptoms. So the idea is longevity."*

Surprisingly, the best thing to do about slow moving NETs is often... nothing - observing the tumor and waiting until the right moment to act, when the urgency of the threat presented by the size and location of the tumor exceeds the toxicity of the treatment.

Fisher: *"When we don't have a clear surgical fix for a tumor, we will sometimes observe it. So, believe it or not, I will oftentimes see a person with a metastatic neuroendocrine tumor with small spots in the liver who feels perfectly fine, has no symptoms whatsoever. And once I try to calm them down and say, 'yes, this is a cancer, yes, this is spread to the liver, but no, we don't necessarily need to treat it immediately.' I will say,*

'well, why don't we just get a scan in another two months? or month?' And so we get a scan and it shows no change. Then I'll say, 'well, maybe we'll get a scan in three months' and we get a scan and it shows no change. And I say, 'well, maybe we'll get a scan in four months' and we see no change. And I say, 'well, you have a very slow growing tumor – so slow that I haven't been able to see any change over the course of a year. We'll just watch it.' And that person, I might see every six months with scans and I might not need to treat it for a few years or even a decade or more."

Metz: *"You may not really need any intervention, because your quality of life is excellent and anything else we would do to you could potentially harm you, or we could run out of treatments in the future. You only have so many bullets in your gun and by the time you've shot them all off, you're stuck because now you've got nothing left to offer at that point. So it's always good to space your therapies slowly and utilize them in a way to be effective."*

Generally speaking in these patients who are feeling well and living normal lives, the aim is to just manage symptoms, to keep them under control until the next good therapy comes along, because you don't want to waste all your treatment upfront, make them sick from your treatment potentially, and not necessarily to give them a long-term benefit."

Kunz: *"So really to think of them as a chronic disease, like we would high blood pressure or diabetes, I think helps patients understand... it's just, it's really hard to wrap your head around this very different type of cancer. Like you're probably going to have it for the rest of your life, and that will be many years, and so you will probably need to deal with this and be on and off treatment for your lifetime, but we have lots of tools in our toolbox."*

In the next episode, we're going to talk about one of the characteristics of NETs that most often causes uncomfortable symptoms and patients – their ability to create unneeded and unwanted hormones. We'll look at how and why these symptoms occur and some of the best ways to treat them.

Thank you for tuning into NET Wise. My name is Laran Hyder. I'm the Director of Education and Outreach for the Neuroendocrine Tumor Research Foundation and serve as Executive Producer and Co-writer for this series. It was produced and co-written by David Hoffman of CitizenRacecar. This episode was made possible by the generous support of The Vincent E. Taylor Patient Education Fund, Advanced Accelerator Applications, a Novartis Company, Lexicon Pharmaceuticals, and Ipsen. Special thanks to everyone we interviewed for this episode. We are grateful for your expertise. This is a production of the NET Research Foundation. We're committed to improving the lives of patients, families, and caregivers affected by neuroendocrine cancer. We fund research to discover cures and more effective treatments

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